

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).<sup>43</sup>

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, there is no need for a plenary, administrative hearing."<sup>44</sup> 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.<sup>45</sup> 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."<sup>46</sup> 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.<sup>47</sup>

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.<sup>48</sup> Under the doctrine before me, the

<sup>43</sup> *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)).

<sup>44</sup> See *Michael G. Dolin, M.D.*, 65 FR 5661 (DEA February 4, 2000); *Jesus R. Juarez, M.D.*, 62 FR 14945 (DEA March 28, 1997); see also *Philip E. Kirk, M.D.*, 48 FR 32887 (DEA July 19, 1983), aff'd sub nom. *Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984).

<sup>45</sup> 21 U.S.C. 802(21).

<sup>46</sup> *Id.*

<sup>47</sup> 21 U.S.C. 823(f).

<sup>48</sup> Government's Motion for Summary Disposition at 7 and cases cited therein.

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.<sup>49</sup> These difficulties do not, however, change the fact that without a state pharmacy license, Respondent is not a "practitioner" and 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.

**Christopher B. Mcneil,**

*Administrative Law Judge.*

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## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **Keith Ky Ly, D.O.; Decision and Order**

On January 24, 2013, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OTSC-ISO or Order) to Keith Ky Ly, D.O. (Respondent), of Mountlake Terrace, Washington. GX 2, at 1. The Order proposed the revocation of Respondent's DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V, as a practitioner, as well as the denial of any pending applications to renew or modify his registration, on the ground that his "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.*

More specifically, the OTSC-ISO alleged that on February 2, 2012, law enforcement officers arrested Respondent's girlfriend, who was then driving his vehicle, for driving with a suspended license and that during a search of the vehicle, found "one pound of marijuana, approximately \$3,900 cash in a vacuum sealed bag located in [her] purse, \$5,000 cash located in a hidden compartment, and three prescription bottles containing controlled substances located in" her backpack. *Id.* at 2. The Order further alleged that Respondent had issued one of the prescriptions found in the backpack to an employee, and that during an interview when he attempted to recover the vehicle, Respondent stated that he lived with his girlfriend, that she worked at his medical practice, and that she and the employee whose medication was found in the backpack "often shared medications." *Id.* The Order then alleged that this showed that Respondent had "knowledge of illegal activity occurring between [his] employees and [took] no corrective action." *Id.*

Next, the OTSC-ISO alleged that law enforcement officers discovered that several premises owned by Respondent were being used as marijuana-grow houses. *Id.* More specifically, the Order alleged that: (1) On May 30, 2012, the Renton, Washington fire department responded to a fire at his Quincy

<sup>49</sup> Respondent's Answer to Movant's Motion for Summary Disposition at 2.

Avenue property and seized approximately 700 marijuana plants; (2) on July 5, 2012, state and local law enforcement officers obtained a search warrant for his property located at 20118 14th Avenue NE, Shoreline, Washington, and seized approximately 489 marijuana plants and six bags of processed marijuana; (3) on July 6, 2012, state and local law enforcement officers executed a search warrant at Respondent's personal residence in Bothell, Washington, and "seized \$12,000 in cash, two firearms, marijuana grow documents, approximately 15 grams of processed marijuana, and multiple prescription bottles containing pills," including an unlabeled bottle containing hydrocodone, and a bottle containing clonazepam, which Respondent had prescribed for patient R.M.; and (4) on July 7, 2012, state and local law enforcement obtained a search warrant for his property located at 5006 104th Place NE., Marysville, Washington and seized marijuana leaves and grow equipment. *Id.* at 2–3.

Next, the OTSC–ISO alleged that on July 13, 2012, DEA personnel "conducted an inspection and audit at [Respondent's] registered address." *Id.* at 3. The Order alleged that Respondent had a 75 percent shortage of both testosterone 200mg/ml and phentermine 37.5mg, as well as a 14 percent shortage of hydrocodone 10/500mg. *Id.* Based on the audit results, the Order further alleged that Respondent "failed to maintain accurate and complete records and failed to account for these controlled substances." *Id.* (citing 21 U.S.C. 827(a)(1) and 842(a)(5); 21 CFR 1301.71, 1304.03, 1304.04 (a) & (g), and 1304.21). The Order then alleged that Respondent had committed additional recordkeeping violations, in that he "failed to take and maintain an initial or biennial inventory of all stocks of controlled substances on hand," "failed to record essential elements on approximately 128 dispensing records," "failed to maintain a dispensing/administration log for testosterone and Testim samples, located during the on-site inspection," and "failed to maintain all Schedule III–V acquisition invoices and record the dates of receipt[ ] on the invoices." *Id.* at 3–4 (citations omitted).

Finally, the OTSC–ISO alleged that Respondent "failed to make required dispensing reports" to the Washington State Prescription Monitoring Program "on approximately 45 separate occasions from January to July 2012." *Id.* at 4. As the legal basis for this allegation, the Government noted that Washington State "requires a dispensing physician to report to the . . . PMP all instances in which he or she dispenses

more than a 24-hour supply of controlled substances." *Id.* (citing Wash. Rev. Code § 70.225.020; Wash. Admin. Code § 246–470–030).

Based on the above, I made a preliminary finding that Respondent "illegally manufactured controlled substances in violation of state and federal law, illegally possessed and distributed highly addictive controlled substances . . . and ha[d] generally failed to maintain effective controls to guard against theft and prevent diversion of controlled substances." *Id.* I therefore ordered that Respondent's registration be suspended effective immediately. *Id.* (citing 21 U.S.C. 824(d)).

According to the Declaration of a DEA Diversion Investigator (DI), on January 28, 2013, DEA Special Agents and DIs went to Respondent's registered location and personally served him with the OTSC–ISO, along with "a sample request for hearing form." DI Declaration, at 9. According to the DI, later that same day, he also hand-delivered a copy of the OTSC–ISO and the hearing request form to Respondent's "attorney at the time." <sup>1</sup> *Id.*

The OTSC–ISO plainly advised that: (1) "[w]ithin 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, you may file with the DEA a written request for a hearing in the form set forth in 21 CFR 1316.47"; (2) "[i]f you fail to file such a request, the hearing shall be cancelled in accordance with paragraph 3"; (3) "[s]hould you decline to file a request for a hearing . . . you shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing"; (4) "[c]orrespondence concerning this matter, including requests [for a hearing] should be addressed to the Hearing Clerk, Office of Administrative Law Judges [OALJ] . . . 8701 Morrissette Drive, Springfield, VA 22152"; and (5) "[m]atters are deemed filed upon receipt by the Hearing Clerk." GX 2, at 4–5 (citations omitted). Notwithstanding this, Respondent did not file a request for hearing with the Office of Administrative Law Judges until April 4, 2013. GX 4, at 1.

The matter was then assigned to an Administrative Law Judge (ALJ), who

ordered that the proceeding be terminated because Respondent had "failed to timely request a hearing and failed to assert good cause for his 36-day delay." *Id.* at 2. Thereafter, on April 18, 2013, Respondent, who was now represented by counsel (a different counsel than identified by the DI in his declaration), filed a motion to reconsider and re-open. GX 5. Therein, Respondent requested a full hearing on the allegations, as well as "additional time to file his Request for Hearing based on this motion showing of good cause." *Id.* at 1.

In the motion, Respondent did "not contest that he was effectively served with a copy of the" OTSC–ISO. *Id.* at 2. He also did not dispute that his prior attorney "was in contact with [him] during and after the period for filing a timely appeal." *Id.* Rather, Respondent maintained that he "sent a letter requesting appeal of the [OTSC–ISO] to [a] local Seattle-based DEA agent . . . by certified mail on February 4, 2013," who "did not respond to the appeal letter or inform Respondent that an appeal of the [OTSC–ISO] could not be perfected by sending it to him." *Id.* at 2–3. Respondent further asserts that he "sought the advice of and had several conversations with [his former] attorney," and that "[b]ased on these conversations, [he] 'filed' an appeal NOT with the DEA . . . Office of Administrative Law Judges, but instead with the Office of the Inspector General (OIG)," and that he faxed the appeal "to the OIG on February 20, 2013, and again on March 8, 2013." *Id.* at 3. According to Respondent, "[t]he OIG suggested [he] contact the DEA." *Id.*

Respondent further asserted that he "discussed the matter with an assistant in his office, who believed the correct place to file the appeal was with the office of the United States Attorney General." *Id.* Respondent stated that "[a]n 'appeal' was sent to that address on February 11, 2013." *Id.*

Next, Respondent contended that on March 14, 2013, he was advised by his then-counsel that the latter "and his partner had decided not to represent [him] in this . . . proceeding," but that "[t]his was after the request for hearing deadline had expired." *Id.* Respondent then contended that on March 28, he spoke with two Seattle-based DEA agents, "who told him he needed to file the request for hearing right away." *Id.* According to Respondent, he then "filed his request for hearing on April 4, 2013 with the DEA" OALJ. *Id.*

Respondent asserted that he "was confused about how and where to file his request for a hearing" and that "[t]he source of his confusion came from his

<sup>1</sup> The courts are clear that service of an initial pleading on an attorney does not constitute adequate service unless a party has granted authority to the attorney to accept process on his behalf. See, e.g., *United States v. Ziegler Bolt & Parts Co.*, 111 F.3d 878, 881 (Fed. Cir. 1997). There being no such evidence showing that Respondent granted such authority to the attorney, I rely only on the DI's statement that Respondent was personally served.

contacts with [his former] attorney . . . , with his office assistant, and from the lack of response by [a DEA Agent], although a late effort to clarify the correct means to request a hearing was provided by the DEA agents.” *Id.* at 3–4. He further maintained that he attempted “in good faith to ask for a hearing” and that “[n]one of the alternatives employed by [him] were done for purposes of delay.” *Id.* at 4.

