DEPARTMENT OF HEALTH AND HUMAN SERVICES
Departmental Appeals Board
Civil Remedies Division

In the Case of: Allstate Medical Laboratory, Inc.,

Petitioner,
v.

Health Care Financing Administration.

Docket No. C-99-309
DATE: October 6, 1999

RULING

The purpose of this ruling is to decide whether Pantaleon de Jesus, M.D., the director of Allstate Medical Laboratory, Inc., has a right to a hearing and, if so, the scope of that hearing right.

Forr the reasons set forth below, I have determined that Dr. de Jesus has a right to a hearing, which flows from the sanctions imposed by HCFA against Allstate Medical Laboratory, Inc. (Allstate). Accordingly, I deny HCFA's Motion to Dismiss.

Backqround

In a January 8, 1999 letter (Notice), HCFA informed Dr. de Jesus and Allstate that because it had not received any response from de Jesus as to why certain proposed sanctions should not be imposed, it was imposing the following sanctions as proposed in earlier letter dated December 23, 1998 [see footnote 1 below].

(1) a directed Plan of Correction of cease testing effective December 28, 1998, and submission of a client list of all clients since February 20, 1998;

(2) a civil money penalty of $10,000 per day for December 28 through December 30, 1998 for a total of $30,000;

(3) suspension of the laboratory's CLIA certificate and cancellation of Medicare and Medicaid payments effective December 31, 1998; and

(4) revocation of the laboratory's CLIA certificate effective February 21, 1999.

HCFA informed Dr. de Jesus further that, upon revocation of the laboratory's CLIA certificate, he would be prohibited from owning, operating, or directing a laboratory for at least two years from the date of the revocation. HCFA noted that Dr. de Jesus was currently directing five other laboratories besides Allstate, which was in itself a violation of the CLIA regulations.

Dr. de Jesus filed a request for hearing dated February 11, 1999 [see footnote 2 below]. His letter did not make any reference to the January 8, 1999 Notice letter sent by HCFA to Allstate, but stated at the end that it was a "formal request for a hearing on HCFA's actions affecting Dr. de Jesus." In his letter, Dr. de Jesus asserted, among other things, that "he [was] not responsible for the deficiencies listed in the survey report."

HCFA filed a motion to dismiss Dr. de Jesus, hearing request. In the alternative, and in accordance with numbered paragraph 2.D. of my June 18, 1999 Order, HCFA also filed its report

of readiness to present evidence for adjudication of the case. Dr. de Jesus filed a response brief in which he opposed HCFA's motion.

The Parties' Positions

HCFA asserts that, under the CLIA statute and the regulations, Dr. de Jesus as an individual and in his capacity as the laboratory director is not a proper party to contest any of the sanctions imposed against the laboratory and does not otherwise have any right to a hearing to challenge the two-year prohibition against his owning or operating a laboratory. HCFA argues that only the laboratory is a proper party to challenge the sanctions imposed by HCFA. In response, Dr. de Jesus argues that he is an "affected party" under 42 C.F.R. § 498.2 and has the right to a hearing, which right flows from the sanctions imposed by HCFA against the laboratory. Dr. de Jesus relies on *Eugene R. Pocock, M.D.*, DAB CR527 (1998) to support his contention that a person who is alleged to be an "operator" of a laboratory under the regulations has a direct right to appeal the prohibition against owning or operating (or directing) a laboratory for at least two years, resulting from a CLIA revocation.

DISCUSSION

I have considered the arguments of the parties and the applicable statutory and regulatory provisions. My analysis begins with an examination of HCFA's Notice dated January 8, 1999. HCFA's Notice is addressed to "Pantaleon De Jesus, M.D., Director" and "Allstate Medical Laboratory, Inc." Thus, on its face, the Notice names Dr. de Jesus as one of the addressees, and refers to him in his capacity as the laboratory director.

The principal sanction affecting Dr. de Jesus as an individual is that he is now prohibited from owning or operating (or directing) a laboratory for at least two years from the date of Allstate's CLIA certificate revocation, which became effective February 21, 1999. Dr. de Jesus' ability to have any meaningful involvement with any other laboratory as a director is now effectively suspended for a two-year period.

In its brief, HCFA recognizes that under 42 U.S.C. § 263a(i)(1), reasonable notice and opportunity for hearing must be given to the owner or operator of the laboratory before a laboratory's certificate may be suspended, revoked, or limited. HCFA contends, however, that the statute does not give any hearing rights to laboratory owners and operators who become prohibited from owning or operating other laboratories for two years following a CLIA certificate revocation. See 42 U.S.C. 263a(i)(3). HCFA asserts that only laboratories have been afforded hearing rights under-the CLIA statute and regulations.

In light of my analysis in *Pocock*, I find that HCFA's assertion that only laboratories are the proper parties to request a hearing to challenge HCFA's sanctions is without merit. The fact that the statutory provision at 42 U.S.C. § 263a(i)(1) references the laboratory's owner or operator signifies that these individuals have standing and would be parties in interest in proceedings which affect a laboratory's CLIA certificate. Simply put, in an administrative proceeding such as the one before me, a laboratory is merely a legal entity. For this reason, a laboratory and its owner and operator are essentially one and the same for purposes of contesting any adverse actions initiated by HCFA. A laboratory's owner and/or operator are the only individuals who could possibly represent its interests. Accordingly, I conclude that a laboratory, its owner, and its operator, all have equal standing and all possess a right to be heard on sanctions imposed by HCFA against the laboratory. I conclude further that a laboratory owner or operator has a right to

a hearing to challenge the mandatory two-year prohibition against owning or operating a laboratory, as set forth in 42 U.S.C. § 263a(i)(3).

Moreover, I disagree with HCFA's argument that Dr. de Jesus is not an "affected party" within the meaning of 42 C.F.R. § 498.2. The regulation at 42 C.F.R. 498.2 defines the term "affected party" as follows:

. . . a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part . . . .

Because Dr. de Jesus is a physician, there can be no dispute that he is also a "practitioner." HCFA's determination to impose sanctions against Allstate adversely affects Dr. de Jesus' rights since, as a result, he will be prohibited for two years from owning or operating a laboratory. Thus, due to HCFA's sanctions, Dr. de Jesus can be characterized as a "practitioner that is affected by an initial determination issued under this part," and therefore falls within the definition of "affected party" under 42 C.F.R. § 498.2. Because Dr. de Jesus is an "affected party," he is entitled to a hearing under 42 C.F.R. §§ 498.40 and 498.42.

It is nonsensical to state that when the statute and the regulations refer to adverse actions taken against the "laboratory", that no individual has a right to a hearing. HCFA's attempt to "play down" the role of a laboratory's owner or operator in the context of appealing adverse actions is contrary to what is reasonable or fair. A laboratory's owner and operator play essential roles in the functioning and conduct of the laboratory. To exclude a laboratory's owner and operator from having hearing rights would cause an outcome that is unacceptable and raises questions of fairness and due process.

The regulation at 42 C.F.R. § 493.2 defines the term "operator" to include "[a] director of the laboratory if he or she meets the stated criteria." HCFA, in its Notice, has named Dr. de Jesus, indicating that he is the director of the laboratory. Were I to accept HCFA's position that Dr. de Jesus, as Allstate's director, is not a proper party and is without any right to a hearing, he would be precluded from asserting in these proceedings that he is not an "operator," as that term is defined in the regulations.

In conclusion, as I interpret 42 C.F.R. § 498.2, Dr. de Jesus has the status of an "affected party" and therefore, has a right to a hearing under 42 C.F.R. § 498.40. The scope of Dr. de Jesus's hearing right encompasses the following issues:

1) whether or not Dr. de Jesus is an "operator" as defined in the regulations;

2) whether any of the laboratory activities which are alleged to be deficiencies were in violation of federal regulatory standards for a laboratory;

- whether any of the alleged deficiencies, if proven, are

subject to sanctions; and

4) whether any of the alleged deficiencies occurred while Dr. de Jesus was an operator, assuming he is found to be an operator.

Edward D. Steinman
Administrative Law Judge

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ATTACHMENT II RULING FOOTNOTES:

(1) In its earlier letter dated December 23, 1998, HCFA informed Dr. de Jesus and Allstate that it concurred with the State agency's November 12, 1998 survey findings and its recommendations, and would be imposing sanctions against Allstate. HCFA recounted that at the November 12, 1998 survey, the State agency had found Allstate to be out of compliance with several conditions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as numerous standard-level deficiencies. Based on these findings, the State agency had determined that immediate jeopardy to patient health and safety existed and directed Allstate to take immediate action to remove the jeopardy situation. HCFA stated in this letter that "due to your failure to remove jeopardy and correct all cited deficiencies, and your failure to properly report a change in ownership within the 30 day time frame as required by 42 C.F.R. § 493.51," it would impose the sanctions of a civil money penalty, directed plan of correction, suspension and revocation of Allstate's CLIA certificate, and cancellation of Allstate's approval to receive Medicare payments. HCFA stated further that under 42 U.S.C. § 263a(i)(3) and 42 C.F.R.§ 493.1840(a)(8), 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 CLIA certificate revocation. HCFA concluded the letter by giving ten calendar days to Allstate to submit any written evidence or other information against the imposition of the proposed sanctions.

(2). Allstate, through its owner, also filed a request for hearing dated January 14, 1999, which contested only the imposition of the CMP. As a result, revocation of Allstate's CLIA certificate became effective February 21, 1999.

In the Case Of: Carlos A. Cervera, M.D.,
Director, San Fernando Diagonostic Laboratory, Inc.
Petitioner

V.

Health Care Financing Administration.

RULING DENYING HCFA'S MOTION TO DISMISS AND GRANTING EXTENSION OF TIME FOR SUBMISSION OF READINESS REPORTS

In its motion, dated December 3, 1999, HCFA contends that Dr. Cervera does not have the right to an appeal in a matter involving sanctions taken by HCFA under the Clinical Laboratory Improvement, Amendments of 1988 (**CLIA**), against San Fernando Diagnostic Laboratory, Inc. HCFA persists in its contention even though the letter imposing sanctions against the laboratory, dated June 17, 1999, was addressed to Dr. Cervera, and even though the sanctions proposed included a two year ban on his owning or directing a laboratory.

On August 1.0, 1999, Dr. Cervera appealed the HCFA determination, and asked that his letter be considered a request for a hearing. Dr. Cervera essentially argued that he never acted as Director of the laboratory in question, that to his knowledge the laboratory never opened, and that he did not have a contract with the laboratory, among other statements in his letter.

The issues raised by this motion have been fully addressed by Judge Steinman in his order in *Allstate Medical Laboratory, Inc*, Docket No. C-99-309, October 6, 1999. (Copy attached). I adopt Judge Steinman's rationale in *Allstate.* In particular, I find that Dr. Cervera is an "affected party" within the meaning of 42 C.F.R. § 498.2, and that to cite Dr. Cervera as laboratory director and prohibit him from owning or operating a laboratory for two years, while at the same time denying him the same right to a hearing that the laboratory has raises significant issues of fairness and due process.

