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DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Docket No. 14-25
THE MAIN PHARMACY
DECISION AND ORDER

On October 7, 2014, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision (hereinafter, R.D.). Therein, the ALJ found it undisputed that Respondent no longer holds a Texas Pharmacy License and is thus not authorized to dispense controlled substances in the State in which it seeks registration under the Controlled Substances Act (CSA). R.D. at 6. The ALJ thus concluded that Respondent is not a "practitioner" within the meaning of the CSA and is therefore not entitled to be registered. R.D. at 7 (citing 21 U.S.C. §§ 802(21) & 823(f)). Accordingly, the ALJ granted the Government's Motion for Summary Disposition and recommended that I deny its application.

The ALJ did not, however, address the Government's further contention that it was also entitled to summary disposition because Respondent's proposed business model of shipping filled controlled substance prescriptions to a patient's prescribing physician rather than directly to the patient, violates federal law. See generally R.D.; see also Mot. for Summ. Disp., at 5-6. The Government takes exception to the ALJ's failure to address the issue,[1] arguing that the ALJ "should have also reached the merits of this case and granted summary disposition to the

[1] Following the issuance of the Recommended Decision, Respondent's counsel filed a pleading entitled: "Notice of Appeal." Therein, Respondent requests that the record be prepared and forwarded "to the appropriate Appeals Court." Notice of Appeal, at 1. Respondent did not, however, file exceptions to the ALJ's decision as provided for in the Agency's regulations. See 21 CFR 1316.66. As for its "Notice of Appeal," the ALJ's Recommended Decision is not a final decision of the Agency and thus, the filing of the record in "the appropriate" court, whatever that maybe, is premature. In the event Respondent files a Petition for Review of this Decision and Order, which is the final decision of the Agency, the Agency will comply with Rule 17 of the Federal Rules of Appellate Procedure.

Government on the additional basis that Respondent intends to dispense controlled substances to non-ultimate users in violation of the [CSA] and its implementing regulations." Gov. Exceptions, at 1.

As support for its contention, the Government argues that I should reach the issue because it "was fully briefed by the parties," "there is no dispute as to any material fact," and "the issue is likely to recur with the Respondent" because its "owner has stated his intent to reapply for a state license and pursue opening the pharmacy." Id. at 2. Finally, the Government argues that "requiring the parties to revisit this issue as part of a future case would be a waste of resources, given that this issue has been briefed and is now ripe for disposition." Id.

While Respondent agrees with the Government,[2] I reject the parties' contentions. Here, even assuming that further factual development is not necessary and that the parties have fully briefed the issue, Respondent's professed intent to reapply for a state license remains speculative, and until such time as Respondent obtains a new state license (and a new Texas DPS registration), it is not authorized to handle controlled substances under state law and cannot obtain a DEA registration. See Texas v. United States, 523 U.S. 296, 300 (1998) ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as

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[2] Respondent asserts that the issue of its proposed business model is ripe for review because "[e]very time [it] applies for a State license all [the Government] has to do is to sit on the application for a period of six months or more and Respondent will have to close [the] Pharmacy. [The Government] can then assert that Respondent has no State license and should be barred from going forward and hence evade review." Resp. Answer to Movant's Mot. for Summ. Disp., at 3.

Respondent's position apparently stems from the Texas Pharmacy Act and a regulation of the Texas Board of Pharmacy which authorize disciplinary action against the holder of a pharmacy license if the Board finds that the holder has "failed to engage in or ceased to engage in the business described in the application for a license." Tex. Occ. Code § 565.002(7); see also 22 Tex. Admin. Code § 291.11(a)(1) ("'Failure to engage in the business described in the application for a license' means the holder of a pharmacy license has not commenced operating the pharmacy within six months of the date of issuance of the license.").

However, Respondent does not explain why it could not have opened for business and dispensed non-controlled drugs while it challenged the denial of its application.

anticipated, or indeed may not occur at all.") (int. quotations and citations omitted). Thus, were I to adopt Respondent's position, it would still not be entitled to a registration.