Respondent argued that his case is similar to that of *Steven J. Watterson*, 67 FR 67413 (2002). Therein, the Agency set aside a final order where a party had failed to file a request for a hearing based on “conflicting guidance” having been “given to” an Applicant by an Agency “official concerning how and when the matter would be resolved.” *Id.* at 67414. Respondent argued that *Watterson* stands for the proposition that “[g]ood cause” . . . to set aside and rescind a decision terminating a proceeding . . . require[s] a showing of both excusable neglect and a meritorious defense.” GX 5, at 5. He then argued that “[t]he acceptance and retention by” the DI of his appeal request “was misleading, particularly when [the DIs] actively encouraged [him] to file his appeal correctly AFTER the appeal period had lapsed,” and that “[t]his was a source of conflicting guidance for Respondent.” *Id.* at 6.

Respondent also relied on *Pincay v. Andrews*, 389 F.3d 853 (9th Cir. 2004) (en banc). There, a lawyer failed to file a notice of appeal within the thirty-day period provided for doing so in the Federal Rules of Appellate Procedure, based on his reliance on the erroneous advice of a paralegal that the notice of appeal need not be filed until sixty days after the issuance of a judgment, rather than the thirty days provided in the applicable Federal Rule of Appellate Procedure. *Id.* at 855. The Ninth Circuit held that the failure to timely file the notice of appeal constituted excusable neglect, notwithstanding its conclusions that the lawyer’s reliance on the paralegal’s reading of the rule was “negligent” and that the “lawyer’s failure to read an applicable rule is one of the least compelling excuses that can be offered.” *Id.* at 859. The court nonetheless held that the district court did not abuse its discretion in concluding that the lawyer’s untimely filing was the result of excusable neglect. *Id.* The court further noted that “the decision whether to grant or deny an extension of time to file a notice of appeal should be entrusted to the discretion of the district court because the district court is in a better position than” the appeals court to evaluate the relevant factors, and that the decision

was to be determined “within the context of the particular case,” which, in *Pincay*, had gone on for fifteen years. *Id.* However, the court also observed that “[h]ad the district court declined to permit the filing of the notice, we would be hard pressed to find any rationale requiring us to reverse.” *Id.*

Based on *Pincay*, Respondent argued that: (1) There is no prejudice to the Agency because his registration remains suspended; (2) the thirty-six day delay in filing his hearing request had no impact on the proceeding; (3) “the reason for the delay was confusion on his part,” that his conduct is no worse than that found excusable in *Pincay* and was “based in part on omissions by” the DI, and was not made in bad faith; and (4) that he acted promptly to rectify his untimely filing. GX 5, at 8–9.

Accordingly, Respondent argued that he has shown good cause for setting aside the ALJ’s termination order. *Id.* at 9.

The ALJ granted Respondent’s motion for reconsideration but then denied his motion to reopen the proceedings. Order Granting Respondent’s Motion for Reconsideration and Denying Respondent’s Motion to Reopen the Case, at 10 (Order on Reconsideration) (GX 7). While concluding that she had jurisdiction to consider Respondent’s motion for reconsideration, the ALJ rejected Respondent’s contention that he had shown good cause for his untimely filing.

First, the ALJ rejected Respondent’s contention that under *Watterson*, he had demonstrated good cause because he had received “conflicting guidance” from the DI to whom he sent his “appeal” letter. *Id.* at 7. The ALJ found that *Watterson* was not controlling because, during the period in which Respondent could have filed his hearing request, the DI did not provide conflicting guidance but rather no guidance at all. *Id.* at 8. Indeed, the DI did not provide any advice to Respondent regarding his hearing request until he met with the DI on March 28, 2013. *Id.*

Next, the ALJ rejected Respondent’s contention that “good cause” existed to excuse his untimely filing because his former attorney “committed ‘excusable neglect.’” *Id.* More specifically, the ALJ noted that the excusable neglect standard of the Federal Rules of Appellate Procedure, *see Pincay*, and the Federal Rules of Bankruptcy Procedure (Rule 9006(b)(1)), which was discussed by the Supreme Court in *Pioneer Inv. Servs. v. Brunswick Assoc.*, 507 U.S. 380, 396 (1993), “do not govern

our [DEA] proceedings.”<sup>2</sup> Order on Reconsideration, GX 7, at 8. The ALJ further noted that even under *Pioneer*, “respondents can ‘be held accountable for the acts and omissions of their chosen counsel.’” *Id.* (quoting *Pioneer*, 507 U.S. at 397).

The ALJ found that Respondent was represented by another attorney “at the time [he] was served with the Order to Show Cause,” and that this attorney did not inform him that he would not represent him in the DEA proceeding until after the deadline had passed for filing his hearing request. *Id.* at 8–9. The ALJ then concluded that while the “[a]ttorney was negligent in failing to tell Respondent in a timely fashion that he would no longer represent [him], . . . Respondent cannot argue that he detrimentally relied on [the attorney] to send out the request for hearing.” *Id.* at 9. This was so because “Respondent, himself, sent out the letters to [the DI],<sup>3</sup> OIG, and [the] Attorney General.” *Id.* The ALJ thus concluded “that Respondent was ultimately responsible for filing a timely request for hearing, despite his former attorney’s shortcomings.” *Id.*

Finally, the ALJ rejected Respondent’s contention that his “confusion . . . support[ed] a finding of ‘good cause.’” *Id.* As the ALJ explained, “[t]he clear language of the Order to Show Cause states that ‘[c]orrespondence concerning

<sup>2</sup> While it true that DEA has not adopted any of the various federal rules of procedure, it has frequently looked to those rules for guidance in interpreting its procedural rules. *See Bio Diagnostic Inc.*, 78 FR 39327, 39328–29 & n.1 (2013) (applying federal court decisions interpreting Fed. R. Civ. P. 56 (governing summary judgment), in determining whether summary disposition was appropriately granted in Agency proceeding); *Glenn D. Kreiger*, 76 FR 20020, 20021 n.3 (2011) (applying federal court decisions and holding that a challenge to the sufficiency of service of a Show Cause Order is waived if not raised in a respondent’s first responsive pleading). In this regard, it is noted that the Federal Rules of Civil Procedure have expressly adopted the “excusable neglect” standard for determining whether “good cause” exists to extend the time for “[w]hen an act may or must be done” when a “motion [is] made after the time has expired.” Fed. R. Civ. P. 6(b)(1). As agency decisions make clear, the good cause standard is not limited to those instances where a respondent or his attorney are blameless in failing to timely file a pleading. *See, e.g., Tony T. Bui*, 75 FR 49979, 49980 (2010) (finding good cause existed to excuse untimely filed hearing request where attorney used an incomplete address to mail the request but when the request was returned, promptly proceeded to mail it to the correct address).

<sup>3</sup> Regarding the letter to the DI, the ALJ noted that Respondent wrote: “I am writing to you as an appeal for the immediate and urgent help in the matter of my DEA license reinstatement.” Termination Order, at 9 n.8 (quoting Motion for Reconsideration, Ex. 29, at 1). The ALJ further noted that “[w]hile Respondent’s intent may have been to request a hearing, Respondent did not explicitly express this intent in the letters he sent before April 4, 2013.” *Id.*

this matter, including requests referenced in paragraphs 1 [*i.e.*, a hearing request] and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.’’ *Id.* (quoting OTSC–ISO, at 5). Finding ‘‘that this language is an unmistakably clear explanation of where to send a request for hearing, especially for an educated professional, such as the Respondent,’’ the ALJ held that ‘‘Respondent’s confusion does not justify a finding of ‘good cause.’’’ *Id.*

The ALJ thus rejected Respondent’s contention that he had shown good cause to excuse his untimely filing. *Id.* She further concluded that ‘‘Respondent’s failure to file a timely request [constituted] a waiver of his right to a hearing under 21 CFR 1301.43(d).’’ *Id.* at 9–10. The ALJ thus denied Respondent’s motion to reopen the matter.

Thereafter, the Government forwarded a Request for Final Agency Action and the Investigative Record to me. Having reviewed the record, I adopt the ALJ’s finding that Respondent did not demonstrate good cause for his failure to file his hearing request within the thirty-day period as required by 21 CFR 1301.43(a).

As the ALJ explained, the OTSC–ISO provided a clear explanation as to the procedure to be followed for filing a hearing request. That procedure required that Respondent or his representative file his hearing request with the ‘‘Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152,’’ and that ‘‘[m]atters are deemed filed upon receipt by the Hearing Clerk.’’ GX 2, at 5.

