

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA

HAI NAM NGUYEN

CIVIL ACTION

V.

NO. 16-2455

UNITED STATES DEPARTMENT OF HEALTH  
& HUMAN SERVICES AND CENTERS FOR  
MEDICARE & MEDICAID SERVICES

SECTION "F"

ORDER AND REASONS

Before the Court is the defendants' motion to dismiss for lack of subject matter jurisdiction. For the reasons that follow, the motion is DENIED. However, because of the serious jurisdictional question, the DHH-CMS is granted leave to apply for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b).

**Background**

This is an action for injunctive relief. On March 24, 2016, the Court granted Dr. Nguyen's motion for a temporary restraining order prohibiting the United States Department of Health and Human Services and Centers for Medicaid and Medicare Services (collectively, DHH-CMS) from imposing sanctions that restricted Dr. Nguyen's medical practice. In this motion DHH-CMS challenges the Court's subject matter jurisdiction to issue the temporary restraining order and to grant injunctive relief.

Dr. Nguyen operates a medical clinic and urgent care facility in Jefferson Parish, Louisiana. His clinic is equipped with a laboratory where he is able to test patients for conditions such

as pregnancy, influenza, diabetes, and strep throat. To operate the laboratory, Dr. Nguyen is required to obtain a certificate under the federal Clinical Laboratory Improvement Amendments (CLIA). At the heart of this dispute is the DHH-CMS's charge that Dr. Nguyen has failed to comply with federal regulations to maintain his CLIA certificate.

The CLIA is a federal regulatory scheme designed to ensure that laboratories that perform tests on human specimens comply with federal safety and quality standards.<sup>1</sup> Compliance is overseen by the Secretary of the Department of Health and Human Services. To verify compliance, the Secretary is permitted to inspect the laboratories of certificate holders. If the inspectors find that the laboratory is not in compliance with federal standards, the Secretary may impose sanctions.

On September 24, 2015, the Louisiana Department of Health and Hospitals (LDHH)<sup>2</sup> conducted an inspection of Dr. Nguyen's laboratory. The inspectors found that the lab was not in compliance with CLIA standards. The LDHH provided Dr. Nguyen with an opportunity to submit a plan of correction to remedy the compliance issues. Dr. Nguyen submitted a plan, but the LDHH rejected it. The lab then submitted a revised plan of correction, which the LDHH

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<sup>1</sup> The regulatory scheme is codified in 42 U.S.C. § 263a.

<sup>2</sup> Apparently, the state agency was acting on behalf of the federal agency to ensure compliance with the CLIA. The state agency is not a party to this suit.

accepted. Dr. Nguyen asserts that the revised plan was fully implemented by January 6, 2016.

On January 13, 2016, the LDHH conducted another, unannounced, inspection of Dr. Nguyen's laboratory to assess whether the revised plan had been implemented. No laboratory personnel were present that day.<sup>3</sup> Dr. Nguyen's office manager gave the inspectors the telephone number of Harold Smith, the lab's technical supervisor. Smith was in Kentucky at the time. The inspectors phoned Smith, who advised them that he had visited the lab on January 6, 2016 to confirm that the compliance issues had been remedied. He told the inspectors that everything required to satisfy the deficiencies was in the revised corrective action plan which could be found in labeled binders in a cabinet in the lab.

The inspectors remained alone in the 16 feet by 14 feet laboratory for an hour and a half. They never contacted Dr. Nguyen, who was on the premises at the clinic, nor did they attempt to contact Mr. Smith after he told them where the binders were located. Instead, the inspectors left the laboratory after telling the office manager that "everything looked good."