Moreover, were I to adopt the Government's position, so long as the Respondent does not hold the requisite state authority and is not entitled to be registered, my decision would be an advisory opinion.[3] While an administrative agency is not subject to the case or controversy requirements of Article III, relevant authority suggests that in the event Respondent sought judicial review of the decision, the federal courts would lack jurisdiction to review that part of the decision. It is settled, however, that where the federal courts lack the power to review an agency decision because of intervening mootness, the court vacates the agency's order. See A.L. Mechling Barge Lines, Inc. v. United States, 368 U.S. 324, 329 (1961) (vacating administrative orders which had become unreviewable in federal court); see also American Family Life Assurance Co. v. FCC, 129 F.3d 625, 630 (D.C. Cir. 1997) ("Since Mechling, we have, as a matter of course, vacated agency orders in cases that have become moot by the time of judicial review."). See also Samuel H. Albert, 74 FR 54851, 54852 (2009). Thus, it is unclear how ruling on the issue would preserve the Agency's resources.

Whether this is deemed to be an issue of mootness, because Respondent once held the requisite state license but chose to surrender it, or ripeness, because Respondent has not obtained a new state license (which is a prerequisite to registration, see 21 U.S.C. §§ 802(21), 823(f)), the same result would likely obtain on judicial review. Under these circumstances, the issue raised by Respondent's proposed business model is not suitable for adjudication in this proceeding.

[3] This is not a case where an applicant, that lacks state authority, has also previously engaged in actionable misconduct under the public interest factors. Under those circumstances, denying an application on both grounds does not present an issue of either mootness or ripeness as it relies on acts that have been committed and not speculation as to a future course of conduct.

I therefore adopt the ALJ's Recommended Decision[4] and will deny Respondent's application.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the application of The Main Pharmacy, for a DEA Certificate of Registration as a Retail Pharmacy, be, and it hereby is, denied. This Order is effective immediately.

Dated: May 1, 2015

Michele M. Leonhart
Administrator

[4] I note, however, that the Order to Show Cause was issued by the Deputy Assistant Administrator, Office of Diversion Control.

Paul E. Soeffing, Esq., for the Government.

Nemuel Pettie, Esq., for the Respondent.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION

AND

RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Nature of the Case and Procedural History

Christopher B. McNeil, Administrative Law Judge. On August 18, 2013, The Main Pharmacy, the respondent in this case, submitted an application to the Drug Enforcement Administration (DEA) seeking a new DEA retail pharmacy registration that would permit the dispensing of Schedules II through V controlled substances.[1] Acting "by and on behalf of the Main Pharmacy,"[2] "Attorney/Applicant"[3] Nemuel E. Pettie, Esq., sought this registration for use at 1226 S. Main Street, Fort Worth, Texas 76109.[4] The pending DEA application number for this application is W13068660A.[5]

On August 18, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause proposing to deny the application pursuant to 21 U.S.C. §824(a)(1), (3) and (4) and 21 U.S.C. § 823(f).[6] As grounds for revocation, the Government alleges that Respondent materially falsified its DEA application, does not have the authority to handle controlled substances in the State of Texas, and that Respondent's registration would be inconsistent with the public interest.[7]

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[1] Order to Show Cause dated Aug. 18, 2014 at 1.
[2] Respondent's Request for Hearing dated Sept. 9, 2014 at 1.
[3] Id.
[4] Id. at 4.
[5] Order to Show Cause at 1.
[6] Id.
[7] Id.