Moreover, the OTSC–ISO included an attachment entitled: ‘‘REQUEST FOR HEARING.’’ *Id.* at 6. The attachment states that ‘‘[a]ny person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format.’’ *Id.* The attachment then provides a sample form, with the following address block: DEA Headquarters, Office of the Administrative Law Judges, Hearing Clerk, 8701 Morrissette Drive, Springfield, Virginia 22152.

*Id.* Notably, neither the OTSC–ISO, nor the attachment, directed Respondent, if he desired a hearing, to file his hearing request with DEA field personnel, the Office of Inspector General, or the Attorney General himself.

Also unavailing is Respondent’s reliance on *Pincay v. Andrews* to argue ‘‘good cause’’ exists to excuse his untimely filing because either he or his lawyer committed ‘‘excusable neglect.’’<sup>4</sup> Motion for Reconsideration, GX 5, at 7. As the Supreme Court explained in *Pioneer*, ‘‘inadvertence, ignorance of the rules, or mistakes construing the rules do not usually constitute excusable neglect.’’ 507 U.S. at 392. Moreover, as the Ninth Circuit noted in *Pincay*, the ‘‘failure to read an applicable rule is one of the least compelling excuses that can be offered.’’ 389 F.3d at 859. Indeed, as the Ninth Circuit noted in *Pincay*, ‘‘had the district court declined to permit’’ the appellant to file his notice late, it ‘‘would [have] be[en] hard pressed to find any rationale requiring us to reverse.’’ *Id.*

In his affidavit, Respondent asserts that he ‘‘sought the advice of and had several conversations with’’ his former attorney ‘‘concerning the OSC and filing an appeal,’’ and that ‘‘[b]ased on these conversations, I ‘filed’ an appeal NOT with the DEA . . . Office of the Administrative Law Judges, but instead with the Office of the Inspector General.’’ Respondent’s Declaration, at 9. To the extent Respondent seeks to rely on the advice he received from his former attorney to support a showing of good cause, his vague assertions do not establish that he was ever told not to comply with the instructions on the OTSC–ISO. Nor does Respondent assert that his former attorney ever agreed to represent him in this matter, let alone that he agreed to file a request for a hearing on Respondent’s behalf. To the extent Respondent relies on his own confusion as the reason for his untimely filing, *see Mot. For Recon.*, at 8; there is no reason to excuse his neglect when the OTSC–ISO was personally served on him and set forth, with unmistakable clarity, the procedures to be followed for requesting a hearing.<sup>5</sup>

<sup>4</sup> While the ALJ interpreted Respondent’s excusable neglect argument as being based on his former attorney’s failure to tell him that he would not represent Respondent until after the deadline had passed, Respondent’s argument appears to rely on his own confusion as to where to file the hearing request and not on the aforesaid conduct of the attorney.

<sup>5</sup> As for Respondent’s letters to the OIG and the Attorney General, Respondent did not submit a copy of any of these letters with his motion. *See generally* Attachments to Respondent’s Motion. Indeed, the only letter relevant to this issue which Respondent submitted for the record (other than his appeal request) was a copy of an April 4, 2013 letter *he received* from the OIG, which ‘‘acknowledge[d] receipt of [his] correspondence dated July 11, 2011’’ and explained that his ‘‘complaint has been forwarded to’’ the DEA ‘‘Office of Professional Responsibility.’’ *Id.* at Ex. 31. Obviously, this letter

Respondent further argues that ‘‘[t]he acceptance and retention by [the DI] of the appeal request . . . was misleading, particularly when he and [another DI] actively encouraged [him] to file his appeal correctly AFTER the appeal period had lapsed’’ and that [t]his was a source of conflicting guidance for’ him. *Id.* at 6. However, as the ALJ noted, this argument goes nowhere because Respondent does not claim that he had any discussion with the DI regarding the manner for properly filing his hearing request within the thirty-day period, let alone that he was given misleading advice as to how to file his request.<sup>6</sup> Indeed, nothing prevented Respondent from filing a separate hearing request with the Office of Administrative Law Judges during the thirty-day period. I therefore reject Respondent’s contention that his untimely filing should be excused because he relied on ‘‘conflicting guidance’’ he received from agency personnel. *See Watterson*, 67 FR at 67413.

Accordingly, I hold that Respondent has failed to demonstrate good cause to excuse his failure to timely file his hearing request. I therefore find that Respondent has waived his right to a hearing on the allegations and issue this Decision and Order based on the Investigative Record (including Respondent’s Declaration) submitted by the Government. I make the following findings.

#### Findings of Fact

Respondent was the holder of DEA Certificate of Registration #BL6283927, pursuant to which he was authorized, prior to the Immediate Suspension of his registration, to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 6603 220th Street SW., Mountlake Terrace, Washington 98043. GX 1.

could not have been a response to a misfiled hearing request given that it referenced his correspondence, which was dated approximately eighteen months before he was even served with the OTSC–ISO. Nor, even if the OIG’s letter was misdated, does it seem likely that it was prepared in response to a hearing request, given that it referred to his ‘‘complaint’’ and referred it to the ‘‘Office of Professional Responsibility.’’ *Id.*

As for Respondent’s assertion that he ‘‘discussed the matter . . . with an assistant in [his] office, who believed that the correct place to send the appeal was to the office of the Attorney General,’’ Resp. Decl., at 9; this begs the question of why he did not discuss where to file his appeal with the attorney (who had also received a copy of the OTSC–ISO) he was then consulting with.

So too, if there was evidence that the DI had told Respondent that he would forward his hearing request to the Office of Administrative Law Judges and failed to do, I would order that a hearing be granted. Respondent, however, makes no such claim, but rather, relies only on the DI’s silence during the period for requesting a hearing.

Respondent's registration was due to expire on March 31, 2014. *Id.* However, according to the registration records of the Agency, on March 13, 2014, Respondent submitted an application to renew his registration. While under the Agency's regulation, his renewal application was untimely because he was subject to an Order to Show Cause and Immediate Suspension of Registration and did not submit the application "at least 45 days before the date on which [his] registration [wa]s due to expire," 21 CFR 1301.36(i), and thus his registration has expired, his application remains pending before the Agency.

Respondent is also licensed by the State of Washington (as well as by the States of Texas and California) as an Osteopathic Physician. Resp. Declaration, at 1. According to Respondent, he has never been subject to discipline by any state licensing body. *Id.* However, Respondent has been subject to discipline by the Texas Medical Board. Moreover, while this matter was pending, the Washington Board of Osteopathic Medicine and Surgery issued Respondent an Ex Parte Order of Summary Action which suspended his state license to practice as an osteopathic physician and surgeon. *In re Keith Ky Ly* (Wash. Bd. Osteopathic Med. & Surg., Sep. 22, 2014) (Ex Parte Order of Summary Action, at 1).

With respect to the Texas Medical Board, on May 20, 2011, Respondent entered into an Agreed Order. See *In re Application for Licensure By Keith Ly, D.O.*, at 6 (Tx. Med. Bd. 2011). Therein, the Texas Board found that Respondent failed to report on his application for a Texas Medical License that in February 1990, while undergoing his "residency training," he had been "placed on probation" for being late and missing shifts, as well as for failing to report a 2007 arrest. *Id.* at 2. While the Board granted Respondent a license, it also assessed an administrative penalty of \$5,000 and placed him on probation for two years.<sup>7</sup> *Id.* at 3–4.

Accordingly, I find that notwithstanding his statement, Respondent has been subject to

<sup>7</sup> Based on the Texas Board's action, the Washington Board filed a Statement of Allegations against Respondent. See *In re Keith K. Ly*, No. M2010-1665, Statement of Allegations and Summary of Evidence (Wash. Dept. Health, Oct. 12, 2012). However, these allegations were settled in a Stipulation To Informal Disposition, the terms of which included that it "is not [a] formal disciplinary action." See Stipulation To Informal Disposition, *In re Ly*, at 2. However, the proceeding was still subject to reporting to the Health Integrity and Protection Databank and the National Practitioner Databank. *Id.*

discipline by a state licensing body. While the basis of the Texas Board's action does not provide a reason under the CSA for DEA to take any action against Respondent's registration, Respondent's statement was nonetheless false and clearly offered to influence the decision of the Agency to grant him a hearing on the allegations. Accordingly, I consider Respondent's lack of candor in assessing the credibility of the various assertions contained in his declaration.

### The Arrest of Respondent's Girlfriend

According to the DI, on February 2, 2012, Respondent's girlfriend (TB),<sup>8</sup> who was driving his Mercedes Benz SL 65,<sup>9</sup> was stopped by local police, cited for driving under a suspended license, and arrested. DI Decl., at 1; Resp. Decl., at 3. Respondent corroborated that the car was his, when in his declaration he addressed the allegation and stated, *inter alia*, that on January 24, 2012, he had withdrawn \$5000 from his bank account to pay for the remodeling of his clinic and left the money "in the small hidden compartment space of the car." Resp. Decl., at 3. Accordingly, I find that Respondent's statements corroborate the DI's assertion that the car was owned by Respondent.