Accordingly, HCF's motion is denied.

The parties are instructed to promptly submit the report of readiness to present evidence as per my September 30, 1999 Order in this case. Since recent correspondence has demonstrated that the parties are having some difficulties regarding communicating with each other I will extend the date of filing this report to **January 10, 2000.** L will set up a prehearing conference in this matter during the week of **January 24, 2000.**

It is so ordered.

Marc R. Hillson
Administrative Law Judge

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Physicians Independent Laboratory, Inc., a California corporation; Sahibzada A. Akhtar, an individual,	CV 00-12209 SVW (CWx)
	ORDER DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
Plaintiffs,	
vs.	
Donna Shalala, In Her Official Capacity As Secretary Of The United States Department Of Health and Human Services; Wayne Moon, In His official Capacity As Director of CLIA Operations, Health Care Financing Administration; Diana M. Bonta, R.N., Dr. P.H., Director of The California Department of Health Services.	
Defendants.	

I. Introduction

This is an action for preliminary injunctive relief pending an ALJ hearing brought by Plaintiffs, Physicians Independent Laboratory, Inc. ("PIL") and Sahibzada A. Akhtar (hereinafter "Plaintiffs" or “PIL” to require the Secretary of the United States Department of Health and Human Services ("the Secretary") to reverse its prior action that revoked the operating license of Mr. Akhtar's clinical laboratory (its "CLIA certificate") without first complying with the ALJ hearing requirements set forth in 42 C.F.R. 493-1840(d) (2).

Additionally, Plaintiffs ask the Court to order that any monies withheld from Medicare payments previously earned be immediately released to Plaintiffs and that any action to cancel Plaintiffs, approval to receive Medicare payments for services rendered be revoked and reinstated retroactively until such time as Plaintiffs receive a hearing before an ALJ.

Plaintiffs' motion for this Court to issue a mandatory injunction to retroactively restore Plaintiffs' CLIA certification and reinstatement of its medicare reimbursements is denied.

II. Statement of Facts

The California Department of Health Services, Laboratory Field Services (the "State Survey Agency"), acting as the agent of the Secretary, conducted a survey of PIL between August 17, 1999 and December 13, 1999, which identified PIL's violation of nine separate CLIA "Conditions of Participation" and numerous “standard level' CLIA requirements.

Under cover of letter dated January 20, 2000, the State Survey Agency provided PIL with a 334-page report of the documented deficiencies. The subject line of the January 20, 2000 correspondence stated "Condition-Level Deficiencies and Not Immediate Jeopardy." The January 20, 2000 letter asked PIL to submit a “credible allegation of compliance” along with evidence documenting correction. PIL submitted what it believed to be a conforming plan of correction in April of 2000. By letter dated June 21, 2000, the State Survey Agency provided PIL with reasons why the April 2000 plan was not acceptable. A second correction plan, submitted by PIL on July 13, 2000, was also found to be unacceptable. PIL submitted a third correction plan dated July 25, 2000.

The State Survey Agency referred the matter to the Secretary. The Secretary accepted the State's recommendation for sanctions. Accordingly, by notice dated September 22, 2000, the Secretary informed PIL's director and owner that the Secretary was imposing certain sanctions including the suspension of the laboratory's CLIA certificate, effective October 6, 2000, and revocation of the laboratory's CLIA certificate, effective November 20, 2000. The September 22, 2000 notice informed PIL that even if it exercised its right to an ALJ hearing, the Secretary would maintain the CLIA certificate suspension prior to and during the hearing.

The September 22, 2000 notice, informing the Plaintiffs of the license suspension and revocation, stated "due to your failure to comply with reasonable requests for information that is necessary to determine your laboratory's compliance with performance standards set by law and its eligibility for a CLIA certificate of compliance" the suspension and revocation were imposed.

On October 2, 2000, PIL submitted materials directly to the Secretary in support of the laboratory's claim that the previously notice sanctions should not be imposed. The Secretary notified PIL, four days later by letter dated October 6, 2000, that "[w]e have carefully reviewed the materials your laboratory submitted on October 2, 2000 and determined that your laboratory has never come into compliance in correcting the deficiencies cited at the December 13, 1999 survey."

The Secretary notified PIL by letter dated October 17, 2000 that the submission was "entirely unacceptable as it failed to either address the deficiencies cited or to show that the alleged correction plan was every implemented." The sanctions were thereafter imposed in accordance with the schedule set forth in the September 22, 2000 notice, including the October 6, 2000 suspension of PIA's CLIA license.

III. State Defendants

It appears to be uncontroverted that the relief sought by Plaintiffs is within the sole authority of the Secretary. Therefore, for that reason, all state defendants and their agents are dismissed from this action, and the Court need not address the state defendants' Eleventh Amendment concerns.

IV. Jurisdiction Over Federal Defendants

The Secretary argues that this Court has no jurisdiction to issue equitable relief to the Plaintiffs because 42 U.S.C. § 263(a) (k) confers jurisdiction upon the Circuit Court for appeal of final agency action. 42 U.S.C. § 263(a)(k) states, in relevant part: "[a]ny laboratory which ... has had its certificate suspended, revoked, or limited ... may, at any time within 60 days after the date the action of the Secretary … becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principle place of business for judicial review of such action." 42 U.S.C. § 263a(k).

It is uncontroverted that the provision is applicable here, and it is equally clear that, by its language, that its grant of jurisdiction to the circuit court is not exclusive. There is no specific provision for alternative jurisdiction in the district court, although clearly the district court has general subject matter jurisdiction.. The Defendants argue that even though the grant of jurisdiction is not exclusive, the Ninth Circuit in Public Utility Commr. v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985) mandates that this court read the permissive language of 42 U.S.C. § 263(a)(k) as conferring exclusive jurisdiction on the circuit court.

In Bonneville Power Administration, the Ninth Circuit held that in a rulemaking proceeding "'where a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Public Utility Commr. v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir., 1985). The Defendants are correct that the Ninth Circuit's holding is applicable even if the grant of jurisdiction to the circuit court is not exclusive. Id. at 625-628. However, the holding of the Ninth Circuit in Bonneville Power Administration is inapplicable here because the suit in this case does "not affect the court's future jurisdiction."

The plaintiff in Bonneville Power Administration challenged the constitutionality of ongoing agency rulemaking proceedings to revise certain rate formulas. Clearly, if the district court had ruled on the constitutionality of rate proceedings in Bonneville Power, the Ninth Circuit court's "future jurisdiction" would be affected in the sense that the Ninth Circuit would adjudicate these matters in an appellate posture and then only if the parties

appealed. Here, this Court is only being asked to grant temporary relief pending the outcome of an administrative proceeding, rather than determine whether a rulemaking proceeding is constitutional. Our relief in this case is confined to requiring the agency to following its own regulations, pending the outcome of an administrative proceeding that the agency failed to properly provide. PIL's appeal from any ALJ ruling would be to the Ninth circuit. Therefore, this Court has jurisdiction to grant plaintiffs a preliminary injunction pending an ALJ hearing.

V. Exhaustion of A,4-inistrative Remedies

In Darby **v.** Cisneros, 509 U.S. 137, 144-146 (1993), the Court explicitly held that federal courts have no authority to require plaintiffs to exhaust administrative remedies prior to seeking judicial review under the APA unless a statute or agency regulation specifically mandates exhaustion as a prerequisite to judicial review. See also, Ciba-Geigy Corp. v. E. P. A., 46 F.3d 1208, 1210 & n. 2 (D.C. Cir. 1995) (summarizing the holding of Darby as "courts cannot require exhaustion of administrative remedies where, as here, it is not expressly required by statute or agency rule").

The Supreme Court in Darby explained that "[a]gencies may avoid the finality of an initial decision, first, by adopting a rule that an agency appeal be taken before judicial review is available, and, second, by providing that the initial decision would be inoperative pending appeal." Darby, 509 U.S. at 137. Clearly, the agency has not provided that its initial decision would be inoperative.

As explained in Darby, "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." Defendant argues that 42 U.S.C. § 263(a)(i) and the regulation promulgated in 42 C.F.R. § 493.1844 impose a statutory requirement of exhaustion. The Court disagrees. 42 U.S.C. § 263(a)(i) merely states that "[t]he opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation." 42 C.F.R. § 493.1844(f)(1) states "[a]ny laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its

services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing."

Without argument or citation, Defendants assume that these provisions specifically provide for exhaustion. However, an examination of other statutory provisions demonstrate the Congress was able, when it so desired, to clearly mandate exhaustion. For example, relating specifically to the Department of Agriculture and its agencies, 7 U.S.C. § 6912(e), titled, Exhaustion of Administrative Remedies, provides: "[n]otwithstanding any other provision of law, a person shall exhaust all administrative appeal procedures established by the Secretary or required by law before the person may bring an action in a court of competent jurisdiction against" the agency and its agents. 7 U.S.C. § 6912(e). Here, however, no such statutorily-mandated exhaustion requirement exists and under Darby none can be required by this Court.

VI. Finality of Agency Action

The APA permits "'non-statutory" judicial review only of "final agency action." 5 U.S.C. § 704. See, Bell v. New Jersy, 461 U.S. 773, 778 (1983) (.recognizing "strong presumption" that judicial review will be available only when agency action has become final). In order for agency action to be final, there must be a "direct and immediate impact." Franklin v. Massachusetts, 505 U.S. 788, 796-97 (1992). Two conditions.will satisfy this requirement. First, "the action must mark the consummation of the agency's decision making process ... [and] ... it must not be of a merely tentative or interlocutory nature ... second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 177 (1997). Determination of finality of agency action for purposes of APA review is to be made in a pragmatic way. See, Pennzoil Co. v. Federal Energy Regulationry Comm'n, 645 F.2d 394, 399 (5th Cir. 1981).

Defendant has asserted that the revocation of the CLIA certification is not final agency action and that it will only become final agency action upon the exhaustion of administrative remedies.[1] Defendant confuses two analytically distinct doctrines. As the Supreme Court stated in Darby v. Cisneros, 509 U.S. 137, 144 "[T]he finality requirement is concerned with whether the initial decision maker has arrived at a definitive position on the issue that inflicts an actual, concrete injury; the exhaustion requirement generally refers to administrative and judicial procedures by which an injured party may seek review of an adverse decision and obtain a remedy if the decision is found to be.unlawful or otherwise inappropriate." See e.g., Association of National Advertisers v. FTC, 627 F. 2d 1151, 1157 (1980) ("'The jurisdictional difficulty arises out of the requirement of finality, a related

doctrine which also comes into play in this case, and which overlaps the requirement of exhaustion of administrative remedies but is analytically distinct.")