Two months later, on March 11, 2016, Dr. Nguyen received a letter from the Survey Branch Manager of DHH-CMS, Diane Murphy. The letter stated that the January 13 inspection revealed that the

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<sup>3</sup> One of the lab technicians had called in sick, and the lab's technical supervisor was out of town.

laboratory demonstrated continued noncompliance due to Dr. Nguyen's "failure to provide documents to demonstrate correction of deficiencies." The letter also stated that "new deficiencies were cited." Importantly, the letter claimed that these deficiencies "have caused, or could cause, serious harm to the patients served by the laboratory." Based on this finding, the DHH-CMS concluded that the deficiencies posed "immediate jeopardy," a designation that exposes the lab to the harshest sanctions under the CLIA.

Based on the "serious nature" of the survey findings (and the designation of "immediate jeopardy"), DHH-CMS imposed the following sanctions:

- 1) Cancellation of the laboratory's approval to receive Medicare and Medicaid payments for lab services, effective March 16, 2016.
- 2) Suspension of the laboratory's CLIA certificate, effective March 16, 2016.
- 3) Revocation of the laboratory's CLIA certificate pending a hearing by an Administrative Law Judge.

Importantly, the cancellation and suspension were to take effect on March 16, 2016, five days after Dr. Nguyen received the letter. The agency's finding of "immediate jeopardy" authorized it to suspend Dr. Nguyen's certificate in the interim between March 16 and the date of his hearing before an Administrative Law Judge

to revoke the certificate. Effectively, these sanctions would close the lab five days after Dr. Nguyen received the letter.<sup>4</sup> The letter advised that no plan of correction would be accepted, but Dr. Nguyen could submit documentation and evidence as to why the sanctions should not be imposed. His submission deadline was March 15, 2016.

On Saturday, March 12, 2016, Dr. Nguyen met with his laboratory business consultant, Jeffrey Mendler, and two technical supervisors, Gustavo de Leon and Staci de Leon (both former DHH-CMS inspectors), to review the findings in the letter. At the lab, they found the documents showing implementation of the revised correction plan. Dr. Nguyen claims that the documents were labeled in binders located in the same cabinet Harold Smith communicated to the inspectors on January 13. Much of the relevant information was in a binder labeled "Post Survey Corrective Action Material."

On Sunday, March 13, 2016, Dr. Nguyen drafted a letter to Diane Murphy, the DHH-CMS Branch Manager, requesting immediate review and reconsideration of the proposed sanctions. The letter addressed each alleged deficiency cited by the DHH-CMS in the March 11 letter and offered evidence to show that each deficiency was

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<sup>4</sup> Dr. Nguyen received the letter on March 11, a Friday. The sanctions were to take effect on the following Wednesday. Dr. Nguyen contends that the timing of the notice appears intentional to give him only three business days to respond.

corrected at the time of the January 13 inspection. Attached to the letter were over 300 pages of supporting documentation.

On Monday, March 14, 2016, Gustavo de Leon, Dr. Nguyen's technical supervisor, flew from New Orleans to the DHH-CMS Survey Branch Manager's office in Dallas to hand-deliver Dr. Nguyen's letter and documentation to Diane Murphy. Mr. de Leon gave the documents to Lt. Commander Lane Vause, who promised to review them before the close of business on the following day. Despite repeated attempts to contact several people in the DHH-CMS office, de Leon did not hear back from them until March 16, the day the suspension of his certificate was to take effect. At 3:47 p.m. on March 16, DHH-CMS representative, Sandra Pearson, sent an email to de Leon stating:

I have sent the documents to the [State Agency] for review. As soon as a review has been done by the [State Agency] and [Regional Office], we will notify you.

The suspension will be put on hold until our review is complete.

Dr. Nguyen and his associates had no further contact with DHH-CMS until March 23, 2016 at 3:37 p.m. when Sandra Pearson emailed Mr. de Leon stating, "The documents submitted did not ensure the immediate jeopardy was addressed and did not provide assurances as to why the sanctions should not be imposed." Attached to the email was a document explaining that, on January 13, the inspectors "checked all four upper and lower cabinets in the

laboratory area and informed Harold Smith that the binder could not be located." Dr. Nguyen asserts that this claim is "quite frankly, impossible."<sup>5</sup>

Also attached to the March 23 letter was an email from Diane Murphy, the DHH-CMS Branch Manager, stating that all of the sanctions would be imposed on March 24, 2016, the following day.