Following the arrest of Respondent's girlfriend, the police apparently impounded his car, and upon searching it, found one pound of marijuana,<sup>10</sup> the aforesaid \$5000, and a backpack which contained pain medication. *Id.*; DI Decl., at 2.<sup>11</sup> As for the marijuana, Respondent asserted that it belonged to a medical marijuana patient (LHE) who was a friend of TB, and points to a statement from the purported owner of the marijuana. Resp. Decl., at 3; see also Resp. Mot., at Ex. 1. Therein, LHE stated that she had an engine problem with her car and that she borrowed Respondent's car from TB "for a few hours to pick-up

<sup>8</sup> According to Respondent, TB has lived with him "for the past 2 years" and "is now [his] wife." Resp. Decl., at 5. Moreover, TB worked in Respondent's clinic. Resp. Decl., at Ex. 4.

<sup>9</sup> According to the DI's affidavit, the car was registered to Respondent. DI Decl., at 1. While the DI's affidavit offers no explanation as to the basis of knowledge for this assertion, Respondent, in his declaration, stated that a friend of TB "had borrowed the car the previous day without my knowledge." Resp. Decl., at 3. I further note that in a March 3, 2012 letter to a local narcotics task force and the King County Prosecuting Attorney's Office, Respondent claimed that he owned the car and sought its return. Resp. Decl., at Ex. 4. Accordingly, I find that Respondent owned the car that TB was driving when she was stopped and arrested.

<sup>10</sup> In his statement, Respondent does not dispute that the arresting authorities found a one pound bag of marijuana. Resp. Decl., at 3.

<sup>11</sup> According to the DI, the police also found \$3900 in cash in a vacuum sealed bag in TB's purse. DI Decl., at 2.

. . . one [m]arijuana prescription bag" from a marijuana collective. Resp. Mot., at Ex. 1. According to LHE, she "was in a hurry to return the car to [TB and] forgot [sic] to remove the bag behind the driver seat." *Id.* However, LHE's statement is unsworn, and given that the purported reason for borrowing Respondent's car was to obtain the marijuana, I find her story that she left a one pound bag of marijuana<sup>12</sup> in the car because she was in such a hurry to return it to be utterly ludicrous.<sup>13</sup>

As for the cash, Respondent offered two explanations for its source. First, he maintained that the day before, a patient paid him \$5000 cash as a deposit for a liposuction procedure. Resp. Decl., at 3. Respondent also produced an unsworn letter from the purported patient to this effect and a form entitled: "SmartLipo & Coolsculpting Price Quote." *Id.* at Ex. 2. While the latter purports to show that the patient paid a \$5000 deposit in cash, the date of the deposit clearly appears to have been altered. *See id.*

Second, as found above, Respondent maintained that he had withdrawn \$5,000 from his bank account on January 24, 2012 to pay for clinic remodeling, and that he had placed the money "in the small hidden compartment space of the car." Resp. Decl., at 3. To support his claim, Respondent produced a bank statement showing that he made a cash withdrawal of \$5,000. Resp. Ex. 3. However, numerous entries in the statement, including Respondent's various balances for both his checking and savings account, are blacked out. *Id.*

Putting aside that Respondent offered two different stories as for why so much cash was found in his car, I find neither explanation credible. As for the claim that the money was from a patient who had paid \$5,000 cash the day before for a procedure, the patient's statement is unsworn and thus lacks even the most basic indicia of reliability. Moreover, on the price quote form, the date of the patient's deposit was clearly written over. Also, even acknowledging that the patient's procedure was likely not covered by insurance, it seems most unlikely that the patient would pay this

<sup>12</sup> According to data collected by the Agency, during the period in which TB was stopped, one pound of marijuana had a street value of \$1500 to \$1800 in the Seattle area. At .5 grams per joint, one pound would be enough to make approximately 900 joints.

<sup>13</sup> I further note that in his March 3, 2012 letter to a local narcotics task force and the King County Prosecuting Attorney's Office, in which he sought the return of his car, while Respondent again denied knowledge of the marijuana, he made no mention of the story that LHE had borrowed the car from his girlfriend.

amount in cash rather than by check or credit card.

As for his second story, it also seems most unlikely that Respondent would pay to remodel his clinic with cash (rather than check or credit card), let alone be carrying that much cash around in his car for nine days. By contrast, carrying large sums of cash is consistent with engaging in the distribution of marijuana.

In his declaration, the DI also asserted that the search of the vehicle found "multiple prescription bottles containing pills," and that one of the bottles bore a label indicating that the drugs had been prescribed to T.V., "an office employee of" Respondent. DI's Decl., at 2 (citing GX 9). The DI further stated that "[t]wo of the bottles found in the vehicle . . . were unlabeled and contained phentermine and phendimetrazine." *Id.* (citing GX 10). Finally, the DI asserted that when Respondent "attempted to recover his vehicle, he told law enforcement officers that his employees often shared their medication." *Id.*

Respondent did not dispute that drugs were found in TB's backpack. Rather, he asserted that they "belonged to my office manager," that he had prescribed the drugs "for her liposuction procedure pain a few months prior," and that the drugs were "left at my house when she visited for [a] dinner party." Resp. Decl., at 3. Respondent then maintained that "[a]s a medical doctor, I do not encourage nor allow any patients to share medication" and that he "would absolutely terminate my employee if found engaging in sharing medication and would report them to the authorities." *Id.* Respondent did not, however, explain when the purported dinner party had occurred.

Consistent with Respondent's admission, the record does include a photograph of a prescription vial; its label lists the patient as a person whose name corresponds with the initials T.V., the drug as hydrocodone/acetaminophen, and Respondent as the prescriber. See GX 9, at 1.<sup>14</sup> Moreover,

<sup>14</sup> Government Exhibit 9, however, contains seven additional photographs, including: (1) A photograph of two unlabeled vials (only one of which clearly contains tablets); (2) a photograph of two plastic bags, which purportedly contain phentermine and a red document, the date of which is unclear; (3) a photograph of a plastic bag containing a drug similar in appearance to the drug in the previous photograph; (4) a photograph of a vial containing yellow capsules and orange tablets, the label of which had been removed; (5) a vial bearing a label for a prescription issued by Respondent for clonazepam to a patient whose initials are R.M.; (6) six bottles bearing manufacturer's labels (several of which are labelled as professional samples) for Viagra, Topiramate, Ultram ER, and Meridia; and (7) two vials, whose

while the photograph does not show whether there were pills remaining in the vial, in his declaration, Respondent does not dispute that the vial contained pain medication, which hydrocodone is. I thus find that substantial evidence supports a finding that Respondent's girlfriend unlawfully possessed hydrocodone, which had been prescribed to another person.

In support of the DI's assertion that two unlabeled vials which contained phentermine and phendimetrazine were also seized, the DI cited Government Exhibit 10, but without regard to the specific page. However, in his declaration, the DI offered no statement to the effect that he participated in the search of Respondent's car, nor otherwise set forth the basis of his knowledge for making this assertion. Nor does the record contain any affidavits or police reports prepared by those officers who did participate in the arrest and search, nor other documents such as an inventory of the search, a chain of custody, and lab test results, which would support the DI's assertion.<sup>15</sup>

Indeed, while Government Exhibit 10 contains eight photographs, in reviewing this matter it is apparent that the exhibit is not limited to the evidence that was seized following the search of Respondent's car, but also contained photographs of evidence that may well have been seized during several of the searches described below. Most significantly, the Exhibit contains two photographs of vials (one showing two vials, the other showing a single vial) which were missing their labels, with no identification of when and from whom the vials were seized. Finally, while at least two of the vials appear to contain tablets (the third vial being murky), the Government provided no evidence (such as lab test results) explaining the basis for the DI's

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labels list Respondent as the prescriber, his girlfriend T.B. as the patient, and the drugs as lorazepam and hydrocodone/acetaminophen, with pills being visible only in the latter vial. Generally, the DI's declaration offers no statements linking these photographs to the various items which were purportedly seized during the various searches of Respondent's car and properties he owned.

Moreover, Government Exhibits 8, 9, 10, 11a, 11b, 13, 14, and 15 each contain the exact same set of eight photographs, although not necessarily in the same order. Providing multiple copies of the exact same set of photographs does not, however, make the first set of photographs any more probative of the facts for which they were offered.

<sup>15</sup> Even giving weight to the DI's assertion that Respondent "purchased these items [*i.e.*, phentermine and phendimetrazine] on August 5, 2011 from Distributor A.F. Hauser," DI's Decl., at 5 (¶ 34), this is not enough to overcome the insufficiency of the evidence with respect to the assertion that these drugs were seized during the February 2, 2012 search.

assertion that these vials contained phentermine and phendimetrazine.

### The Searches of Respondent's Properties

As noted above, the Show Cause Order also alleged that state and local law enforcement officers conducted searches of four different premises which Respondent owned, and found marijuana plants at his properties which were located in Renton and Shoreline, Washington, as well as six bags of processed marijuana at the latter property. GX 2, at 2. In addition, the Show Cause Order alleged that marijuana grow documents and "15 grams of processed marijuana" were found at Respondent's personal residence, and that both marijuana grow equipment and marijuana leaves were found at a fourth property he owns. *Id.* at 3.

