UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ANAZAOHEALTH CORPORATION,

Plaintiff,

v. CASE NO: 8:10-cv-1953-T-26TBM

ERIC HOLDER, Attorney General, United States Department of Justice, in his official capacity, and MICHELLE LEONHART, Acting Administrator, United States Drug Enforcement Administration, in her official capacity,

Defendants.
_____/

O R D E R

Before the Court is Defendants' Motion to Dismiss (Dkt. 14), Plaintiff's Memorandum of Law in Opposition (Dkt. 17), and Defendants' Reply. (Dkt. 18). After careful consideration of the allegations of the Verified Complaint for Declaratory Judgment and Injunctive Relief (Dkt. 1), the submissions of the parties and the applicable law, the Court concludes that the motion should be granted.

PERTINENT ALLEGATIONS

Plaintiff is a pharmacy licensed in Florida as a national intrathecal compounding pharmacy. Morphine is one of the narcotics often compounded in the pharmaceuticals combined by Plaintiff in prefilled hypodermic syringes for intrathecal administration to patients by prescribing physicians. Plaintiff alleges that the Drug Enforcement

Administration (the DEA) has taken the position that Plaintiff's practice of receiving the patient-specific narcotics and delivering them to the particular patient's physician constitutes "delivery" or "distribution," as opposed to "dispensing," of Schedule II narcotics pursuant to the Controlled Substance Act, 21 U.S.C. § 801 *et seq*. (the CSA). This determination would require Plaintiff to become licensed with the DEA as a drug manufacturer with possible negative consequences for its status as a pharmacy, potentially requiring it to cease operating as a pharmacy. The DEA eventually issued a manufacturer's registration to Plaintiff in August 2010, despite Plaintiff's directives to withhold registration. (Dkt. 1, paras. 40 & 41).

In paragraph 21 of the Verified Complaint, Plaintiff alleges, and Defendants agree, that "the DEA has taken no enforcement action against Anazao relating to its delivery methods." (Dkt. 1, para. 21). Plaintiff relies on, and alleges in the Verified Complaint, the case of Wedgewood Village Pharmacy v. Drug Enforcement Administration, 509 F.3d 541 (D.C. Cir. 2007),[1] in support of its position, a case which this Court has previously distinguished in its order dated September 8, 2010. (Dkt. 5). Plaintiff takes issue with the DEA's action of disseminating to its prescriber-customers, or physicians, as opposed to the patients, a letter regarding complaints received about the delivery to the physicians. (Dkt. 1, para. 32). The letter stated that the physician's issuing of prescriptions placed them at risk for prosecution. (Dkt. 1, para. 32, Exh. C). Plaintiff alleges that its business

[1] See docket 1 at paragraphs 23-29.

with the physicians ceased the following day. (Dkt. 1, para. 33). Based on the alleged injuries suffered by Plaintiff, it requests declaratory and injunctive relief.

ANALYSIS

The issue before this Court is whether it has subject matter jurisdiction under the Administrative Procedure Act, 5 U.S.C. § 704 (the APA), based on the absence of final agency action with respect to Plaintiff. If it were final agency action, as Defendants note, judicial review is reserved for the circuit courts of appeal under the CSA. 21 U.S.C. § 877.[2] Defendants argue that on its face, the Verified Complaint fails to establish subject matter jurisdiction based on ripeness[3] and the absence of final agency action. This Court agrees.

The DEA interpreted the CSA with respect to Plaintiff's actions of delivering pharmaceuticals to the prescriber-physicians rather than the individual patient. As such, the DEA's decision did not "affect the legal rights and obligations of the parties." Tennessee Valley Auth. v. Whitman, 336 F.2d 1236, 1248 (11th Cir. 2003). Although the

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[2] Section 877 of the CSA provides in pertinent part:

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located . . .

[3] "One consideration for determining whether a challenge to an agency action is ripe is whether that action is 'final.'" Ipharmacy v. Mukasey, 268 Fed. Appx. 876, 878 (11th Cir. 2008) (unpublished).

DEA wrote to Plaintiff and some of the prescriber-physicians about the "distribution" of the narcotic orders, the DEA's decision did not "directly determine[] the rights and obligations of the Plaintiffs." Ipharmacy v. Gonzalez, 2007 WL 1725200, at *3 (M.D. Fla. June, 2007), aff'd, 268 Fed. Appx. 876 (11th Cir. 2008). An investigation merely amounts to "an initial step for further investigation that may or may not be litigated." Ipharmacy, 2007 WL 1725200, at *2-3. Thus, in this case also, the DEA's actions constitute an investigation of Plaintiff's practices and an issuance of clarification of the validity of the practices in view of the CSA, much like the actions of the DEA in Ipharmacy.

In Ipharmacy, the DEA determined that the practices of an online pharmacy were violating the CSA with respect to the nature of the physician-patient relationship, initiated a civil forfeiture action, and seized property from the pharmacy owner's home pursuant to a search warrant. Even though the online pharmacy was essentially shut down from the seizure, the "general policy of deterring third-parties from illegal internet pharmacies challenges only a general program rather than a particular agency action." Ipharmacy, 2007 WL 1725200, at *4. The voluntary decisions of third parties to not do business with a pharmacy, like the prescriber-physicians in this case, are considered an "indirect effect" and therefore not final for purposes of ripeness or for purposes of finality of action by the

agency.[4] The district court's finding in Ipharmacy that the case was not ripe and that the agency had not made a final determination was affirmed by the Eleventh Circuit on appeal.[5]

Even if this Court had concluded that the DEA had made a final determination with respect to Plaintiff, jurisdiction would be vested in the circuit courts of appeals in accordance with the CSA. 21 U.S.C. § 877; John Doe, Inc. v. Drug Enforcement Admin., 484 F.3d 561, 568 (D.C. Cir. 2007); Ipharmacy, 2007 WL 1725200, at *5. With respect to finality under the APA, none of the authority cited by Plaintiff supports a finding of "final agency action" under the facts alleged in the Verified Complaint.

It is therefore **ORDERED AND ADJUDGED** as follows:

(1) Defendants' Motion to Dismiss (Dkt. 14) is **GRANTED.**

(2) The clerk is directed to terminate all pending motions/deadlines and to **CLOSE** the case.

DONE AND ORDERED at Tampa, Florida, on January 6, 2011.

s/*Richard A. Lazzara*

[4] An "agency's awareness campaign" does not constitute "final agency action." Ipharmacy, 2007 WL 1725200, at *4.

[5] The case of Monson v. Drug Enforcement Admin., 589 F.3d 952 (8th Cir. 2009), relied on by Plaintiff, is not binding precedent and is distinguishable. In Monson, the plaintiff sought to challenge DEA's authority to prosecute under the CSA in the face of a North Dakota state law condoning the actions of Monson. The instant case does not involve a challenge to the DEA's authority under the CSA.

RICHARD A. LAZZARA
UNITED STATES DISTRICT JUDGE

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Counsel of Record