On September 9, 2014, Respondent, through its Applicant, Nemuel E. Pettie, Esq., filed a timely request for hearing.[8] Respondent does not dispute that The Main Pharmacy does not possess a pharmacy license issued by the Texas State Board of Pharmacy.[9] Instead, Respondent asserts that the issue is not moot as Respondent plans to re-apply for another Pharmacy License.[10] The required professional license that had permitted Main Pharmacy to provide retail pharmacy services in Texas was terminated on approximately July 28, 2013 after The Main Pharmacy notified the Texas State Board of Pharmacy that The Main Pharmacy was closed.[11]

I received the Government's Motion for Summary Disposition on September 10, 2014, with proof of service upon Respondent, accompanied by supporting documentation. In my Order of September 10, 2014, I directed the Government to provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances. The factual premise relied upon by the Government in support of its motion is that Respondent does not have a pharmacy license issued by the Texas State Board of Pharmacy, the state in which Respondent seeks to be registered.[12] Additionally, in the same Order, I provided Respondent the opportunity to respond to the Government's Motion for Summary Disposition.[13] That response was due by September 24, 2014.[14] On September 22, 2014, I received Respondent's timely response.[15] The Government exercised its right to reply to the response and submitted a reply on September 25, 2014.[16] Drawing from the motion and briefs submitted, I find as follows:

Issue

[8] Respondent's Request for Hearing dated Sept. 9, 2014 at 1, received by DEA Sept. 10, 2014.
[9] Respondent's Request for Hearing at 2.
[10] Id.
[11] Order to Show Cause at 2.
[12] Government's Motion for Summary Disposition dated Sept. 10, 2014 at 1–2.
[13] Order Authorizing Briefs Regarding Summary Disposition dated Sept. 10, 2014 at 1.
[14] Id.
[15] Respondent's Answer to Movant's Motion for Summary Disposition dated Sept. 22, 2014 at 1.
[16] Government's Reply to Respondent's Answer to Government's Motion for Summary Disposition dated Sept. 25, 2014 at 1.

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's application must be summarily denied because Respondent does not have a pharmacy license issued by the state in which it intends to operate.[17] Under DEA precedent, an application for a retail-pharmacy DEA Certificate of Registration must be summarily denied if the applicant is not authorized to handle controlled substances in the state in which it seeks DEA registration.[18] Unless from the pleadings now before me there is a material issue regarding Respondent's authority to handle controlled substances in Texas, the application must be denied summarily, without a hearing.

Respondent's Contentions

In Respondent's Answer to Movant's Motion for Summary Disposition, Respondent never disputed the Government's contention that The Main Pharmacy was not currently licensed by the State of Texas to operate a pharmacy.[19] Instead, Respondent asserted that the Government is barred by the equitable doctrine of "clean hands" from moving for summary disposition.[20] Respondent, utilizing the diction of Professor Ori Herstein of Cornell University, defines unclean hands as "[a]ny willful conduct that is iniquitous, unfair, dishonest, fraudulent, unconscionable, or performed in bad faith."[21]

Respondent stated that the Texas State Pharmacy Board requires that a pharmacy be open and in operation within six months of the issuance of its license.[22] Respondent alleged that the Drug

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[17] Government's Motion for Summary Disposition at 6–8.

[18] See 21 U.S.C. §§ 801(21), 823(f), 824(a)(3); see also House of Medicine, 79 Fed. Reg. 4959, 4961 (DEA 2014); Deanwood Pharmacy, 68 Fed. Reg. 41662-01 (DEA July 14, 2003); Wayne D. Longmore, M.D., 77 Fed. Reg. 67669-02 (DEA November 13, 2012); Alan H. Olefsky, M.D., 72 Fed. Reg. 42127-01 (DEA August 1, 2007); Layfe Robert Anthony, M.D., 67 Fed. Reg. 15811 (DEA May 20, 2002); George Thomas, PA-C, 64 Fed. Reg. 15811-02 (DEA April 1, 1999); Shahid Musud Siddiqui, M.D., 61 Fed. Reg. 14818-02 (DEA April 4, 1996); Michael D. Lawton, M.D., 59 Fed. Reg. 17792-01 (DEA April 14, 1994); Abraham A. Chaplan, M.D., 57 Fed. Reg. 55280-03 (DEA November 24, 1992). See also Bio Diagnosis Int'l, 78 Fed. Reg. 39327-03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other "practitioners" in the context of summary disposition analysis).