In his declaration, the DI made various assertions with respect to each of the searches. For example, with respect to the May 30, 2012 search of the Renton residence, the DI stated that the Renton Fire Department had responded to an electrical fire at the premises, which "is owned by" Respondent and "discovered a large marijuana grow," and that thereafter, "[t]he Renton Police Department executed a search warrant of the residence and seized approximately 700 marijuana plants." DI Decl., at 2. The DI further stated that Respondent "told law enforcement that he rented the [premises] to [one] Jack Tran," but that the police "were unable to locate and/or identify Mr. Tran." *Id.* at 3. While all of this may be true, here again, the DI's declaration offers no statement to the effect that he participated in the search, nor otherwise sets forth the basis of his knowledge.

With respect to the July 5, 2012 search of the Shoreline residence, the DI stated that it was owned by Respondent, and that during the search by state and local law enforcement, "approximately 489 marijuana plants and six (6) bags of processed marijuana" were seized. *Id.* at 3. The DI further stated that TB and three other "marijuana tenders were arrested leaving the Shoreline residence," that TB "admitted" to the police "that she was learning to grow marijuana at the Shoreline residence," and that two "of the marijuana tenders arrested at the Shoreline residence possessed loose phentermine tablets in their pockets." *Id.* (citing GX 11).<sup>16</sup> Here

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<sup>16</sup> As explained below, while Respondent denies knowledge as to how his properties were being used, he does not dispute that marijuana was being grown at the various properties. Thus, his

too, all of this may be true, but the DI's affidavit offers nothing bordering on substantial evidence to support any of these assertions.<sup>17</sup>

The DI further asserted that L.E. was one of the marijuana tenders arrested during this search, and that using the Washington State Prescription Monitoring Program, “[i]t was discovered . . . that in June 2012, [Respondent] prescribed 30 dosage units of 10/500 mg hydrocodone to L.E.” *Id.* Citing Government Exhibit 12, the DI further stated that he “verified the prescriptions [sic] by obtaining a hard copy of the prescription through” the pharmacy which filled it. *Id.* at 3–4. The

declaration corroborates the basic thrust of the DI's assertions.

That being said, the DI's affidavit contains numerous assertions for which there is no foundation to conclude that they are based on the DI's “personal knowledge” as that term is commonly understood. Indeed, many of the DI's assertions regarding the searches of Respondent's properties appear to be based on hearsay statements, the reliability of which cannot be assessed because the DI did not identify the source of the information and the Government did not include various documents (such as police reports, search inventories, and test results) in the record.

More specifically, the DI asserts that TB and three other persons were arrested during the search of the Shoreline residence; that during an interview with law enforcement, TB admitted that she was learning how to grow marijuana; and that two of the persons had loose phentermine tablets in their pockets. Again, the DI offered no statement to the effect that he participated in either the search of the Shoreline residence or the interview of TB. Nor did he set forth any other basis for these assertions.

As for the two marijuana tenders who purportedly possessed loose phentermine, the DI further asserted that “[s]tate law requires the labeling of dispensed medication” and that “[t]he lack of labeled prescription bottles suggests the controlled substances were diverted.” DI's Decl., at 3. This too may be true, but there is no evidence in the record establishing the names of these individuals and that they obtained the controlled substances from Respondent. Indeed, while the DI cited GX 11 as support for his assertion that these individuals possessed phentermine, this exhibit simply contains a series of photographs including two of white tablets (one of which contains a red form which is illegible), various prescription vials (some of which contain pills, others which it is unclear if they do) and bottles containing various drug samples. Even assuming that the white tablets are phentermine (even though there is no evidence they were tested), nothing in the record establishes from whom and when these tablets were seized.

<sup>17</sup> Here too, even giving weight to the DI's assertion that Respondent “purchased this exact item [*i.e.*, more phentermine] on March 16, 2012 from Distributor A.F. Hauser,” DI Decl., at 5 (¶ 35), this evidence does not overcome the insufficiency of the evidence with respect to the assertion that these drugs were seized from the marijuana tenders during the search of the Shoreline residence. And because the evidence is insufficient to establish that loose phentermine was seized from the two marijuana tenders who were purportedly at the Shoreline residence, the assertions of the DI that: (1) One of the tenders “was never seen by” Respondent, and (2) that while one of the tenders was seen by Respondent, he was not prescribed any controlled substance, *id.* at 5–6 (¶ 36), is insufficient to establish that Respondent unlawfully distributed the phentermine to either person.

DI then stated that on July 13, 2012, he subpoenaed “L.E.'s patient chart from” Respondent, but that “[t]he office staff could not locate a patient chart for L.E., nor could they find his/her name in the electronic medical records.” *Id.* at 4.

Government Exhibit 12 is a copy of a prescription issued by Respondent on June 28, 2012 for thirty (30) tablets of Lortab (hydrocodone/acetaminophen) 10/500. *See GX 12.* However, the prescription was issued to a patient whose initials are H.L., and not L.E. *See id.* Thus, the prescription does not support the DI's assertion, and the Government points to no other evidence that Respondent prescribed a controlled substance to a patient whose name corresponds with the initials of L.E., let alone that he violated the CSA's prescription requirement in doing so. *See GX 2, at 2, ¶ 3–b.* (OTSC–ISO).

Regarding the July 6, 2012 search of Respondent's and TB's residence (which is owned by the former), the DI asserted that state and local law enforcement seized “firearms, marijuana grow documents, approximately 15 grams of processed marijuana, and multiple prescription bottles containing pills.” DI Decl., at 4. The DI then stated that Investigators found “an unlabeled” vial, “which contained hydrocodone”; one labeled vial, “which contained clonazepam that [Respondent] prescribed to patient R.M. in 2010”; and two “stock bottles that contained Meridia and diazepam”; even though Respondent “was not, nor has ever been, registered with DEA at his Bothell residence.” *Id.* (citing GXs 13, 14, and 15).

As for the unlabeled prescription bottle which purportedly contained hydrocodone, here again, the DI's Declaration is devoid of any statement that he was present during the search and there is no other evidence establishing that the vials were seized from Respondent's residence. And while GX 13 contains a photograph of two vials, with pills that are barely visible in the vials, there is no photograph of the pills outside of the vials, which might have shown that the pills bore the NDC Code for hydrocodone. Nor is there any evidence establishing that the pills were tested by a laboratory and found to be hydrocodone.<sup>18</sup>

<sup>18</sup> Even giving weight to the DI's assertion that Respondent “purchased this item [*i.e.*, hydrocodone] on March 16, 2012 from Distributor A.F. Hauser, Inc.,” DI Decl., at 6 (¶ 37); this statement likewise does not overcome the lack of substantial evidence establishing that these drugs were seized during the search of Respondent's residence.

As for the DI's assertion that the police also seized a vial containing clonazepam, here again, there is no evidence either that the DI was present during the search of Respondent's residence or that a vial containing this drug was seized during that search. And while the record contains a photograph of a vial, which bears a label listing Respondent as the prescriber, the drug as clonazepam, and the patient's name corresponding with the initials R.M., there is no evidence establishing that any pills were in the vial, let alone that the pills were clonazepam.<sup>19</sup>

Turning to the DI's assertion that Respondent “also possessed two (2) stock bottles that contained Meridia and diazepam,” here again, there is no evidence establishing that the DI participated in the search of Respondent's residence, or any other evidence establishing that these drugs were seized during that search. To be sure, the Government cites to an exhibit, which contains several photographs, including one which shows six white bottles (several of which are clearly marked as professional samples) which bear the manufacturer's label for such drugs as Viagra, Topiramate, Ultram ER, and Meridia. *See GX 15, at 1.* However, of these drugs, only Meridia (sibutramine) is a controlled substance under federal law, 21 CFR 1308.14(e), and putting aside the absence of any evidence as to where and when this drug was seized, here again, there is no evidence that there actually was any of the drug in the bottle at the time it was seized. As for the DI's assertion that a stock bottle of diazepam was also seized during the search of Respondent's residence, here too, there is no evidence (indeed, not even a photograph of the bottle) to support the DI's contention.

Finally, the DI stated that on July 7, 2012, state and local law enforcement executed a search warrant at a fourth residence which is owned by Respondent and located in Marysville, Washington. DI Decl., at 5. The DI further stated that during the search, the officers “seized some marijuana grow equipment and marijuana leaves.” *Id.* Here again, the DI's affidavit does not establish the basis of his knowledge.

Regarding the searches of the properties other than his residence, Respondent acknowledged that he owned “three rental properties.” Resp. Decl., at 3. He also acknowledged that

<sup>19</sup> In his Declaration, Respondent denied that he “ha[s] or store[s] any [hydrocodone or clonazepam at home.]” Resp. Decl., at 5. He further stated that “[t]he prescription bottles are prescribed for my wife for her liposuction procedures post-operative pain where she had four liposuction procedures performed from 7/9/11 to 11/3/12.” *Id.*

"one of the rental houses had an electrical burn that shed light on the others that had illegal activities." *Id.* at 4. He then asserted that he "had irresponsible tenants that took advantage of the locations by cultivating [m]arijuana for 6 months without [his] knowledge" and that he "do[es] not personally inspect, supervise, or manage the rentals on a regular basis," because he works six days a week in his medical practice, and that "[w]hen the rent is timely paid with no complaints that need repair, [he has] no need to bother tenants at their home." *Id.* at 3–4. Later in his declaration, Respondent stated that "[i]f something is broke they send me a bill for repair and I deduct it from the rent." *Id.* at 5.