Here, Defendant does not assert that Plaintiff must proceed through an administrative review process. In fact, 42 U.S.C. § 263(a)(k) merely provides that "any laboratory ... may .. petition

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[1.] At oral argument, the Secretary stated chat because the imposition of its various sanctions including the license suspension was not final agency action, neither this court nor the Ninth Circuit could enjoin the agency from suspending plaintiff's license even if a violation of constitutional rights or the agency's own regulators had occurred. This represents a reversal of the Secretary's position taken at oral argument in. their opposition to the plaintiff's motion for a temporary restraining order when the Secretary represented that the action was final and that immediate relief was available from the Ninth Circuit. Either way, the court finds the Secretary's argument incorrect, and believes that this Court has jurisdiction to review the matter.

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for review." If administrative appeals are not mandated the action is final. Darby v. Cisneros, 509 U.S. 137, 137-138 (1993) ("[s]ince neither the National Housing Act nor applicable HUD regulations mandate further administrative appeals, the ALJ's decision was a 'final' agency action.") Therefore, the finality of an action is not affected by the. mere availability of an administrative remedy.

Additionally, from a pragmatic standpoint, the revocation of the CLIA license is final agency action. It is quite clear that the rights of the Plaintiff are dramatically affected by the revocation of its operating license and that the revocation "imposes an obligation, denies a right, or fixes a legal relationship." United States Dep't of Justice v. Fed. Labor Relation Auth., 727 F.2d 481, 493 (5th Cir. 1984). Therefore, the Court finds that revocation of the Plaintiff's CLIA certification was final agency action under the APA.

VII. A Pre-Deprivation Hearing Was Required

It seems clear to the Court, and Defendants do not argue to the contrary in their motions, that the suspension and revocation should have followed rather than proceeded a hearing.

The Code of Federal Regulations state that only in specific instances may an agency revoke a CLIA license prior to a hearing before an ALJ. Section 493-1840(d) states, in relevant part: "'HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision that upholds suspension or limitation" except when "(i) The laboratory's deficiencies pose immediate jeopardy; (ii) The laboratory has refused a reasonable request for

information or work on material; (iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operations."

It appears, at least from the record presented to the court that none of the sections of section 493.1840(d)(2) apply.

An agency may not rely on after the fact rationalizations to justify its actions. SEC v. Chenery Corp., 332 U.S. 194 (1947). Therefore, the statement submitted in the various declarations on behalf of Plaintiff now claiming that there may be other reasons, including health dangers for the suspension and revocation of the CLIA license, are not considered in our review of the Secretary's decisions.[2] At the time of the decision, the deficiencies cited in the Statement of Deficiencies issued by the State DHS as a result of the on-site inspection survey of the laboratory premises in August 1999 were determined by "State DHS" to be "not immediate jeopardy." Therefore, the Secretary cannot justify its decisions under the first exception by post-hoc submissions alleging potential health related harms.

An agency may "not proffer conclusory statements or unsubstantiated claims in defense of its decisions." National Treasury Employees Union v. Horner, 654 F. Supp. 1159, 1163 (D.C.

[2.] If the Secretary believes that there are genuine health issues and that it merely made a mistake in justifying its suspension and revocation of the license on a different grounds it may resort to 42 U.S.C. § 263(a)(j) which provides for injunctive remedies whenever "the Secretary has reason to believe that the continuation of any activity by a laboratory would constitute a significant hazard to the public health the secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity."

Cir. 1987). Yet the Secretary has done precisely that here. While it claims that "due to [PIA's] failure to comply with reasonable requests for information" the CLIA certificate was suspended, defendants in their submissions to this Court have not produced evidence of a single non-compliance with a request for information. Rather, the record establishes that Plaintiff was very forthcoming with information and that this information was the basis upon which the violations were found.[3]

It is quite clear that the allegation of failure to provide information is conclusory, as it is not mentioned in the Defendants' pleadings, declarations, and any other evidence before this Court. Therefore, the second exception is inapplicable.

Finally, the Secretary does not contest that the third exception is applicable. Because no exception applies, the Code of Federal Regulations required that PIA be granted a hearing prior to the revocation of its license.

VIII. Standard For Preliminary Injunction

The standard for a preliminary injunction balances the plaintiff's likelihood of success against the relative hardship to the parties. Sun Microsystems, Inc. v. Microsoft Corp., 188 F.3d 1115, 1118 (9th Cir. 1999). Generally, to obtain a preliminary injunction, plaintiff is required to demonstrate either: (1) a likelihood of success on the merits and the possibility of

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[3.] Defendants do not contest that over 2,300 pages of documentation responding to the deficiencies were filed. This does not include additional original business records of PIA.

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irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor. Id. These two alternatives represent "extremes of a single continuum," rather than two separate tests. Id. (quoting Sega Enters, v. Accolade, Inc., 977 F.2d 1510, 1517 (9th Cir. 1992). Thus, the greater the relative hardship to plaintiff, the less probability of success must be shown. See, National Ctr-. For Immigrants Rights v. INS, 743 F.2d 1365, 1369 (9th Cir. 1984).

a. Irreparable Injury

Plaintiff alleges that, without its operating license, the laboratory will be forced to close, and its employees will have to find other work. Defendants direct our attention to cases holding that a preliminary injunction is an inappropriate remedy where the potential harm to the plaintiff is strictly financial. This is true as general rule, but an exception exists where the potential economic loss is so great as to threaten the existence of the plaintiff's business. See, Wright and Miller, Federal Practice and Procedure: Civil § 294B, Doran v. Salem Inn, Inc., 422 U.S. 922 (1975) (threat of bankruptcy constitutes irreparable harm); John B. Hull, Inc. v. Waterbury Petroleum, 588 E.2d 24 (2nd Cir. 1978), cert. denied, 440 U.S. 960 (1979) (possibility of going out of business is irreparable harm); Tri-State Generation v. Shoshone River-Power, Inc., 805 F.2d 351 (10th Cir. 1986) (threat to trade or business viability is irreparable harm; Milsen Co. v. Southland Corp., 454 F.2d 363 (7th Cir. 1971) (irreparable harm found where, without injunction, movants would lose businesses and their ability to carry on their lawsuit would have been crippled, if not destroyed.) However, Plaintiffs' claim that it is suffering irreparable harm is placed into question by the actions of Plaintiffs' to delay their ALJ hearing. Most recently, Plaintiffs' filed for a sixty day extension of the ALJ hearing previously scheduled for January 22, 2001. Although the Court finds that there is certainly a possibility of irreparable harm here, the Court need not decide this matter because the Plaintiffs have failed to prove a likelihood of success on the merits sufficient to warrant a grant of a preliminary injunction.

b. Likelihood of Success On The Merits Regarding CLIA Revocation

The Secretary makes a number of arguments as to why PIL will not succeed on the merits. First, the secretary argues that exhaustion is required. This argument is addressed and rejected in a previous section. Second, the Secretary argues that because PIA is likely to lose before the ALJ that it has little chance of success on the merits.

Plaintiffs do not allege that they have a high likelihood of retaining their CLIA license after a full hearing on the merits before an ALJ. Rather, Plaintiffs argue that the Court should not look to the probable resolution of the

ALJ hearing to determine likelihood of success on the merits, but rather look to the likelihood that Plaintiffs deserved a hearing prior to suspension and revocation of the CLIA license.

As previously discussed, the Court finds that a hearing was required prior to deprivation of the Plaintiff's CLIA certificate. However, Plaintiff is incorrect in his assertion that, in applying the likelihood of success on the merits standard in the context of preliminary injunctions, as opposed to a claim for other relief, Courts look only to the question of whether proper procedures were provided.

In Wheeler v. Office of the Controller Currency of The United States, 1998 WL 872945 (N.D. Tex. 1998), Plaintiff petitioned a federal district court for review of a Temporary Cease and Desist Order issued by the Office of the Controller of the Currency. Plaintiff sought preliminary and permanent injunctive relief to set aside the OCC's Order. Plaintiff alleged that the OCC was without authority to issue the Order against him, and, therefore, the issuance of the order should be enjoined. The Court found that, in the context of examining the likelihood of success for a preliminary injunction "the issue of whether the OCC had statutory authority to issue the Order is entwined with the issue of whether [Plaintiff] is likely to prevail on the merits of the underlying action." Id. at 6. c.f., D'Amico v. United States Svc. Indus., Inc., 867 F. Supp. 1075, 1088 (D.D.C. 1994) (stating, in dicta, that the "a substantial case or the merits in the underlying proceeding before the “Board” is required to meet the likelihood of success on the merits standard for a preliminary injunction).

Similar to the Plaintiff in wheeler, the Plaintiffs in this case have alleged failure to provide a pre-hearing deprivation is sufficient to grant a preliminary injunction, without regard to the success of the underlying claim. The Court in Wheeler disagreed with that assertion. Plaintiff cites no authority for the proposition that likelihood of success on the merits is to be judged by looking at a procedural matter rather than the substantive underlying issue. Plaintiff has, therefore, failed to meet his burden of proof that he has sufficient likelihood of success on the merits to warrant a grant of a preliminary injunction.

c. Likelihood of Success On The Merits Regarding Medicare Repayments

With regard to Plaintiff's request that this Court reinstate its eligibility to receive Medicare payments, the Court finds that the Plaintiff has not demonstrated that its has a right, either originating from due process or the Code of Federal Regulations, to a hearing prior to revocation of its eligibility to receive Medicare reimbursements.

ix. Conclusion

Therefore, Plaintiffs' motion for preliminary injunction to retroactively restore his CLIA license is denied. Plaintiffs' request that any Medicare monies withheld be released is denied at this time, subject to a supplementation to plaintiff's pleading that demonstrates a right to a hearing prior to the revocation of those benefits.

IT IS SO ORDERED.

DATED: 1/24/2001

STEPHEN V. WILSON

UNITED STATES DISTRICT JUDGE

EDISON MEDICAL LAB., INC.,

Petitioner

v.

HEALTH CARE FINANCING ADMINISTRATION

ON APPEAL FROM THE DEPARTNMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL APPEALS BOARD APPELLATE DIVISION
(DAB App. Div. No. A-99-96)

Argued: January 25, 2001
Before: NYGAARD, ALITO, and RENDELL, Circuit -Judges.

JUDGMENT

This cause carne to be heard on the record from the Department of Health and Human Services Departmental Appeals Board Appellate Division on January 25, 2001.

After careful review and consideration of all contentions raised by the appellant, it is hereby ORDERED and ADJUDGED that the judgment of the Department of Health and Human Services entered on December 23, 1999, be and is hereby affirmed, all in accordance with the opinion of this Court.

Costs taxed against appellant

ATTEST:

Clerk

DATED: February 15, 2001

Certified as a true copy and issued in lieu of a formal mandate on April 9, 2001.
Teste:

Clerk, United States Court of Appeals for the Third Circuit

UNREPORTED / NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 00-3138

EDISON MEDICAL LAB., INC.,

Petitioner

V.