[19] Respondent's Answer to Movant's Motion for Summary Disposition at 2.

[20] Id.

[21] Id. See Herstein, Ori J. "A Normative Theory of the Clean Hands Defense." (2001) Cornell Law Faculty Publications. Paper 210. http://scholarship.law.cornell.edu/facpub210, p.3.

[22] Respondent's Answer to Movant's Motion for Summary Disposition at 2. See TEX. ADMIN. CODE 291.9 (2012).

Enforcement Administration's failure to approve The Main Pharmacy's DEA registration in a "reasonable time" forced Respondent to close The Main Pharmacy to avoid disciplinary proceedings by the Texas State Pharmacy Board.[23] As a result of the DEA's failure to act, Respondent seeks to prohibit summary disposition by the doctrine of unclean hands.[24]

Respondent alternatively argues that the case should not be dismissed under the doctrine of Southern Pacific Terminal Co. v. I.C.C., 219 U.S. 498 (1911). Respondent cites Southern Pacific Terminal Co. for the proposition that a case is not moot when it presents an issue "capable of repetition, yet evading review."[25]

Scope of Authority

On August 18, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause proposing to deny the application pursuant to 21 U.S.C. §824(a)(1), (3) and (4) and 21 U.S.C. § 823(f).[26]

The case before me is presented under a grant of authority to recommend that the Administrator either grant or deny Respondent's application for a DEA retail-pharmacy license. Pursuant to 21 U.S.C. § 823(f), the DEA may grant such an application only to a pharmacy "practitioner." Under 21 U.S.C. § 802(21), a "practitioner" must be "licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]" Given this statutory language, the DEA Administrator does not have the authority under the Controlled

[23] Respondent's Answer to Movant's Motion for Summary Disposition at 2.
[24] Id.
[25] Respondent's Answer to Movant's Motion for Summary Disposition at 3.
[26] Order to Show Cause at 1.

Substances Act to grant a registration to a practitioner if that practitioner is not authorized to dispense controlled substances.[27]

Respondent asserted that the Government is barred by the equitable doctrine of "clean hands" from moving for summary disposition.[28] However, DEA Administrative Law Judges lack the authority to exercise equitable powers when making their decisions. The one and only purpose in this type of proceeding for a DEA Administrative Law Judge is to determine whether under 21 U.S.C. § 823(f), a practitioner's application to dispense controlled medications is consistent with the public interest.[29] Agency precedent supports this premise. In James Dell Potter, M.D., respondent attempted to invoke the principle of equitable estoppel to argue that the DEA could not revoke his registration, as the DEA previously granted him a registration.[30] In the opinion, DEA Administrator Francis M. Mullen, Jr. stated that:

> [The] DEA is charged by statute to protect the public. [P]rinciples of equitable estoppel cannot be applied to deprive the public of the protection of a statute because of the mistaken action, or lack of action, on the part of public officials. . . . Generally, a governmental unit is not estopped when functioning in a governmental capacity [citation omitted].[31]

Therefore, the protection of the public is preeminent, and the Agency is limited in its authority to direct relief under equitable principles.

In a case that has strong parallels to the case at hand, Saihb S. Halil, M.D., a doctor faced with an order to show cause made the argument that the Government is estopped from taking adverse action based upon its failure to process his application in a timely manner.[32] Deputy Administrator Donnie R. Marshall

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[27] See Abraham A. Chaplan, M.D., 57 Fed. Reg. 55280-03, 55280 (DEA November 24, 1992), and cases cited therein. In Chaplan, DEA Administrator Robert C. Bonner adopts the ALJ's opinion that "the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances." Id.
[28] Respondent's Answer to Movant's Motion for Summary Disposition at 2.
[29] 21 U.S.C. § 823(f).
[30] James Dell Potter, M.D., 49 Fed. Reg. 9970-01 (DEA Mar. 16, 1984).
[31] Id. at 9971.
[32] Saihb S. Halil, M.D., 64 Fed. Reg. 33319-01 (DEA June 22, 1999).