On May 22, 2013, Respondent was indicted in United States District Court for the Western District of Washington and charged with conspiracy to manufacture and distribute marijuana. DI Decl., at 11; *see also* GX 31. Moreover, on October 22, 2013, a superseding indictment was filed against Respondent and his girlfriend.

The superseding indictment alleged that Respondent and others conspired to grow marijuana at several residential properties and that Respondent "made at least three of those properties available . . . for the purpose of manufacturing marijuana," that he "purport[ed] to rent [the houses] to others, knowing that the persons listed as 'tenants' for these properties did not, in fact, reside there and/or did not pay rent," that he and his co-conspirators "set up large-scale marijuana grows for the purpose of manufacturing marijuana within the houses" and "caused the electrical power in these houses to be diverted around the meters, thus stealing power to run the marijuana grows," and that he and his co-conspirators "recruited and directed others to help grow and harvest the marijuana plants, and maintain the houses and yards at these properties." Superseding Indictment, at 2, *United States v. Thi Nguyen Tram Bui and Keith Ky Ly*, No CR13-157JCC (W.D. Wash. 2013) (citing, *inter alia*, 21 U.S.C. 841(a)(1) and (b)(1)(A), 846). The Indictment further charged Respondent with three counts of manufacturing marijuana at his properties in Renton, Shoreline and Marysville, Washington, as well as three counts of maintaining drug-involved premises. *Id.* at 4–7 (citing 21 U.S.C. 841(a)(1) and (b)(1)(B); 856(a)(1) and 856(b)). The indictment also set forth additional allegations regarding the quantities of marijuana plants and/or harvested marijuana that were seized during the searches of his Renton and Shoreline properties, as

well as the quantity of marijuana which was seized from his girlfriend. *Id.* at 3.

Respondent went to trial; the jury found him guilty on all counts.<sup>20</sup> On December 19, 2014, the United States District Court convicted Respondent on each of the above counts and sentenced him to 60 months of imprisonment, imposed a four-year term of supervised release following his release from imprisonment, imposed an assessment of \$1,000, and ordered that various property be forfeited. Judgment, at 1–6, *United States v. Keith K. Ly* (W.D. Wash. Dec. 19, 2014).

### The DEA Investigation

According to the DI's affidavit, on July 13, 2012, DEA Investigators visited Respondent's registered location and upon obtaining his consent, conducted an inspection. DI's Decl., at 6; *see also* GX 20 (Notice of Inspection manifesting Respondent's consent to the inspection and witnessed by the DI). As part of the inspection, the Investigators asked Respondent to produce his records, including his controlled substance inventories, dispensing and administration logs, invoices, returns, distributions, as well as theft and loss reports. *Id.*

The DIs determined that Respondent "failed to take and maintain an initial or biennial inventory of all stocks of controlled substances on hand." *Id.*

While Respondent produced a dispensing log, which covered the period from December 23, 2010 to July 11, 2012, according to the DI, 128 of the entries lacked required information. *Id.* More specifically, the DI asserted that 82 entries did not have the patient's address, the name of the controlled substance, the finished form, and the dispenser's initials. *Id.* at 6–7.

According to the DI, another 46 entries lacked the patient's address, name of the controlled substance, the quantity dispensed, and the dispenser's initials. *Id.* at 7.

As part of the record, the Government submitted a copy of Respondent's dispensing log, GX 21. A review of the log corroborates the DI's assertion that many of the entries which record the dispensing of controlled substances lack various items of information required by federal law, including the patient's address and the dispenser's initials. *See id.* at 6–9. As for the contention that numerous entries did not contain the name of the controlled substance that was dispensed, it is true that numerous entries were missing the "Medication ID

<sup>20</sup> Respondent was also charged and convicted of three counts of wire fraud, based on claims he made to an insurance company.

Sticker." *Id.* at 1–5. Yet the Government produced no evidence to prove that these dispensings actually involved controlled substances as opposed to non-controlled drugs.

The DI also asserted that Respondent "failed to maintain or provide any dispensing/administration records for Testosterone and Testim samples located at the registered location." DI Decl., at 7. The DI further asserted that Respondent did not "maintain[ ] at least four Schedule III–V acquisition invoices and by not recording the dates of receipt on at least five invoices." *Id.*<sup>21</sup>

The DIs also conducted an audit of the controlled substances which were located at Respondent's registered location. *Id.* In his declaration, the DI stated that "DEA used an initial inventory date of January 1, 2012, beginning of business, and noted that the initial inventory was 'zero' due to the lack of an initial or biennial inventory." *Id.* To determine the amounts of the various drugs Respondent purchased, the DIs relied on "a summary of the invoices provided by distributor A.F. Hauser"; they also used his dispensing log to determine the amounts that he dispensed. *Id.* The DI further stated that he used "the closing inventory assembled by DEA investigators during the on-site inspection." *Id.*

The DI then asserted that the "audit revealed large shortages of testosterone, phentermine, phendimetrazine, and a 14% shortage or[sic] hydrocodone." *Id.* More specifically, the DI asserted that Respondent had a shortage of 300 mg of Testosterone 200 mg/ml, 6,028 tablets of phentermine 37.5 mg,<sup>22</sup> 2,102 tablets of phendimetrazine 35 mg, and 71 tablets of hydrocodone 10/500 mg. *Id.* at 8.

The Government also submitted a document which appears to be the aforesaid summary of Respondent's controlled substance purchases from A.F. Hauser between January 1, 2010 and July 24, 2012, *see* GX 16, as well as the audit computation chart, GX 23. Significantly, the audit chart lists the initial inventory date as "1–1–2010 COB" and not January 1, 2012 as set

<sup>21</sup> The DI also stated that during the inspection, Respondent did not provide any "Report[s] of Theft or Loss of Controlled Substances" (DEA Form 106). DI Decl., at 7. He also reviewed all of the hard copy Theft and Loss Reports on file with the Seattle Field Office, as well as queried the Drug Theft Loss database, which gathers all of the Form 106s which are submitted online, and determined that Respondent had not submitted any such reports. *Id.*

<sup>22</sup> According to the DI's declaration, the shortage was 6,028 tablets. DI Decl., at 8. Based on the audit chart, which lists the shortage as 6,028 tablets, GX 23, I conclude that the former figure is a typographical error.

forth in the DI's declaration. Compare GX 23 with DI Decl., at 7.

This disparity has a material impact on the accuracy of the audit results. For example, according to the DI's declaration (and the computation chart), Respondent was short more than 6,000 dosage units of phentermine. Yet, according to the summary of Respondent's purchases and the invoices, Respondent only purchased 3,000 dosage units of phentermine during 2012. Thus, if—as stated by the DI—the beginning date of the audit period was January 1, 2012 and zero was assigned as the opening inventory, Respondent could not have been short 6,000 dosage units.

So too, in his declaration, the DI asserted that Respondent was short more than 2,100 phenidmetrazine tablets (the same figure listed on the computation chart, which also lists 3,000 dosage units as having been purchased). However, the Government's other evidence shows that Respondent did not purchase any phenidmetrazine during 2012. See GX 16. Here again, Respondent could not have been short 3,000 dosage units if the beginning date of the audit period was January 1, 2012, as stated by the DI in his sworn declaration.

As for the testosterone, while there is evidence that Respondent also purchased testosterone in February 2012, the data as presented in the computation chart suggests that he purchased 400 10ml bottles and that he could not account for 300 bottles. See GX 23 (listing drug as "Testosterone 200mg/ml—10 ml bottle" and listing the "[t]otal purchased" as 400.) However, the Government's other evidence, i.e., the listing of Respondent's purchases, which according to the DI was prepared by A.F. Hauser, lists the quantity of Respondent's purchases as only "2.00." GX 19. Thus, here again, there is reason to question the reliability of the audit results.<sup>23</sup>

With respect to the remaining drugs, there is evidence that Respondent purchased 500 dosage units of hydrocodone during 2012 (GX 19) and was short 71 tablets. GX 23. There is also evidence that at the time of the July 2012 inspection, Respondent had on hand 21 Testim 1% samples. While the DIs concluded that Respondent had an overage of these 21 samples, there is no evidence as to who distributed the samples to him and there is no evidence the DIs asked Respondent for any of the

documentation establishing the amount of Testim that was distributed to him.<sup>24</sup> Finally, the Government's evidence shows that in March 2012, Respondent purchased 1,000 dosage units of Lorazepam, GX 16, and the computation chart indicates that the audit balanced with respect to this drug. GX 23.

In his declaration, the DI further asserted that Respondent failed to report to the State of Washington's Prescription Monitoring Program (PMP), "at least 45 occasions from January through July 2012" in which he "dispensed more than a 24-hour supply of controlled substances." DI Decl., at 8. According to the DI, this was a violation of Washington law. *Id.* The Government did not, however, submit the PMP reports which establish the basis for its assertion.

Regarding this allegation, Respondent stated that he "was not aware of this Washington State law requirement . . . [and] thus cannot have . . . repeatedly failed" to comply or to have shown a "consistent disregard" for this requirement. Resp. Decl., at 8. Respondent then stated that "I am now made fully aware and will comply with the law. This is not an intentional violation." *Id.*<sup>25</sup>

## Discussion

Under the CSA, "[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section."<sup>26</sup> 21 U.S.C. 824(a)(4). The Act further provides that in determining "the public interest" with respect to a practitioner's

<sup>24</sup> It is further noted that while the computation chart contains a column for the "Total Purchased," which was added to the "Initial Inventory" to arrive at the "Amount Accountable For," samples are not typically purchased and the chart contains no column for other means of acquisition. GX 23.