HEALTH CARE FINANCING ADMINISTRATION,
Respondent

ON APPEAL FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTNENTAL APPEALS BOARD APPELLATE DIVISION

(DAB App. Div. No. A-99-96)

Argued: January 25, 2001

Before: NYGAARD, ALITO, and RENDELL, Circuit Judges.

(Opinion Filed: February 15, 2001)

MEMORANDUM OPINION OF THE COURT

Kenneth B. Falk (Argued)
Deutch & Falk
843 Rahway Avenue
Woodbridge, NJ 07095

Counsel forPetitioner

David W. Ogden,
Assistant Attorney General
Robert J. Cleary,
United States Attorney
Scott R. McIntosh,
Attorney, Appellate Staff
Constance A. Wynn,
Attorney, Appellate Staff
(Argued)
Civil Division, Room 9550
Department Of Justice
601 D Street, N.W.
Washington, DC 20530-0001

Counsel for Respondent

ALITO, Circuit Judge:

Petitioner Edison Medical Laboratories, Inc. appeals the December 23, 1999 decision of the Department of Health and Human Services Departmental Appeals Board upholding the suspension and subsequent revocation of Petitioner's certificate of accreditation for failure to meet condition-level requirements of the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and regulations promulgated thereunder at 42 C.F.R. Part 493. After careful review of the record and arguments advanced by Petitioner, we have determined that the findings of the Departmental Appeals Board are supported by substantial evidence. Accordingly, pursuant to our jurisdiction under 42 U.S.C. § 263a(k)

(3), we affirm the action of the Department of Health and Human Services in revoking Petitioner's certificate of accreditation.

TO TBE CLERK OF THE COURT:

Kindly file the foregoing Opinion.

/s/Samuel A. Alito

Circuit Judge

MAY 10 2001

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Physicians independent Laboratory, Inc., a California corporation; Sahibzada A. Akhtar, an individual,

Plaintiffs,

vs.

Donna Shalala, In Her Official Capacity As Secretary Of The United States Department of Health and Human Services; Wayne Moon, In His Official Capacity As Director of CLIA Operations, Health Care Financing Administration; Diana M. Bonta, R.N., Dr. P.H., Director of The California Department of Health Services.

Defendants.

CV 00-12209 SVW (CWx)

ORDER GRANTING DEFENDANTS, MOTION

TO DISMISS

I. Introduction

Plaintiff Physician's Independent Laboratory, Inc. (“PIL") and Akhtar filed this action on November 16, 2000, seeking preliminary injunctive relief pending an ALJ hearing, to require the Secretary of the United States Department of Health and Human Services (“the Secretary”) to reverse its prior action that revoked the operating license of Mr. Akhtar's clinical laboratory (its “CLIA certificates”) without first complying with the ALJ hearing requirements set forth in 42 C.F.R. 493.1840(d) (2).

Additionally, Plaintiffs asked this Court to order that any monies withheld from Medicare payments previously earned be immediately released to Plaintiffs and that any action to cancel Plaintiffs

approval to receive Medicare payments for services rendered be revoked and reinstated retroactively until such time as Plaintiffs receive a hearing before an ALJ.

This Court denied in our January 25, 2001 (the "January 25, 2001 Order") Plaintiffs' request to issue a mandatory injunction to retroactively restore Plaintiffs' CLIA certification and reinstate its medicare reimbursements because Plaintiffs did not demonstrate a substantial likelihood of success of the merits after an ALJ hearing.

In its second amended complaint now pending before the court, Plaintiffs, seek money damage against Donna Shalala and Wayne Moon and Mary Jew as Federal employees acting in their official capacities. Defendants bring a motion to dismiss all causes of action in the second amended complaint arguing that this Court is without jurisdiction to grant the relief sought by the Plaintiffs, that a Bivens action is not available to Plaintiffs, and that Plaintiffs must exhaust administrative remedies. Defendant motion to dismiss is granted.

II. Statement of Facts

The California Department of Health Services, Laboratory Field Services (the "State Survey Agency), acting as the agent of the Secretary, conducted a survey of PIL between August 17, 1999 and December 13, 1999, which identified PIL's violation of nine separate CLIA “Conditions of Participation” and numerous "standard level" CLIA requirements.

Under cover of letter dated January 20, 2000, the State, Survey Agency provided PIL with a 334-page report of the documented deficiencies. The subject line of the January 20, 2000 correspondence stated "Condition-Level Deficiencies and Not Immediate Jeopardy." The January 20, 2000 letter asked PIL to submit a “credible allegation of compliance” along with evidence documenting correction. PIL submitted what it believed to be a conforming plan of correction in April of 2000. By letter dated June 21, 2000, the State Survey Agency provided PIL with reasons why the April 2000 plan was not acceptable. A second correction plan, submitted by PIL on July 13, 2000, was also found to be unacceptable. PIL submitted a third correction plan dated July 25, 2000.

The State Survey Agency referred the matter to the Secretary. The Secretary accepted the State’s recommendation for sanctions. Accordingly, by notice dated September 22, 2000, the Secretary informed PIL's director and owner that the Secretary was imposing certain sanctions including the suspension of the

laboratory's CLIA certificate, effective October 6, 2000, and revocation of the laboratory's CLIA certificate, effective November 20, 2000. The September 22, 2000 notice informed PIL that even if it exercised its right to an ALJ hearing, the Secretary would maintain the CLIA certificate suspension prior to and during the hearing.

The September 22, 2000 notice, informing the Plaintiffs of the license suspension and revocation, stated "due to your failure to comply with reasonable requests for information that is necessary to determine your laboratory's compliance with performance standards set by law and its eligibility for a CLIA certificate of compliance" the suspension and revocation were imposed.

On October 2, 2000, PIL submitted materials directly to the Secretary in support of the laboratory's claim that the previously notice sanctions should not be imposed. The Secretary notified PIL, four days later by letter dated October 6, 2000, that "[w]e have carefully reviewed the materials your laboratory submitted on October 2, 2000 and determined that your laboratory has never come into compliance in correcting the deficiencies cited at the December 13, 1999 survey."

The Secretary notified PIL by letter dated October 17, 2000 that the submission was "entirely unacceptable as it failed to either address the deficiencies cited or to show that the alleged correction plan was every implemented." The sanctions were thereafter imposed in accordance with the schedule set forth in the September 22, 2000 notice, including the October 6, 2000 suspension of PIA's (sic) CLIA license.

In a letter dated November 7, 2000, from PIL's attorney, which was received by HCFA on November 20**,** 2001, PIL requested a hearing before an ALJ. In a letter dated November 21, 2000**,** HCFA requested that an administrative law judge be assigned to this administrative action. The matter was set for a hearing on January 22, 2001.

However, Plaintiffs refused to participate in an ALJ hearing. On or about January 18, 2000, PIL requested a continuance of the administrative hearing or, in the alternative, withdrawal of its request for a hearing. The administrative law judge issued an Order Dismissing the Case on January 23, 2001. This Order has become final.

III. discussion

a. Jurisdiction Over Federal Defendants

Plaintiffs previously brought a motion for a preliminary injunction which this Court denied in our January 25, 2001 Order. In opposition to Plaintiffs' motion for a preliminary injunction Defendants argued that this Court has no jurisdiction to grant equitable relief to the Plaintiffs because 42 U.S.C. § 263(a) (k) confers jurisdiction only upon the Circuit Court for appeal of final agency action under the CLIA. The Court found that "this Court has jurisdiction to grant Plaintiffs a preliminary injunction pending an ALJ hearing." See January 25, 2001 order.

Defendants now argue that, because Plaintiffs have declined to participate in any ALJ hearing and seek monetary rather than preliminary injunctive relief pending an ALJ hearing, that this Court no longer has jurisdiction over this matter. Defendants are correct.

42 U.S.C. § 263(a) (k) of the Clinical Laboratory Services Amendment of 1988 states, in relevant part: "[a]ny laboratory which ... has had its certificate suspended, revoked, or limited ... may, at any time within 60 days after the date the action of the Secretary …becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has it principle place of business for judicial review of such action." 42 U.S.C. § 263a(k).

It is uncontroverted that the provision is applicable here, and it is equally clear that, by its language, its grant of jurisdiction to the circuit court is not exclusive. There is no specific provision for alternative jurisdiction in the district court, although the district court has general subject matter jurisdiction.

The Defendants argue that even though the grant of jurisdiction in 42 U.S.C. § 263(a) (k) is not exclusive, the Ninth Circuit in Public Utility Commr. V. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985) mandates that this court read the permissive language as conferring exclusive jurisdiction on the circuit court. The Ninth Circuit in Bonneville Power stated that "where a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Id. Jurisdiction is exclusive in the Court of Appeals "even in the absence of an express statutory command of exclusiveness." Id. citing Central Lincoln Peoples Utility District v. Johnson, 735 F.2d 1101, 1109 (9th Cir. 1984) (Central Lincoln II); Assure Competitive Transportation, Inc. v. United States, 629 F. 2d 467, 470-72 (7th Cir. 1980),cert. denied, 449 U.S. 1124 (1981); Nevada Airlines, Inc. v. Bond, 622 F.2d 1017, 1020 (9th Cir. 1980); City of

Rochester v. Bond, 603 F. 2d 927, 935 (D.C. Cir. 1979); UMC Industries v. Seagorg, 439 f. 2d 953, 955 (9th Cir. 1971).

This Court acknowledged Bonneville Power in Plaintiffs' motion for a preliminary injunction but found Bonneville Power to be inapplicable to a request for a preliminary injunction pending an ALJ hearing because the Ninth Circuit would receive Plaintiffs' appeal from an ALJ hearing in the same posture as it otherwise would whether or not the district court granted temporary relief.

Although granting temporary relief would not affect the posture of this case before the Ninth Circuit, allowing Plaintiffs to proceed in this action would deprive the Ninth Circuit of the experrtise of the ALJ in this matter because Plaintiffs' appeal would, of course, be directly to the Ninth Circuit. Plaintiffs in this case, as the Plaintiffs in Bonneville Power attempted to do, seek to challenge agency proceedings on constitutional grounds in the district court. Bonneville Power provides that a statutory review mechanism providing for an ALJ hearing followed by an appeal within the agency, and subsequent appeal to the Ninth Circuit is Plaintiffs' exclusive remedy even if the statutory language is only permissive.

Therefore, this Court lacks jurisdiction over Plaintiffs, causes of action.

b. Exhaustion of Administrative Remedies

Previously, Defendants argued that the CLIA requires exhaustion of administrative remedies prior to judicial review of any kind - including a request for preliminary injunctive relief under the APA. This Court found, citing the United States Supreme Court in Darby v. Cisneros, 509 U.S. 137, 144-146 (1993), that federal courts have no authority to require plaintiffs to exhaust administrative remedies prior to seeking judicial review under the APA unless a statute or agency regulation specifically mandates exhaustion as a prerequisite to judicial review. As explained in Darby, "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by the agency rule as a prerequisite to judicial review." Id.