agreed with DEA ALJ Gail Randall in finding the chronology of the case "troubling" as it took 13 months for the Government to respond after the initial reply to the OTSC.[33] However, Judge Randall cited Potter for the proposition that estoppel does not deprive the public of the protection of a statute because of lack of action.[34] Deputy Administrator Marshall further agreed with Judge Randall's statement that "[a]lthough worthy of consideration and concern, such lack of timeliness does not overcome the public interest in this case. Equitable estoppel does not operate under these circumstances to preclude the DEA from protecting the public health and safety."[35]

Respondent's alternative argument, that this is a case "capable of repetition, yet evading review," does not compel a contrary outcome.[36] Respondent faults the Government for the delay that led to Respondent voluntarily surrendering its state pharmacy license.[37] However, as noted by the Government in the Government's Reply to Respondent's Answer to Government's Motion for Summary Disposition, Respondent could have "stocked and dispensed non-controlled substances while its DEA application was pending."[38]

The Government does not directly address the premise that The Main Pharmacy is intended to "cater to accident victims only."[39] Presumably, a pharmacy catering exclusively to accident victims would likely face substantial limitations if it was unable to deliver critical medication to its customers. Nonetheless, The Main Pharmacy chose this business model, doing so while being subject to the regulatory environment established under the Controlled Substances Act. Despite these limitations, there is no factual basis for finding the pharmacy could not have conducted a legally "sufficient"[40] number of transactions while it waited for its DEA Registration.

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[33] Id. at 33319-33320.
[34] Id. at 33320.
[35] Id.
[36] Respondent's Answer to Movant's Motion for Summary Disposition at 3.
[37] Id. at 2.
[38] Government's Motion for Summary Disposition dated September 25 at 2.
[39] Respondent's Request for Hearing at 2.
[40] Respondent's Answer to Movant's Motion for Summary Disposition, Exhibit 1.

Facts

Given this body of law, the material fact here, indeed the sole fact of consequence, is whether Respondent is authorized by the State of Texas to dispense controlled substances. Where, as here, no material fact is in dispute, there is no need for an evidentiary hearing and summary disposition is appropriate.[41] The sole question of fact before me can be addressed, and has been addressed, by the pleadings submitted to me by the parties. Our record includes no dispute regarding the Government's contention that the authority of The Main Pharmacy to dispense prescription medication in Texas was voluntarily withdrawn on approximately July 28, 2014.[42] The reasons for withdrawal are not material, given the statutory language set forth above.

Analysis, Findings of Fact and Conclusions of Law

In determining whether to grant the Government's Motion for Summary Disposition, I am required to apply the principle of law that holds such a motion may be granted in an administrative proceeding if no material question of fact exists:

> It is settled law that when no fact question is involved or the facts are agreed, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., is not obligatory - even though a pertinent statute prescribes a hearing. In such situations, the rationale is that Congress does not intend administrative agencies to perform meaningless tasks (citations omitted).[43]

In this context, I am further guided by prior decisions before the DEA involving certificate holders who lacked licenses to distribute or dispense controlled substances. On the issue of whether an evidentiary hearing is required, "it is well settled that when there is no question of material fact involved,

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[41] See Michael G. Dolin, M.D., 65 Fed. Reg. 5661 (DEA February 4, 2000); see also Philip E. Kirk, M.D., 48 Fed. Reg. 32887 (DEA July 19, 1983), aff'd sub nom. Kirk v. Mullen, 749 F.2d 297 (6th Cir. 1984).

[42] Government's Motion for Summary Disposition at 6.