<sup>25</sup> Based on the DI's Declaration, the Government proposes that I make a factual finding that following the issuance of the Immediate Suspension Order, Respondent "issued at least three (3) prescriptions to two (2) separate patients on February 1, March 2, and March 30, 2013, in violation of the Order." Request for Final Agency Action, at 5 (citing DI's Declaration at 9–10). However, in its Request for Final Agency Action, the Government does not propose that I make any conclusion of law based on this conduct. See *id.* at 6–12. Accordingly, I do not consider this conduct.

<sup>26</sup> Pursuant to 28 CFR 0.100(b), this authority has been delegated by the Attorney General to the Administrator of the Drug Enforcement Administration.

application, the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f).

"[T]hese factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). It is well settled that I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem appropriate in determining whether a registration should be revoked." *Id.*; see also *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222 (quoting *Hoxie*, 419 F.3d at 482)).<sup>27</sup>

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. 824(a) are met. 21 CFR 1301.44(e). This is so even in a non-contested case.

In this matter, I have considered all of the factors. While I find that some of the allegations are not supported by substantial evidence, I nonetheless find that the Government's evidence with respect to factors one, two, three, and four establishes that he has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 823(f). While I have also considered Respondent's declaration with respect to the various allegations, I conclude that he has not presented sufficient evidence to rebut this conclusion. Accordingly, I will affirm the suspension of his registration and

<sup>27</sup> "In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. See *MacKay*, 664 F.3d at 821.

<sup>23</sup> Moreover, even if the entry in the computation chart was actually intended to be 400mg (or two bottles) as opposed to 400 bottles, at most Respondent would not be able to account for 1.5 bottles.

further order that his pending application be denied.

#### **Factor One—The Recommendation of the State Licensing Board**

As found above, on September 22, 2014, the Washington Board of Osteopathic Medicine and Surgery issued Respondent an Ex Parte Order of Summary Action, pursuant to which, his authority to practice medicine in the State was suspended. Under the CSA, a practitioner's possession of authority to dispense controlled substances under the laws of the State in which he seeks registration is a prerequisite to obtaining a registration. *See* 21 U.S.C. 823(f) (“The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.”); *see also id.* § 802(21) (defining “[t]he term ‘practitioner’ [to] mean[] a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . [or] administer . . . a controlled substance in the course of professional practice”).

Because Respondent is no longer authorized by the State of Washington to practice medicine and dispense controlled substances, he is not authorized to hold a registration in that State. This provides reason alone to deny his application. However, because the Government also seeks a final order based on the allegations of the Order to Show Cause and Immediate Suspension of Registration, I address the evidence with respect to the other public interest factors.

#### **Factor Two—Respondent’s Experience in Dispensing Controlled Substances**

The Government contends that Respondent unlawfully distributed controlled substances to various persons who were arrested during the search of his Shoreline property. Req. for Final Agency Action, at 10 (citing, *inter alia*, 21 U.S.C. 841(a)(1)). More specifically, the Government contends that Respondent “prescribed hydrocodone . . . to an individual arrested at the Shoreline” property and could “not locate a patient file at [his] registered location for this particular individual.” *Id.* Based on the Investigators’ “determin[ation] that [Respondent] also purchased the loose phentermine tablets located on individuals at the Shoreline residence on March 16, 2012, despite the fact that he could not produce patient records when requested by law enforcement,” the Government also apparently contends that Respondent

unlawfully distributed the tablets to these individuals. *Id.* at 11.

Neither of these allegations is proved by substantial evidence. As for the allegation regarding the hydrocodone prescription, as found above, in his Declaration, the DI repeatedly referred to this person as L.E. Yet to support the allegation, the Government offered a copy of a prescription which was issued to a patient whose initials are H.L. and not L.E. Moreover, the Government points to no other evidence that Respondent even prescribed hydrocodone (or any controlled substance for that matter) to a person whose initials are L.E. Thus, the allegation is unsupported by substantial evidence.

As for the allegation that the phentermine was found on two persons who were arrested during the Shoreline search and was distributed to them by Respondent, while the Government produced evidence that Respondent had ordered phentermine from his distributor several months earlier, the evidence offered to establish that phentermine was found on these individuals was limited to the DI’s assertion that it was. The DI did not, however, offer any basis for concluding that he personally participated in the search—notwithstanding his assertion that his declaration was based on “personal knowledge”—nor otherwise explain the basis for his statement. Finally, the Government offered no other evidence to prove this assertion such as a police report, an affidavit of the arresting officer, or an inventory of the items found during the search conducted incident to the purported arrest of these individuals. The allegation therefore fails for lack of substantial evidence.

The evidence further shows that Respondent purchased controlled substances including hydrocodone with acetaminophen, phentermine, phenidimetrazine, testosterone, and lorazepam, which he dispensed directly to his patients. Under federal law, Respondent was required upon “first engag[ing] in the . . . dispensing of controlled substances, and every second year thereafter, [to] make a complete and accurate record of all stocks thereof on hand.” 21 U.S.C. 827(a)(1). Also, under federal law, because he engaged in the dispensing of the controlled substances, Respondent was required to “maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him.” *Id.* § 827(a)(3). DEA regulations further require that a dispenser maintain a record “of the number of units or

volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.” 21 CFR 1304.22(c). Finally, under this regulation, Respondent was required to maintain records of the controlled substances he acquired, to include “[t]he name of the substance”; “[e]ach finished form . . . and the number of units or volume of finished form in each commercial container”; and “[t]he number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from the units were acquired.” *Id.* § 1304.22(a)(2)(i), (ii), and (iv).

Here, I give no weight to the audit results given the numerous problems found above, including the conflict in the Government’s evidence as to what the DIs used as the beginning date for the audit period. Nonetheless, I find that the DI’s declaration establishes that during the July 2012 inspection, Respondent could not produce the required inventories for the controlled substances he was handling, and was thus in violation of 21 U.S.C. 827(a)(1).<sup>28</sup> Moreover, the DI’s declaration establishes that while Respondent was engaged in dispensing controlled substances, many of the entries for his phentermine dispensings lacked the patient’s address and the name or initials of the person who did the actual dispensing.<sup>29</sup> Thus, Respondent violated the CSA and DEA regulations for these reasons as well.<sup>30</sup> *See* 21 U.S.C. 827(a)(3); 21 CFR

<sup>28</sup> Regarding the lack of inventories, Respondent stated that he “ha[d] invoices from [his distributor] as my initial inventory.” Resp. Decl., at 7. Contrary to Respondent’s contention, under the CSA, the requirement to take and maintain complete and accurate inventories is separate from the requirement to maintain records of the controlled substances a registrant acquires. Compare 21 U.S.C. 827(a)(1) with *id.* § 827(a)(3); compare also 21 CFR 1304.11 with *id.* § 1304.22. I therefore reject Respondent’s contention. I further note that during the inspection, the DI found that Respondent did not have all of the invoices.

<sup>29</sup> While in his declaration Respondent states that this information was in the patient charts and that there is only limited space in his dispensing log, *see* Resp. Decl., at 7; DEA regulations require that the patient’s address be documented in the dispensing log. 21 CFR 1304.22(c).

<sup>30</sup> As for the various entries in the dispensing log which lacked the name of the drug, because the Government provided no evidence that the dispensings involved controlled substances, I place

1304.22(c). Finally, the DI's declaration establishes that Respondent lacked complete records of the controlled substances he acquired from his distributor, in violation of 21 U.S.C. 827(a)(3), as well as 21 CFR 1304.22(c). *See also* 21 CFR 1304.22(a)(2)(i), (ii), and (iv).

As both the Agency and the federal courts have explained, recordkeeping is one of the CSA's fundamental features for preventing the diversion of controlled substances. *See Gonzales v. Raich*, 545 U.S. 1, 14 (2005) ("The CSA and its implementing regulations set forth strict requirements regarding . . . recordkeeping."); *United States v. Poulin*, 926 F. Supp. 246, 250 (D. Mass. 1996) ("The [CSA] focuses on recordkeeping, in an attempt to regulate closely the distribution of certain substances determined by Congress to pose dangers, if freely available, to the public at large.") (int. quotations and citation omitted); *Paul H. Volkman*, 73 FR 30630, 30644 (2008) ("Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.").

Respondent's recordkeeping violations alone are sufficiently egregious to support the conclusion that he "has committed such acts [which] render[ed] his registration . . . inconsistent with the public interest." 21 U.S.C. 824(a)(4); *see also* *Volkman*, 73 FR at 30644 (holding that recordkeeping violations alone can support revocation or denial of an application).