Although the judicially created doctrine of exhaustion cannot be applied to actions brought under the APA, "the exhaustion doctrine continues to apply as a matter of judicial discretion in cases not governed by the APA." Id. Therefore, in Bivens actions, a district court has discretion in its application of the judicially created exhaustion doctrine. See Stauffer Chemical Co. V. FDA, 670 F. 2d 106, 107 (9th Cir. 1982); SEC v. G.C. George Securities, Inc., 637 F. 2d 685, 687-88 (9th Cir. 1981) ; Reid

v. Engen, 765 F. 2d at 1462; United States v. California Care Corp., 709.F. 2d at 1248; Southeast Alaska Conservation Council, Inc. V. Watson, 697 F. 2d 1305, 1309 (9th.Cir. 1983); Aleknagik Natives Ltd. v. Andrus, 648 F. 2d 496, 500 (9th Cir. 1980).

The Ninth Circuit, in Montgomery v. Rumsfeld, 572 F. 2d 250, 252-53 (9th Cir. 1978), explained that exhaustion of administrative remedies was either "specifically required by statute" or "judicially developed." Id. In Montgomery, the Ninth Circuit stated that, in determining whether to apply the judicially developed doctrine of exhaustion "[t]he district judge should carefully weigh the need for an administrative record for proper judicial review, the agency's interests in applying its expertise, in correcting its own errors, and preserving the efficacy and independence of its administrative system, and particularly, the district court should carefully consider "whether allowing all similarly situated individuals to bypass the administrative avenue in question would seriously impair the agency's ability to perform its functions." Id. at 254.

In applying these factors, the Court finds that Plaintiffs must exhaust their administrative remedies and seek its appeals through the process described in 42 U.S.C. § 263(a) (k).

First, the Court finds that there is a significant need for an administrative record and a strong interest in the agency applying its expertise. Plaintiffs argues that the revocation of its license prior to an ALJ hearing was forbidden by 42 C.F.R. § 493.1840(d). Defendants argue that their revocation was proper because under, Section 493.1840 (d) , "the laboratory [had] refused a reasonable request for information or work an material." Deciding whether a laboratory has sufficiently complied with requests for information seeking to probe its safety and compliance with complex regulations is a task significantly better suited for an ALJ.

Second, allowing all similarly situated individuals to bypass the statutory procedures by refusing to attend an ALJ hearing significantly undermines the Clinical Laboratory Amendment of 1998, 42 U.S.C. § 263, which clearly states that violations of regulations promulgated under it should receive initial scrutiny by an ALJ. Therefore, even if the Court could properly exercise jurisdiction in this matter, it would require Plaintiffs to exhaust their administrative remedies before appealing an adverse decision as set forth in 42 U.S. C. § 263 (a) (k).

III. Conclusion

Defendants' motion to dismiss is granted.

IT IS SO ORDERBD.

DATED: *5/9/2001*

STEPHEN V. WILSON

UNITED STATES DISTRICT JUDGE

United States Attorney
STUART A. MINKOWITZ
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2925
SAM-2692

UNITED STATES OF AMERICA,
Plaintiff,

v.

EDISON MEDICAL LABORATORY SERVICE CORPORATION,
Defendant.

Hon.

Civil Action No. 01-2872 [(k?)sh]

ORDER TO SHOW CAUSE AND TEMPORARY RESTRAINING ORDER (Fed. R. Civ. P. 65(a), (b); 42 U.S.C. § 263a(j) and 42 C.F.R. § 493.1846)

TO: KENNETH B. FALK, ESQ.
Deutch & Falk
843 Rahway Ave.
Woodbridge, NJ 07095-3699

THIS MATTER HAVING BEEN opened by the plaintiff, by and through its counsel, Robert J. Cleary, United States Attorney for the District of New Jersey (Stuart A. Minkowitz, Assistant U.S. Attorney appearing), upon an application for an Order to Show Cause and a Temporary Restraining Order, and the Court having considered the Complaint and the papers filed therewith, and it appearing to the Court that defendants continue to commit the acts specified in this Order, and that unless restrained by the Court, the defendants will cause a significant hazard to the public health before notice can be given and the defendant or defendant's attorney can be heard in opposition to the granting of a temporary restraining order, and for good cause having been shown; therefore

IT IS on this **18th** day of June, 2001 at **4:00** a.m/**[p.m,]**

ORDERED THAT:

1. Plaintiff's application for an Order to Show Cause and a Temporary Restraining Order be and is hereby granted.

2. Pursuant to 42 U. S.C. § 263 a(j) and 42 C.F.R. § 493.1846, and pending a hearing on the preliminary injunction, defendant, its owners, operators, employees, agents, representatives, successors or assigns, and all persons in active concert or participation with them are hereby restrained from operating a clinical laboratory, or soliciting or accepting materials derived from the human body for laboratory examination or other procedure without certification pursuant to the requirements of the Clinical Laboratories Improvement Amendments of 1988 ("CLIA") (Public Law 100-578), and as set forth in 42 C.F.R. § 493, et seq.

3. The foregoing temporary restraints shall remain in force until the close of business on the **2nd** day of **July**, 2001, or at such later date as may be set by the Court or agreed upon by the parties.

4. Defendants she show cause before this Court on the **2nd** day of **July**, 2001 at **2:00p.m**. why an Order granting a preliminary injunction in the form annexed hereto should not be granted.

5. Written opposition by defendant, if any, to plaintiff's application shall be filed with this Court and received by the United States Attorney on or before the **25th** day of **June**, 2001.

6. The plaintiff may file, and serve upon defendant, a reply to any opposition filed by defendant no later than the **29th** day of **June**, 2001. *by 12:00 pm*

7. True copies of this Order to Show Cause with Temporary Restraining Order, together with the other papers filed with this application shall be served upon defendant or their attorney within **I** days of the date of this Order, Service of these documents may be effected by sending the same via next-day mail or by hand delivery. a*nd by fax.*

8. Pursuant to 42 U.S.C. § 263a(j), the plamff need not post a bond.

HON.

UNITED STATES DISTRICT JUDGE

ROBERT J. CLEARY
United States Attorney
STUART A. MINKOWITZ
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2925
SAM-2692

UNITED STATES OF AMERICA,
Plaintiff,

Hon. Katharine S. Hayden

Civil Action No. 01-2872 (KSH)

v.

EDISON MEDICAL
LABORATORY SERVICE
CORPORATION,
Defendant.

CONSENT DECREE

WHEREAS, Plaintiff, the United States of America, on behalf of its agencies the Department of Health and Human Services and Centers for Medicare and Medicaid Services ("CMS") (formerly the Health Care Financing Administration ("HCFA")) (collectively "the Government"), having filed its complaint against the defendant, Edison Medical Laboratory Service Corporation ("EMLS"); seeking to permanently enjoin defendant, owners, operators, employees, agents, assigns and/or successors from violating the Clinical Laboratories Improvement Act Of 1967; Clinical Laboratories Improvement Amendments of 1988 ("CLIA") (42 U.S.C. § 263a(b) and (j) and its associated regulations (42 C.F.R. 493.1846); and

WHEREAS, the parties have engaged in discussions in an effort to resolve all issues raised by the Complaint; and

WHEREAS, the defendant has consented to entry of this Decree without contest and the Government has consented to the entry of this Decree; therefore,.

NOW, it is hereby ORDERED, ADJUDGED AND DECREED as follows:

1. The Court has subject matter jurisdiction over this ation under 28 U.S.C. § 1345, 42 U.S.C. § 263a(j) and 42 C.F.R. § 493.1946, and its general equity and ancillary jurisdiction.

2. Venue lies in the District of New Jersey under 28 US.C. § 1391(b) and (c) and 42 U.S.C. § 2634a(j), as the place where the claims arose and where the defendant's laboratory is located.

3. The Complaint states a valid claim against the defendant under CLIA.

4. Defendant does not contest the allegations contained in the Complaint.

5. Defendant, EMLS, and its owners, operators, employees, agents. assigns and/or successors, are hereby permanently enjoined and restrained from soliciting or accepting materials derived from the human body for laboratory examination or other procedure unless and until there is in effect for the laboratory a valid certificate issued by the Secretary of HHS under 42 U.S.C. § 263a. The permanent restraint includes, but is not limited to, (1) the diagnosis, prevention or treatment of any human disease or impairment, or (2) the assessment of the of health of any person, (3) procedures to determine, measure, or otherwise describe the presence or absence of substances or organisms in the human body, or (4) the taking of specimens or samples derived from the human body.

6. Defendant, its owners, operators, employees., agents, assigns and/or successors agree that HHS, CMS or New Jersey Department of Health and Senior Services, or their agents, may periodically inspect EMLS, unannounced, at any time during regular business hours to verify that the laboratory has not resumed diagnostic testing without a valid CLIA certificate. Defendant, its owners, operators, employees., agents, assigns and/or successors consent to such periodic inspections and acknowledge that they may be required to bear the cost of each inspection, if the defendant is found to be in violation of this Consent Decree.

7. In the event EMLS, its owners, operators, employees., agents, assigns and/or successors, violate any provision of this Consent Decree, upon notice by HHS, CMS or the New Jersey Department of Health and Senior Services, EMLS, it owners, operators,

employees., agents, assigns and/or successors shall, within 10 days of receipt of such notice, pay a penalty of $5, 000.00 per violation. In addition, EMLS, it owners, operators, employees., agents, assigns and/or successors, shall pay $500.00 per day for each day the violation continues beyond the date of the receipt of the notice of a violation. The penalties shall be made payable to the United States Department of Justice. This remedy is not in lieu of, but in addition to any other remedy available to the Government by statute, regulation or the common law, including an order for contempt. If EMLS, it owners, operators, employees., agents, assigns and/or successors disagree with the findings of HHS, CMS, or the New Jersey Department of Health and Senior Services, that there has been a violation of this Consent Decree, it shall be entitled to challenge such findings in this Court, but solely on the grounds that the violation did not occur and by demonstrating the nonoccurrence by a preponderance of the evidence.

8. Without leave of Court, the Government may take discovery reasonably calculated to determine whether persons or entities bound by this Consent Decree are in full compliance with the provisions of this Consent Decree.

9. If any person or entity bound by this Consent Decree fails to comply with any provision of this Consent Decree or is found in civil or criminal contempt thereof, that defendant shall, in addition to other relief, reimburse the Govenment for its reasonable attorney's fees, investigational expenses and costs.

10. Nothing in this Consent Decree shall be deemed to excuse defendant, it owners, operators, employees., agents, assigns and/or successors , from hereinafter complying with CLIA and the regulations promulgated thereunder, or any other obligations under applicable law or regulation.