On March 24, however, this Court entered a temporary restraining order preventing DHH-CMS from imposing the sanctions. In its Order and Reasons, the Court found that Dr. Nguyen had shown "a substantial likelihood of success on the merits of his claim that the defendants have violated his Constitutional right to due process by failing to give him adequate warning before imposing sanctions to restrict his medical practice." The Court found further that "the sanctions imposed by the defendants substantially threaten to cause irreparable injury to Dr. Nguyen's medical practice and reputation." A hearing date for injunctive relief is set for April 15, 2016.

DHH-CMS belatedly challenges the Court's jurisdiction to grant injunctive relief in favor of Dr. Nguyen. DHH-CMS contends that Dr. Nguyen is attempting to circumvent the administrative process by having this Court adjudicate the merits of the

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<sup>5</sup> Dr. Nguyen submits photographs of the laboratory's open cabinets. The binders are clearly visible. The photographs, however, are not dated.

compliance dispute. According to DHH-CMS, Dr. Nguyen is entitled to a hearing before an Administrative Law Judge. If he is dissatisfied with the result, he may seek review from the Department Appeals Board. DHH-CMS urges that only after exhausting these administrative remedies may Dr. Nguyen seek judicial review. And that the proper reviewing court is the Fifth Circuit, not this Court.

Dr. Nguyen denies that he is seeking judicial review of his administrative claims. Rather, he asks this Court to maintain the status quo pending the administrative process, not instead of it. Dr. Nguyen contends that the sanctions imposed by DHH-CMS are an unconstitutional deprivation of his property and liberty without due process of the law. He submits that this Court is the proper venue to protect his constitutional rights.

#### I.

In support of his constitutional claims, Dr. Nguyen submits that DHH-CMS failed to comply with its own protocols in finding that his lab posed "immediate jeopardy." According to the LDHH<sup>6</sup> operations manual,<sup>7</sup> the surveyors must conduct an exit conference

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<sup>6</sup> The LDHH is the state agency that conducted the inspection on behalf of DHH-CMS. The LDHH refers to its inspectors as "surveyors."

<sup>7</sup> Dr. Nguyen submitted excerpts from Chapter 6 of the "State Operations Manual." The manual can be found at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c06.pdf>.



with the lab's administrator or director to informally explain their findings after the inspection. If immediate jeopardy status is identified, the surveyors must inform the lab of the seriousness of the problems. No later than two working days after the inspection, the surveyor must telephone the DHH-CMS regional office to advise that that immediate jeopardy deficiencies exist. No later than three working days after the inspection, the surveyor must send written notice to the lab explaining the deficiencies and proposing sanctions. Absolutely none of these protocols were followed.

According to Dr. Nguyen, the surveyors did not conduct an exit conference after the January 13 inspection. Indeed, none of the laboratory administrators or directors were contacted after the inspection, even though they were on the premises. Dr. Nguyen claims that the inspectors told his office manager that "everything looked good" before exiting the clinic. Moreover, the inspectors took no immediate action. Curiously, seemingly neglectfully, certainly ineptly, they waited for eight weeks before sending Dr. Nguyen written notification that his lab posed "immediate jeopardy." DHH-CMS does not dispute these facts, nor does it offer any explanation for its arguably abusive behavior. The elapsed time between the inspection and the notification shows either that the finding of immediate jeopardy was disingenuous or that the agency was irresponsible.

In light of these facts, the Court reiterates that Dr. Nguyen has a high chance of success on the merits of his claim for due process violations.

## II.

It is undisputed that this Court has no authority to review the merits of Dr. Nguyen's administrative claims. The CLIA designates the authority for judicial review to the appropriate Circuit Court of Appeals:

Any laboratory which has had . . . its certificate suspended, revoked, or limited . . . may, at any time within 60 days after the date the action of Secretary . . . becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action.