[43] NLRB v. International Assoc. of Bridge, 549 F.2d 634, 638 (9th Cir. 1977) (quoting United States v. Consolidated Mines & Smelting Co., Ltd., 455 F.2d 432, 453 (9th Cir. 1971)).

there is no need for a plenary, administrative hearing."[44] Under this guidance, the Government's motion must be sustained unless a material fact question has been presented.

The sole determinative fact now before me is that Respondent lacks a Texas pharmacy license. In order for a pharmacy to receive a DEA registration authorizing it to dispense controlled substances under 21 U.S.C. § 823(f), it must meet the definition of "practitioner" as found in the Controlled Substances Act.[45] Such an entity must be "licensed, registered, or otherwise permitted by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice."[46] Delegating to the Attorney General the authority to determine who may or may not be registered to perform these duties, Congress permitted such registration only to "practitioners" as defined by the Controlled Substances Act.[47]

As cited by the Government in its Motion for Summary Disposition, there is substantial authority both through agency precedent and through decisions of courts in review of that precedent, holding that an application for a retail pharmacy DEA registration is dependent upon the applicant having a state license to dispense controlled substances.[48] Under the doctrine before me, the Government meets its burden of establishing grounds to deny an application for registration upon sufficient proof establishing the applicant does not possess a state pharmacy license. That proof is in the record before me, and it warrants the summary denial of Respondent's application for a DEA Certificate of Registration.

I am mindful of the arguments raised by Respondent in its Answer to Movant's Motion, including the fact that Respondent's lack of a pharmacy license is based on Respondent's voluntary withdrawal of its pharmacy license to avoid state sanctions as a result of delays by the DEA.[49] These difficulties do not, however, change the fact that without a state pharmacy license, Respondent is not a "practitioner" and

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[44] See Michael G. Dolin, M.D., 65 Fed. Reg. 5661 (DEA February 4, 2000); Jesus R. Juarez, M.D., 62 Fed. Reg. 14945 (DEA March 28, 1997); see also Philip E. Kirk, M.D., 48 Fed. Reg. 32887 (DEA July 19, 1983), aff'd sub nom. Kirk v. Mullen, 749 F.2d 297 (6th Cir. 1984).
[45] 21 U.S.C. § 802(21).
[46] Id.
[47] 21 U.S.C. § 823(f).
[48] Government's Motion for Summary Disposition at 7 and cases cited therein.
[49] Respondent's Answer to Movant's Motion for Summary Disposition at 2.

cannot be granted a Certificate of Registration. Equitable principles, even were they available in this forum, fail to lead to a different outcome. As made clear in Potter and Halil, the lack of timeliness in processing an application for a DEA Certificate of Registration does not overcome the public interest.

Some care should be taken to assure the parties that the actions taken in this administrative proceeding conform to constitutional requirements. I have examined the parties' contentions with an eye towards ensuring all tenets of due process have been adhered to. There is, however, no authority for me to evaluate the facts that underlie Respondent's contentions. In the proceedings now before me, the only material question was answered by Respondent in its Request for Hearing. Further, while the Order to Show Cause sets forth a non-exhaustive summary of facts and law relevant to a determination that granting this application would be inconsistent with the public interest under 21 U.S.C. § 823(f), the conclusion, order and recommendation that follow are based solely on a finding that Respondent is not a "practitioner" as that term is defined by 21 U.S.C. § 802(21), and I make no finding regarding whether granting this application would or would not be inconsistent with the public interest.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a "practitioner" as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which it seeks to operate under a DEA Certificate of Registration. I find no other material facts at issue, for the reasons set forth in the Government's Motion for Summary Disposition. Accordingly, I **GRANT** the Government's Motion for Summary Disposition.

Upon this finding, I **ORDER** that this case be forwarded to the Administrator for final disposition and I **RECOMMEND** the Administrator **DENY** Respondent's application for a DEA Certificate of Registration.

Date: October 7, 2014 s/CHRISTOPHER B. MCNEIL

Administrative Law Judge

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