11. If the present owners or operators of EMLS become affiliated as an owner, operator or otherwise, with any laboratory other than EMLS, or applies for a CLIA certificate on behalf of any laboratory, they must notify the Government within seven days, identifying the name, address, owners, officers and nature of the laboratory.

12. All notices and corespondence required by this Consent Decree shall be sent by first class mail to the parties at the following addresses, and, if possible, by facsimile unless otherwise indicated:

To the Government

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Jacob K. Javits Federal Bldg.
26 Federal Pza., Rm. 3809
Now York, NY 10278

With a copy to:

U.S. Department of Health and Human Services
Office of the General Counsel, Region II
Jacob K. Javits Federal Bldg.
26 Federal Pza., Rm. 3908
New York, NY 10278
Fax: (212) 264-6364

Chief, Civil Division
United States Attorney's Office
970 Broad St., Ste. 700
Newark, NJ 07102
Fax: (973) 297-2010

To the-Defendant

Kenneth B. Falk, Esq.
Deutch & Falk, P.C.
843 Rahway Ave.
Woodbridge, NJ 07095-3699
Fax: (732) 636-3575

Edison Medical Laboratory Services Corporation
1692 Oak Tree Pza.
Edison, NJ 08820

The parties will notify each other promptly upon any change in the above information.

13. This Consent Decree shall be binding upon defendant, it owners, operators, officers, agents, employees, lessess, assigns, successors in interest, and those persons who are in acitive concert or participation with them directly or indirectly.

14. The individuals executing this Consent Decree on behalf of EMLS represent that they are duly authorized to execute this Consent Decree on EMLS's behalf.

15. Nothing herein shall be deemed to limit the Government's ability to enforce CLIA and its regulations.

16. This Court shall retain jurisdiction for the purpose of enforcing or modifying this Consent Decree, and for the purpose of granting such addiional relief as may hereafter appear neccessary or appropriate.

17. With the exception of inspection costs outlined in paragraph 6, above, each party shall bear its own costs, including attorney's fees.

18. The Government reserves the right to seek costs, investigation and attorney's fees against defendant, its owners, operators, employees, agents, assigns, and/or successors, should defendant violate the terms and conditions of this Consent Decree.

19. If any provision of this Consent Decree is declared invalid, such declaration shall not effect the validity of any other provision herein.

IT IS SO ORDERED,

Dated: *7/6/01*

HON. KATHARINE S. HAYDEN
United States District Judge

AGREED AND CONSENTED TO:

For the Plaintiff, United States of America

ROBERT J. CLEARY
United States Attorney
District of New Jersey

By: STUART A. MINKOWITZ
Assistant U.S. Attorney

Dated: *7/2/01*

For theDefendant, Edison Medical Laboratory Service Corporation

DEUTCH & FALK, P.C.

By: Kenneth B. Falk, Esq. Dated: *6/28/01*
Attorney(s) for Edison Medical Laboratory Service Corporation

EDISON MEDICAL LABORATORY
SERVICE CORPORATION

By: Dated: *6/26/2001*
Name: Edison Medical Laboratory Services Corporation
Title: President

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT Of MICHIGAN

SOUTHERN DIVISION

PREFERRED FAMILY MEDICINE, P.C.
A Michigan Professional Corporation,
MARC WEISMAN, D.O. and
JASON TALBERT, M.D.

Case No-. 01 -72447
v. Honorable Victoria A. Roberts

TOMMY G. THOMPSON, SECRETARY OF HEALTH
AND HUMAN SERVICES, and THOMAS SCULLY,
ADMINISTRATOR OF THE CENTERS FOR
MEDICARE AND MEDICAID SERVICES, formerly
known as the Health Care Financing Administration

OPINION & ORDER DENYING PLAI ITIFF'S MOTION FOR

INJUNCTIVE RELIEF AND REQUEST FOR DECLARATORY

JUDGMENT AND MANDAMUS, AND GRANTING

DEFENDANTS' MOTION TO DISMISS

I. Introduction

This matter is before the Court on Plaintiff s' Verified Complaint for Declaratory Judgment, Mandamus and Injunctive Relief, as well as their Motion for a Temporary Restraining Order and Preliminary Injunction pursuant to Fed. R. Civ. P. 65(a) and (b).

Plaintiffs contend that they are entitled to injunctive relief in order to prevent Defendants from canceling Preferred Family Medicine's ("PFM") approval to receive Medicare payments for its laboratory services. This cancellation went into effect or, July 2, 2001, pursuant to 42 C.F.R. § 493.1808(a), 493.1842(o) (1) and 493.1844(d) (3). Additionally, Plaintiffs are requesting injunctive relief to prevent the revocation of their CLIA ("Clinical Laboratory Improvement Amendment") Certificate of

Accreditation. Plaintiffs maintain that if either of these two events occur, it would effectively force the closure of PFM's laboratory and cause irreparable harrn to Plaintiffs and numerous Medicare and other patients. Plaintiffs also seek declaratory relief and relief in the form of a writ of mandamus.

Secondly, Plaintiffs argue that this Court has subject matter jurisdiction even though they have not exhausted their administrative remedies prior to judicial review, as required by 42 U.S.C. § 405(h). Plaintiffs state that the waiver exception under 42 U.S.C. § 405(g) applies to their factual circumstances, thus giving this Court jurisdiction.

Defendants' response is two-fold. First, they assert that this Court does not have subject matter jurisdiction, thereby requiring the dismissal of Plaintiffs' claim without reaching the merits. Defendants also maintain that Plaintiffs are not entitled to a writ of mandamus or declaratory relief because the facts and circumstances of this case do not warrant such extraordinary relief.

Second, if this Court reviews Plaintiffs' Motion on the merits. Defendants argue that Plaintiffs are not entitled to injunctive relief because this matter does not meet the requisite factors before injunctive relief con be granted.[1]

_____

(1) whether the movant has a "strong" likelihood of success on the merits;

(2)whether the movant would otherwise suffer irreparable injury; (3) whether

_____

Defendants claim that: (1) nonpayment of Medicare claims for laboratory services is not irreparable harm; (2) the public interest would be disserved by requiring the Secretary to continue Medicare payments to a laboratory that engaged in such serious misconduct with respect to the handling of proficiency testing samples; and, (3) the balance of the equities weighs against granting injunctive relief.

For the reasons set forth below, Plaintiffs' Motion for Injunctive Relief is **DENIED**, Plaintiffs' request for declaratory judgment and mandamus is **DENIED**; and, Defendants Motion to Dismiss is **GRANTED**.

II. Background

A. The Parties

PFM provides family/primary care physician services including laboratory testing. Plaintiffs, Drs. Weisman and Talbert, are practicing physicians with PFM and are also the President and Director, respectively, of PFM. Defendant, Secretary Health and Human Services, through the Centers for Medicare and Medicaid Services (CMS - a component of the Department of Health and

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issuance of a preliminary injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of a preliminary injunction. *United Food & Commercial Workers Union,* Local *1099 v. Southwest Ohio Regional Transit Auth.,* 163 F.3d. 341, 347 (6th Cir. 1998)

Human Services)[2] is responsible for operating the Medicare Program and is statutorily empowered with enforcement authority for the regulations regarding clinical laboratories. Defendant, Administrator of CMS, is responsible for the administration of the Medicare Program and shares responsibility for the proposed actions by CMS against Plaintiffs which are at issue here.

B. PFM Accreditation

As a clinical laboratory, PFM is required to comply with the provisions of the Social Security Act and with CLIA regulations. PFM is entitled to payment from Medicare for medically necessary, covered laboratory services it renders to its Medicare patients so long as PFM is deemed to be compliant with the above referenced statutory law. In order to assist in the compliance with and enforcement of the CLIA requirements, CMS has approved COLA (formerly the Commission on Office Laboratory Accreditation) as an accreditation organization for laboratories under the CLIA program.

Prior to such approval, HCFA conducted a detailed and in-depth comparison on COLA's requirements[3] for its laboratories to those of CLIA and

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[2] CMS was formerly known as the Health Care Financing Administration (HFCA).

[3] The COLA Accreditation Manual was created to inform persons involved with laboratory medicine how COLA works. The Manual also includes the following references to the CLIA and HCFA: (1) "COLA has been approved by the federal government as a private non-profit accrediting organization for CLIA purposes;" (2) "COLA accreditation has

been deemed by the federal government to be equivalent to the CLIA regulations. (3) 'Deeming authority' (i.e.,

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dermined that it should grant approved status to COLA as a private nonprofit organization for accrediting laboratories under CLIA for specific specialty or subspecialty areas of human specimen testing.[4]

On July 31, 1992, HCFA issued a final rule (57 FR 33992). Under section 353(e)(2) of the Public Health Service Act (PHSA), HCFA may approve a private nonprofit organization to accredit clinical laboratories (an "approved accreditation organization") under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program if the organization meets certain requirements.

An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 Code of Federal Regulations (CFR), part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved

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equivalent standard) is a COLA status recognized by HCFA; (3) Laboratories accredited by COLA are 'deemed' to meet the government standards; and COLA-accredited labs are not routinely inspected by the government; (4) "As a result of being granted deeming authority, some COLA criteria now mirror federal CLIA requirements;" (5) Once a laboratory applies to COLA for accreditation, HCFA recognizes the lab as a COLA-accredited laboratory; and (7) Although it's useful to see the relationship between the COLA and CLIA standards, COLA-accredited laboratories are quartered to meet COLA standards, not CLIA. *COLA* Accreditation *Manua[, §3*

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[4] Baciedology, mycobacteriology, mycology, parasitology, virology, syphilis serology, general immunology, routine chemistry, endocrinology, toxicology, urinalysis, and hematology, immunohematology.

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accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) of part 493 specify the requirements an accreditation organization must meet to by an approved accreditation organization. HCFA approves an accreditation organization for a period not exceed 6 years. 65 FR 64966.

In establishing laboratory compliance with CLIA requirements, COLA must, among other conditions and requirements (1) use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by CMS; (2) apply standards and criteria that are equal to or more stringent than CMS requirements; (3) provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories; (4) provide CMS with the name of any laboratory that had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action; (5) notify CMS in writing at least 30 days before the effective date of any proposed changes in its standards; and, (6) if CMS withdraws its approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal. *65 FR* 64966 (October *31, 2000).* COLA's requirements for PT are equivalent to those of CLIA. ld.