42 U.S.C. § 263a(k)(1).

This Court recognizes its lack of jurisdiction to resolve the merits of Dr. Nguyen's underlying administrative claims. The remaining question, however, is whether this Court has jurisdiction to determine whether DHH-CMS has deprived Dr. Nguyen of Due Process under the Constitution.

### A.

In his complaint, Dr. Nguyen invokes this Court's jurisdiction under 28 U.S.C. § 1346: "The district courts shall have original jurisdiction, concurrent with the United States Court of Federal Claims, of . . . [a]ny other civil action against the United States, not exceeding \$10,000 in amount, founded either

upon the Constitution, or any Act of Congress, or any regulation of an executive department . . . ." Dr. Nguyen also invokes the Administrative Procedure Act as a basis for this Court's jurisdiction:

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or right pending conclusion of the review proceedings.

5 U.S.C. § 705.

Dr. Nguyen contends that Section 705 allows the district court to halt agency action to preserve the status quo pending the conclusion of administrative proceedings. DHH-CMS responds that the APA does not apply to the CLIA statute, and if it does, the proper reviewing court is the Fifth Circuit. The Court considers other applications of Section 705 for guidance.

In Gardner v. Alabama, 385 F.2d 804 (5th Cir. 1967), the state of Alabama sought injunctive relief in the district court to restrain the Secretary of Health, Education and Welfare from enforcing an order that would terminate payment of approximately \$100 million in federal funds to the Alabama Department of Pensions and Security. At issue was Alabama's compliance with the Civil Rights Act of 1964. The Secretary found that Alabama had not

eradicated certain discrimination practices and thus was not entitled to federal funds.

The Civil Rights Act specifically granted jurisdiction to the Circuit Court for judicial review of agency action. The district court granted a preliminary injunction but expressly refrained from passing on the merits of the case. The Fifth Circuit vacated the district court's injunction, holding that it had exclusive jurisdiction to review the validity of the Secretary's order. The Court reasoned that because the Civil Rights Act granted the Circuit Court reviewing authority, its jurisdiction to review the Secretary's order was "sole and exclusive." Id. at 810. The Court instructed, "It is well settled that if Congress, as here, specifically designates a forum for judicial review of administrative action, the forum is exclusive." Id.

The facts on this record are distinguishable. Unlike the plaintiff in Gardner who sought review of the Secretary's order, Dr. Nguyen does not seek review of DHH-CMS's determination that he is out of compliance with the CLIA. Rather, he seeks preservation of the status quo until he is granted a revocation hearing before an Administrative Law Judge. Dr. Nguyen's action for injunctive relief requires the Court to assess the merits of his

constitutional claims, not the merits of his administrative claims.<sup>8</sup>

Additionally, DHH-CMS wholly failed to comply with its own protocols in implementing its harshest sanctions. Moreover, the tenuous basis for which the sanctions were imposed - the inspectors' inability to find a clearly labeled binder in a small laboratory - are cause for this Court's serious concern. DHH-CMS is adamant that its determination of "immediate jeopardy" status is not subject to any review whatsoever. But certainly, federal agencies are not exempt from the United States Constitution. Dr. Nguyen is entitled to due process under the law.

The Court looks for further guidance from other Circuit Courts.

B.

In Telecommunications Research and Action Center v. F.C.C., 750 F.2d 70, 71 (D.C. Cir. 1984), the District of Columbia Circuit held, "[W]here a statute commits final agency action to review by the Court of Appeals, the appellate court has exclusive jurisdiction to hear suits seeking relief that might affect its

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<sup>8</sup> DHH-CMS argues that Dr. Nguyen's constitutional claims are "inextricably intertwined" with his CLIA claims. The Court disagrees. The due process question is whether DHH-CMS's dubious process in suspending Dr. Nguyen's certificate violated Dr. Nguyen's constitutional due process rights. The administrative question is whether Dr. Nguyen's lab was in compliance with the CLIA statute. The two are distinct.

future statutory power of review." There, a group of nonprofit corporations petitioned the District of Columbia Circuit for a writ of mandamus to compel the Federal Communications Commission to decide certain unresolved matters pending before the agency. As a threshold issue, the Circuit Court addressed whether it had jurisdiction to issue the writ, or if jurisdiction lied with the district court. The Court reasoned that "even where Congress has not expressly stated that statutory jurisdiction is 'exclusive,' . . . a statute which vests jurisdiction in a particular court cuts off original jurisdiction in other courts in all cases covered by the statute." Id. at 77.