C. September 3,1999 COLA Letter to PFM

In a letter dated September 3, 1999 PFM was first notified by COLA of a pending denial of COLA accreditation due to PFM's complicity in proficiency test (PT) averaging, resulting in an improper referral, collaboration, and integration at PFM's laboratory in 1998 and 1999. (See September 3, 1999 Letter from COLA to Plaintiff Talbert attached to Plaintiffs' Verified Complaint as Exhibit B). Upon receipt of the Letter, Plaintiffs Weisman and Talbert contend that they conducted an immediate investigation into the allegations by COLA and learned that while PFM's laboratory technician, Marilyn Nichols, had properly tested the proficiency of PFM's laboratory as required by COLA and CLIA, she had averaged the test results with test results she had obtained at two other laboratories where she worked. She then reported the averaged test results to Medical Laboratory Evaluation (MLE), a COLA and CMS approved proficiency test program.

On or about October 19,1999, COLA denied PFM's COLA accreditation based upon "knowingly comparing results of proficiency test prior to the proficiency test program end-date for receipt of the results." (See October 19, 1999 letter from COLA to Plaintiff Talbert attached to Plaintiffs' Verified Complaint as Exhibit). At some point after the PT averaging discovery, Plaintiffs terminated Marilyn Nichols and hired Lawrence S. Michaelski, a certified chemist with over thirty years of clinical laboratory experience and the Chemistry Supervisor of Crittenton Hospital in Rochester, Michigan. After hiring Mr. Michaelski, Plaintiffs designed and implemented a Quality Assurance Program which has been in place at

PFM since January 2000. Plaintiffs submitted proof of their remedial efforts to COLA and requested a reconsideration of the denial of COLA accreditation. Ultimately, after a hearing on February 19, 2000, the COLA Accreditation Committee voted to reverse the initial decision to deny accreditation (reversal "constitutes the final action of the Accreditation Committee") and notified Plaintiffs in a letter dated March 3, 2000. (See March 3, 2000 letter from COLA to Plaintiff Tolbert attached to Plaintiffs' Verified Complaint as Exhibit J). From early March 2000 until the present, Plaintiffs allege that PFM has been fully compliant with all applicable CLIA and COLA requirements.

Defendants have not presented any evidence to the contrary. Plaintiffs further allege that during an on-site survey at PFM in April 2001, no new deficiencies were noted[5]; only the violation of which PFM was notified by COLA in September of 1999, and determined by COLA in March 2000 not to warrant the revocation of the laboratory accreditation.

D. May 29, 2001 CMS Letter to PFM

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[5] On April 10, 2001, a complaint investigation survey was conducted by Lucy Estes, CLS, MSA, who is a laboratory evaluation specialist and employed by the Michigan Department of Consumer and industry Services (MDICS), Laboratory Improvement and Special Projects Section. (Declaration of *Lucy Estes, CLS, MSA)*

Despite this compliance, Quality Assurance Program and "final action of the Accreditation Committee" to not deny accreditation, based on the 1998 and 1999 testing events, Plaintiffs were informed in a letter dated May 29, 2001 from HCFA (CMS) that the Michigan Department of Consumer and Industry Services (MDCIS) conducted a complaint investigation survey at PFM on April 10, 2001 to determine whether "improper referral, collaboration, and integration occurred at PFM's laboratory during proficiency testing events of 1998 and 1999." (See May *29, 2001* letter from HCFA *to Plaintiff Talbert attached to Plaintiffs' Verified* Complaint *as Exhibit K).*

In the May 29, 2001 letter, HCFA (CMS) alleged that PFM'S laboratory was not in compliance with CLIA as a result of an "improper referral, collaboration, and non-integration [which] occurred during specific 1998-1999 testing events;" and, therefore, PFM was deemed non-compliant with 42 C.F.R. § 493.1441, 493.61 (b) (1); and 493.801 (b) (3) and 42U.S.C.§ 263a(d) (1) (E). Consequently, certain

penalties were imposed: (1) cancelling PFM's laboratory's approval to receive Medicare payment for services effective July 2, 2001; and (2) the future revocation of PFM's CLIA Certificate of Accreditation.

E. Procedural Process Undertaken By Plaintiffs In Response To The May 29, 2001 Letter

On June 14, 2001, Plaintiffs presented their request to Defendant Secretary of Health and Human Services to reverse CMS' determination to impose these additional sanctions upon PFM. (See *Plaintiffs' Verified* Complaint, pg. 13, ¶*46).* Plaintiffs allege that they have no idea when the procedural process will get underway. Plaintiffs allege that they requested an expedited hearing with the Administrative Law Judge (ALJ) on June 18, 2001, and were told by Jacqueline Williams, Chief of the Civil Remedies Division at CMS, "it happens [the hearing] when it happens." Id. *at* ¶*47.* On June 27, 2001, Plaintiff filed a request for a hearing before an ALJ of the Department of Health and Human Services pursuant to 42 C.F.R. § 493.1844. Id. *at* ¶*48.*

F. Pendency ot ALJ Hearing

Plaintiffs acknowledge that revocation of PFM'S CLIA Certificate of Accreditation will not take effect until a decision is rendered by the ALJ of the Department of Health Services pursuant to 42 C.F.R. § 493.1844(d)(2). However, the effective date of the cancellation of PFM's approval to receive Medicare payment for its laboratory services, July 2, 2001, was prior to any opportunity for an ALJ decision. Moreover, Defendants are permitted to publish in a local newspaper and in the laboratory registry, information about PFM and its directors being sanctioned. 42 C. F. R. § 1844 (g) (1).

G. The CMS Complaint lnvestigation

CMS imposed its sanction determination based on a complaint investigation survey performed at Plaintiffs' laboratory by the MDCIS at CMS's request. CMS requested the survey of PFM after inspections by MDCIS of two

other Detroit-area laboratories employing the same laboratory technician for proficiency testing as PFM (Marilyn Nichols). This investigation uncovered the alleged prohibited referral and/or collaboration of PT results. PFM was identified as the third laboratory involved in this alleged unlawful conduct detailed above which occurred in 1998 and 1999. (See *Declaration of Richard J.* Benson ¶ 9-18 attached to Defendants' Memorandum of Low *in* Opposition *to Plaintiffs'* TRO *Motion as Exhibit 1).* It is important to point out that COLA had an obligation to notify CMS in September 1999 when it made the decision to deny

accreditation to PFM. 65 *FR* 64966 (October 31, 2000). Plaintiffs have presented no evidence that COLA did that, and Defendants state that COLA did not notify CMS about its withdrawal of Plaintiff' accreditation status. (Defendants' Motion to *Dismiss, pp. 7-12).*

III. Standard of Review

A. Subject Matter Jurisdiction

Pursuant to Federal Rule of Civil Procedure 12(b) (1), when "considering a motion to dismiss for lack of subject matter jurisdiction, the person asserting jurisdiction bears the burden of showing that the case is properly before the court at all stages of the litigations." *Fed. Realty Inv. Trust v.* Juniper Props. *Group*, No. 99-3389, 2000 WL 45996, at 3 (E.D.Pa.2000) (citing Packard *v. Provident Nat'l Bank, 994* F.2d 1*039, 1045 (3d Cir. 1993), cert.* denied, 51 0 U.S. 964, 114 S.Ct. 440, 126 L.Ed.2d 373 (1993)). The district court, when reviewing a motion to dismiss for lack of subject matter jurisdiction, "must accept as true the allegations contained in the plaintiff's complaint, except to the extent federal jurisdiction is dependent on certain facts." Id. *(citing Hoydo v. Amerikohl Mining,* Inc., 830 F.2d 494, 496 (3d Cir. 1987)).

The district court is not confined to the face of the pleadings when deciding whether subject matter jurisdiction exists. Id. *(citing Armstrong World Indus.* v. *Adams,* 961 F.2d 405, 410, n. 10 (3d Cir.1 992)). "in assessing a Rule 12 (b) (1) motion, the parties may submit and the court may consider affidavits and other relevant evidence outside of the pleadings." *Id. (citing Berardi v.* Swanson Mem'l Lodge No. *48 of Fraternal Order* of Police, 920 F.2d 198, 200 (3d Cir. 1 990)). In the case where the defendant attacks jurisdiction with supporting affidavits, "the plaintiff has the burden of responding to the facts so stated." Id. "A conclusory response or a restatement of the allegations of the complaint is not sufficient." Id. *(citing lnt'i Ass'n* of Machinists & Aerospace Workers v. *Northwest Airlines,* Inc., 673 F.2d 700, 711 (3d Cir. 1982)).

IV. Finding of Fact

For purposes of resolving the issues before the Court, the following are accepted as fact:

1. While COLA is an approved accreditation organization for laboratories under the CLIA program, CMS reserves the right to conduct validation and complaint investigation surveys in order to ensure compliance with CLIA requirements. 65. *FR 64966.*

2. The language in the COLA Accreditation Manual conflicts with 65 FR 64966 (October 31, 2000) to the extent that in the COLA Manual, CMS appears to confer full authority upon COLA to work through noncompliance issues. However, in the Federal Register, it is recognized that although a COLA accreditation "provides reasonable assurance that the laboratories accredited by it meet the conditions required by CLIA law and regulations," these accredited laboratories remain subject to federal validation and complaint investigation surveys. Id.

3. COLA cited PFM for PT Violations and denied PFM an accreditation as a result. After reconsideration by COLA and implementation of a Plan of Correction which has been followed by PFM, CMS was never notified in accordance with 65 FR 64966 by COLA about PFM's alleged PT deficiencies and the process that followed.

4. If COLA had given CMS notice of its accreditation activity with PFM, CMS would have been able to begin its investigation sooner, especially since CMS was already investigating two other Detroit laboratories which also had PT deficiencies and which also employed Marilyn Nichols.[6]

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[6] Accredited laboratories (i.e., COLA) are obligated pursuant to 65 FR 64966-01 to "[p]rovide HCFA with the name of any laboratory that has had its accreditation denied, suspended, withdrawn limited, or revoked within 30 days of the action taken.

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5. CMS and COLA View the issue of "intent" differently when determining whether a laboratory should be held responsible for "knowingly comparing results of proficiency tests prior to the PT program end-date for receipt of results."

6. In reversing itself, COLA did not impute the actions of PFM's laboratory technician to the laboratory director. On the other hand, CMS holds the laboratory and its director accountable for all business activity related to the functioning of the laboratory.

V. Conclusions of Law

A. Subject Matter Jurisdiction

The express language of 42 U.S.C. § 405(h) bars district court jurisdiction over an action to compel payment of Medicare reimbursement because the

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[7] During the COLA investigation process, it determined that "the knowledge of the lab technician should not be imputed to the laboratory itself," *(Exhibit* J of *Plaintiffs' Verified.Compliaint for* Declaratory *Judgment, Mcindamus and Injunctive Relief).* Conversely, CMS imputes the actions of a laboratory technician upon the laboratory director and the laboratory itself by indicating that "as laboratory director, [you] have not fulfilled your responsibility of assuring that PT samples are tested as required under 42 CFR 493, subpart H. The deficiencies noted in this letter and the HCFA-2567 demonstrate that you have failed to fulfill your responsibility for the overall operation and administration of your laboratory. Therefore, the *condition* level *requirement for* a laboratory director *is out* of compliance *at 42* CFR § 4930.1441." Exhibit K of Plaintiffs' Verified Complaint for Declaratory Judgment, Mandamus and Injunctive Relief).