Similarly, in Public Utility Commissioner of Oregon v. Bonneville Power Administration, 767 F.2d 622 (9th Cir. 1985), the Ninth Circuit held that it had exclusive jurisdiction over suits that challenge ongoing agency proceedings on constitutional grounds. There, several utilities companies sought an injunction preventing the Bonneville Power Administrator from participating in proceedings to revise certain rate formulas because they urged that his bias violated their right to due process under the Constitution. The Pacific Northwest Electric Power Planning and Conservation Act provided:

Suits to challenge the constitutionality of this chapter, or any action thereunder, final actions and decisions taken pursuant to this chapter by the Administrator or the [Northwest Power Planning] Council, or the implementation of such final actions . . . shall

be filed in the United States court of appeals for the region.

Id. at 625-26. The district court dismissed the suit for lack of subject matter jurisdiction. The Ninth Circuit found that that the district court properly dismissed the suit for injunctive relief. Relying on the D.C. Circuit's reasoning in TRAC v. FCC, the Ninth Circuit held 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 exclusive review." Id. at 626.

Again, the facts on this record diverge from both cases. The relief sought in TRAC was a writ of mandamus; here, the relief sought is an injunction. Moreover, in both cases, the Circuit Courts qualified their "exclusive jurisdiction." In TRAC, the D.C. Circuit found that the grant of statutory jurisdiction "cuts off original jurisdiction in other courts *in all cases covered by the statute*. 750 F.2d at 77 (emphasis added). Here, Dr. Nguyen's suit for injunctive relief arises under the Fifth Amendment of the Constitution, not the CLIA. Likewise, in Bonneville, the Ninth Circuit limited its exclusive jurisdiction to "any suit seeking relief *that might affect the court's future jurisdiction*." Bonneville Power Administration, 767 F.2d at 626 (emphasis added). Here, DHH-CMS has not persuaded the Court that granting an injunction to protect Dr. Nguyen's constitutional rights will

affect the Fifth Circuit's jurisdiction to review the underlying administrative claims. At issue presently is quite a simple and direct question: did the disregard of mandatory administrative protocols violate due process?

This Court has serious concerns that Dr. Nguyen may suffer irreparable harm due to a violation of his constitutional right to due process on the present record. However, the Court also has serious questions as to its jurisdiction to grant injunctive relief. The parties have not directed the Court's attention to any binding precedent that squarely addresses the jurisdictional issues presented here.

Accordingly, pursuant to 28 U.S.C. § 1292(b), the Court finds that the issues presented in this motion involve a controlling question of law as to which there is substantial ground for difference of opinion, and an immediate appeal from this order may materially advance the ultimate termination of the litigation.

IT IS ORDERED that the defendants' motion to dismiss is DENIED.

IT IS FURTHER ORDERED that good cause exists to extend the temporary restraining order for 14 days to allow DHH-CMS to apply for an appeal to this order and reasons pursuant to 28 U.S.C. § 1292(b).



IT IS FURTHER ORDERED that the injunctive proceedings in this Court are stayed pending DHH-CMS's decision to appeal.<sup>9</sup>

New Orleans, Louisiana, April 12, 2016

  
MARTIN L. C. FELDMAN  
UNITED STATES DISTRICT JUDGE

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<sup>9</sup> If DHH-CMS chooses not to appeal, the Court will reschedule a hearing for injunctive relief at the appropriate time.