Medicare Act requires exhaustion of administrative remedies before judicial review.

Since Plaintiffs' claim arises under the Medicare Act, the general rule is that this Court does not have subject matter jurisdiction. *Shalala V. Illinois Couvncil* on Long *Term* Care, Inc. 529 U.S. 1. 10 (2000); *Heckler v. Ringer, 466* U.S. 602 (1984); *Weinberger v. Salfi,* 422 U.S. 749 (1975); *Cathedral Rock of North* College *Hill v.* Shalala, 223 F.3d 354 (6th Cir. 2000); *Michigan Association of* Homes and Services for *the Aging v. Shalala,* 127 F.3d 496, 500-01 (6th Cir. 199*7); Monakee* Professional Medical *Transfer* Service, Inc. v. *Shalala, 71* F.3d 574 (6th Cir. 1995); *Farkas v. Blue Cross & Blue* Shielct of *Michigan,* 24 F.3d 853 (6th Cir. *1994); Livingston* Care Center *v.* United States, 934 F.2d 719, 721 (6th Cir.), cert. denied., 502 U.S. 1003 (1991).

Having concluded that this Court lacks subject matter jurisdiction, it is unnecessary and inappropriate, for the Court to reach the other issues raised by Plaintiffs.

Conclusion

Even though this Court finds in favor of Defendants, the Court is troubled that the law allows COLA to make determinations concerning violations; communicate with PFM about the problem; and, work out a Corrective Plan, yet CMS can enter the picture over a year later and, in effect, vitiate COLA's entire investigation and efforts to reinstate accreditation for P FM, which has remained in compliance with CLIA requirements. There are several references in the Federal Register as to how comparable and “equivalent" COLA accreditation standards are to those of CLIA.[8]

However, the law also seems to allow CMS to completely ignore the COLA finding and the Corrective Plan that is in place, as well as impose stiffer sanctions for the some conduct in however long a time frame it desires.

This Court finds that PFM justifiably believed that it had resolved its accreditation problems based upon the fact that it had been in compliance with its Corrective Plan for over a year; and, because COLA represented its

actions to be final.

Therefore, it is unfortunate that PFM, must in effect, be subjected to the entire validation and complaint investigation all over again.

However, the Court finds that, despite the apparent inequity of the matter, the express language of 42 U.S.C. § 405(h) and the above cited case low bars

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[8] COLA has been approved as an accreditation organization for laboratories under the CLIA programm; COLA requirements for PT are equivalent to those of CLIA according to the Federal Register; accreditation and approval of a laboratory by COLA meets the applicable CLIA condition level requirements for laboratories as indicated in the Federal Register; COLA has complied with the requirements under CLIA for approval as an accreditation organization according to the Federal Register; COLA's requirements are equal to the CLIA requirements; and COLA's laboratory enforcement and appeal policies are essentially equivalent to the requirements of the Federal Register as they apply to accreditation organizations.

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this Court from compelling payment of Medicare reimbursement, under either 28 U.S.C. § 1 331 or 28 U.S.C. § 1346. Therefore, upon consideration of the Verified Complaint and motions and briefs of the parties, it is hereby **ORDERED** that Plaintiffs' Motion for Temporary Restraining Order & Preliminary Injunction [**Doc. # 2-1**] is **DENIED**.

IT IS fURTHER ORDERED THAT this Court is without subject matter jurisdiction and that accordingly, Defendants' Motion to Dismiss [**Doc. #6-1**] is **GRANTED**.

IT IS FURTHER ORDERED THAT Plaintiffs' request for declaratory relief and request for a mandamus action in Plaintiffs' Verified Complaint [**Doc. #1 –1**] is **DENIED**.

IT IS SO ORDERED.

Victoria A. Roberts

United States District Judge

DATED: **JUL 31 2001**

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

PREFERRED FAMILY MEDICINE, P.C.,
a Michigan Professional Corporation,
MARC WEISMAN, D.O. and
JASON TALBERT, M D.,

Plaintiffs

vs

Case No: 01-72447

Honorable Victoria A. Roberts

TOMMY G. THOMSON, SFCRETARY OF HEALTH AND HUMAN SERVI'IES and THOMAS SCULLY, ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, formerly known as HEALTH CARE FINANCING ADMINISTRATION.

Defendants.

SUPPLEMENTAL OPINION & ORDER DENYING PLAINTIFFS' MOTION FOR INJUNCTIVE RELIEF AND REQUEST FOR DECLARATORY JUDGMENT AND MANDAMUS, AND GRANTING DEFENDANS' MOTION TO DISMISS

1. Introduction

On July 31, 2001, this Court entered an Order denying Plaintiff s Motion for Temporary Restraining Order & Preliminary Injunction. The Court also denied Plaintiff's request for declaratory relief and request for a mandamus action. Accordingly, Defendant's Motion to Dismiss was granted. Upon review of the July 31, 2001 Opinion and Order, the Court finds that clarification is warranted concerning the issue of whether the factual circumstances of this case come within the exception to the general rule

that district courts do not have original subject matter jurisdiction over claims arising under the Medicare Act. The Court found that this matter did not fall within the exception, thus precluding this Court from having subject matter jurisdiction rule upon the issues presented by Plaintiff. The rationale of the Courts ruling on this issue is detailed below.

II. applicable Law & Analysis

A. Subject Matter Jurisdiction

Plaintiffs argue that this Court has subject matter jurisdiction of this matter, even though they admittedly have not exhausted their administrative remedies prior to judicial review as required by 42 U.S.C. § 405(h). Plaintiffs state that the waiver exception under 42 U.S.C. § 405(g) applies to their factual circumstances, thus giving this Court jurisdiction.

Defendants' response is that this Court does not have subject matter jurisdiction to hear this matter, thereby requiring the dismissal of Plaintiff s claim without reaching the merits.

The express language of 42 U.S.C. § 405(h) bars district court jurisdiction over an action to compel payment of Medicare reimbursement because the Medicare Act requires exhaustion of administrative remedies before judicial review. Since Plaintiff's claim arises under the Medicare Act, the general rule is that this Court does not have subject matter jurisdiction. *Shalala v. Illinois Council on Long Term Care, Inc*. 529 U.S. 1, (?)0 (2000); *Heckler v. Ringer*, 466 U.S. 602 (1984); *Weinberger v. Salfi*, 422 U.S. 749 (1975); *Cathedral Rock of North College Hill v. Shalala*, 223 F.3d 354 (6th Cir. 2000); *Michigan. 4ssociation of Homes* and *Services for* the Aging v. *Shalala*, 127 F.3d 496, 500-01 (6th Cir. 1997); Manakee *Professional Medical Transfer Service, Inc. v. Shalala,* 1 F 3d 574 (6th Cir. 1995); *Farkas v. Blue Cross & Blue Shield of Michigan*, 24 F.3d (?)53 (6th Cir. 1994); *Livingston Care Center* v. *United States*, 934 F.2d. 719, 721 ((?)th Cir.), *cert. denied*., 502 U.S. 1003 (1991).

Based upon the evidence presented, Plaintiffs have not met the waiver requirements set forth in *Matthews v. Eldridge*, 424 U.S. 319 (1976). Pursuant to *Matthews* and its progeny, the exhaustion of administrative remedies may be waived where the plaintiff: (1) raises a colorable constitutional claim collateral to the substantive claim of entitlement (2) shows that irreparable harm would result from exhaustion; and (3) shows that the purposes of exhaustion would not be served by requiring further administrative procedures, i.e., futility. *Matthews*, at 330-31.

First, this Court finds that Plaintiff s Verified Complaint does not raise any colorable constitutional claim, and especially not one “wholly collateral to a claim for benefits." *Id*. Plaintiffs' claim is squarely one for continued Medicare payments. It is well settled that procedures that provide for a hearing before an administrative law judge after the effective date of a determination which cancels Medicare payments, meet the requirements of due process. See *Cathedral Rock, supra* (termination of nursing home's provider agreement); Lavapies *v. Bowen*, 883 F.2d 465 (6th Cir. 1989) (exclusion of physician from Medicare participation); *Nothlake Community Hospital v. United States*, 654 F.2d 1234 (7th Cir. 1981) (termination of Hospital Medicare provider agreement).

Plaintiff’s attempt to rebut this by claiming that administrative res judicata applies in this case because COLA already conducted an investigation, instituted discipline and assisted in implementing a Corrective Plan. Therefore, Plaintiffs contend that to repeat this process with CMS for the same alleged wrongful conduct. would in effect be res judicata. Since this Court finds as a matter of fact that COLA is not an administrative arm of CMS and has no authority over CMS. COLA’s findings are immaterial to CMS' present complaint investigation.

Since this Court finds that there is no colorable constitutional claim, Plaintiffs' ability to come within the *Matthews* exhaustion exception and 42 U.S.C. § 405(g) is not possible. However, this Court further finds, addressing the second prong of the waiver exhaustion requirement, that Plaintiffs have not shown that they will be irreparably harmed if a temporary restraining order is not put into place. Plaintiffs claim that their business will likely fold; and, as a result their patients will be harmed due to the potential severance of the physician/patient relationship. Moreover, Plaintiffs allege that they will lose a significant amount of money if they do not receive Medicare payments. Finally, Plaintiffs maintain that they will suffer irreparable harm in the form of damage to their reputation, based upon the publication of the sanctions.

The Sixth Circuit has concluded that injuries stemming from stoppage of Medicare payments are avoidable, and thus not irreparable. *Livingston*, 934 F.2d at 721. Subsequently, thie Sixth Circuit stated that such injuries are not necessarily irreparable even if they force a health care provider out of business. *Manakee*, 71 F.3d at 581. Regarding the physician/patient relationship harm, this Court agrees with Defendants in that such a claim is speculative and such claims do not constitute irreparable harm.

War(ner?) v. *Central Trust Co.*, 715 F.2d 1121, 1123 (6th Cir. 1983). Finally, regarding the harm to Plaintiffs' reputation, courts have recognized that Plaintiffs have an opportunity to clear their names through the administrative appeal process. *A(?)nett v. Kennedy*, 416 U.S. 134, 157 (1974).

Thus, the Court finds that Plaintiffs have not shown that exhausting administrative remedies would be futile or that it would not serve the purpose of the exhaustion requirement.

As a result of the foregoing, this Court finds that it is bound by 42 U.S.C. § 405(h) and that Plaintiffs do not come within the exception under 42 U.S.C. § 405(g). Consequently, this Court does not have subject matter jurisdiction. The Court's July 31, 2001 Order is affirmed as clarified.

IT IS SO ORDERED.

Victoria A. Roberts
United States District Judge

Dated: **AUG 2 8 2001**