#### **Factor Three—Respondent's Conviction Record Under Federal and State Laws Related to the Manufacture, Distribution, and Dispensing of Controlled Substances**

As found above, following a jury trial, on December 19, 2014, Respondent was convicted by the United States District Court on seven felony counts related to the manufacture and distribution of marijuana, including conspiracy to distribute or manufacture marijuana, three counts of manufacturing marijuana, and three counts of

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no weight on this evidence. As for the Government's assertion that Respondent failed to maintain a "dispensing/administration log for testosterone and Testim samples," Request for Final Agency Action, at 8; there is no evidence that he dispensed any Testim samples. As for the testosterone, the evidence does suggest that Respondent administered approximately 300 mg or 1.5 vials without documenting the administrations in his dispensing log. *See* 21 CFR 1304.03(d).

maintaining drug involved premises.<sup>31</sup> Each of these convictions provides reason alone to deny his application. And under the doctrine of collateral estoppel, the convictions also preclude any challenge to the allegations that he was engaged in the unlawful manufacture of marijuana. *See Robert L. Daugherty*, 76 FR 16823, 16830 (2011).

#### **Factor Four—Compliance With Applicable Laws Related to Controlled Substances**

With respect to this factor, the Government raises three main allegations. First, based on the various searches, the Government argues that Respondent possessed and was engaged in the manufacture of marijuana, a schedule I controlled substance. Request for Final Agency Action, at 8–9 (citing 21 U.S.C. 841(a)(1), 844(a); 812(c)). Second, the Government alleges that during the search of Respondent's residence, several vials of controlled substances were found including one each of clonazepam and hydrocodone, the latter being in an unlabeled vial, as well as stock bottles of Meridia and diazepam, and that Respondent's possession of the drugs violated federal law because he was not registered at his residence. *Id.* (citing 21 U.S.C. 844(a); 21 CFR 1301.75(b)). Third, the Government alleges that Respondent violated state law by failing to report to the Washington Prescription Monitoring Program some 45 instances in which he dispensed more than a twenty-four hour supply of a controlled substance. *Id.* at 9.

As for the latter allegation, Respondent did not dispute that he had failed to report various dispensings to the State's PMP. Resp. Decl., at 8. Rather, he claimed his violations were unintentional because he was unaware of the law but would now comply. *Id.*

However, this is not a valid defense as the Washington courts follow the traditional rule that ignorance of the law is no excuse. *See State v. Reed*, 928 P.2d 469, 471 (Wash. Ct. App. 1997) (other citation omitted). Accordingly, I find that Respondent violated Washington law by failing to report various dispensings to the State's PMP. *See Wash. Rev. Code § 70.225.020(2).*

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<sup>31</sup> As to the latter offense, the CSA renders it unlawful to "knowingly use[] or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance." 21 U.S.C. 856(a)(1). As the evidence shows that Respondent used and maintained the three properties for the purpose of manufacturing marijuana and not simply as places to use the drugs, I conclude that his convictions for maintaining drug-involved premises fall within factor three.

As for the allegations pertaining to the controlled substances that the police found during the search of Respondent's residence, I conclude that the Government did not provide substantial evidence to support the allegations with respect to any of the four drugs (Meridia, diazepam, clonazepam (in a vial indicating that Respondent had prescribed the drug to R.M.) or hydrocodone (in an unlabeled vial)). With respect to the diazepam, the Government produced absolutely no evidence that the drug was even seized during the search. With respect to the Meridia, the Government's evidence was limited to a photograph of a white professional sample bottle and the DI's unsupported assertion, with no other evidence to establish that the bottle was seized from Respondent's residence, let alone that there were any pills in the bottle when it was seized.

So too, with respect to the hydrocodone and clonazepam, there is no evidence other than photographs and the DI's unsupported assertion that these drugs were seized during the search of Respondent's residence. To be sure, in his declaration, Respondent stated that he prescribed the hydrocodone and clonazepam to his wife for several procedures. However, Respondent explicitly denied having or storing clonazepam or hydrocodone at his home and his statements do not constitute an admission of any part of this allegation. Accordingly, these allegations fail for lack of substantial evidence.

I also find that substantial evidence supports the remaining marijuana-related allegation—that on February 2, 2012, Respondent violated federal law by possessing marijuana, and that he did so with the intent to distribute. Most significantly, it is undisputed that upon the February 2, 2012 arrest of TB, (Respondent's then live-in girlfriend and now wife), who was then driving his car, the police impounded his vehicle and during the subsequent search of the vehicle found one pound of marijuana and \$5,000 in cash; the police also found \$3,900 in cash in TB's purse.

As found above, the street value of the marijuana was approximately \$1,500 to \$1,800, and the quantity would provide approximately 900 joints. Respondent denied having any knowledge of the marijuana, asserting that it had been left in his car by LHE, a friend of TB and a purported medical marijuana patient who TB allowed to borrow his car, and provided an unsworn statement from LHE to this effect. However, as I found above, her statement (that she left the marijuana in the car because she was in

such a hurry to return the car to TB and forgot it) is utterly ludicrous.<sup>32</sup> I therefore reject Respondent's explanation for why the police found one pound of marijuana in his car.

Moreover, given the closeness of the relationship between Respondent and TB in that they were living together and that TB also worked for him, I find it implausible that Respondent lacked knowledge of the marijuana. Rather, I find that Respondent had the ability to exercise dominion or control over the marijuana through TB and thus constructively possessed the drug. *See United States v. Sanders*, 341 F.3d 809, 816 (8th Cir. 2003) ("To prove constructive possession, the government had to present evidence that appellants had knowledge and ownership, dominion or control over the contraband itself, or dominion over the vehicle in which the contraband is concealed.") (quoting *Ortega v. United States*, 270 F.3d 540, 545 (8th Cir. 2001)).

So too, Respondent's attempt to explain the presence of the large sum of cash (nearly \$9,000) that was found in his car and on his wife's person does not persuade. As for the money which was purportedly paid by a patient the day before as a deposit on a liposuction procedure, as found previously, while the "Price Quote" document indicates that the patient paid a \$5,000 cash deposit, the date was clearly written over. And while the purported patient provided a letter to support Respondent, it too was unsworn.

As an additional explanation for why so much money was found in his car, Respondent stated that the money had been withdrawn to pay for remodeling his clinic. To support this claim, Respondent submitted a copy of a bank statement (on which the various balances are blacked out), which documents that he made a withdrawal nine days before his girlfriend was arrested. However, Respondent offered no further evidence to support this contention, and in any event, his explanation begs the question of why he would risk the potential theft or loss of a large sum of cash, rather than pay for the purported remodeling with a check or credit card.

I therefore find that both the quantity of the marijuana (which would provide a single person with three joints a day for approximately ten months), and the large amount of cash which was found

<sup>32</sup> As also noted, in a March 3, 2012 letter to the local prosecutor in which Respondent sought the return of his car, he denied having any knowledge of the marijuana that was found therein. *See* Resp. Decl., at Ex. 4. Yet he made no mention of LHE's story. *See id.*

in Respondent's vehicle, support a finding that the marijuana was intended for distribution. *See United States v. Collins*, 412 F.3d 515, 519 (4th Cir. 2005) (holding that "intent to distribute can be inferred from a number of factors, including . . . the quantity of drugs" and "the amount of cash seized with the drugs."). I further find that Respondent "had the right to exercise dominion and control over" the marijuana "either directly or through" TB. *United States v. Staten*, 581 F.2d 878, 883 (D.C. Cir. 1978). I therefore find that Respondent knowingly possessed marijuana with the intent to distribute it.<sup>33</sup> *See* 21 U.S.C. 841(a)(1).

Based on Respondent's violation of federal law by possessing marijuana with the intent to distribute, as well as his admitted failure to report multiple dispensings of controlled substances to the Washington PMP, I find that factor four also supports a finding that he has committed acts which rendered his registration "inconsistent with the public interest."<sup>34</sup> 21 U.S.C. 823(f) & 824(a)(4).

#### Sanction

Under Agency precedent, where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, the registrant must 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'" *Medicine Shoppe—Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a

<sup>33</sup> In his Declaration, Respondent disputed that he owned the marijuana plants, the processed marijuana, and related items that were seized in the searches of his three properties. *See* Resp. Decl., at 3 ("I have three rental properties. I had irresponsible tenants that took advantage of the locations by cultivating Marijuana for 6 months without my knowledge."). He also claimed that because he was a busy physician, who did not bother his tenants if they paid their rent and did not request repairs, he "did not know of . . . nor . . . in any way participate in the growing of marijuana at these rental houses." *Id.* at 4. Based on Respondent's convictions for conspiracy to manufacture marijuana, unlawful manufacture of marijuana at each of the three grow houses, and maintaining drug-involved premises at each of the three residences, I reject his assertions as utterly false.

<sup>34</sup> Having already addressed the various false statements regarding the marijuana-related allegations which Respondent has made in his declaration, I deem it unnecessary to repeat this discussion under factor five.

registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." *Medicine Shoppe*, 73 FR at 387; *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie*, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[] in the public interest determination). So too, in making the public interest determination, "this Agency also places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding." *Robert F. Hunt*, 75 FR 49995, 50004 (2010) (citing *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy*, 72 FR 74334, 74338 (2007) (quoting *Hoxie*, 419 F.3d at 483) ("Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.")).

Moreover, while a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that granting his application for registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining whether to grant or deny an application. *See, e.g., Joseph Gaudio*, 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate disposition. *Cf. Jacobo Dreszer*, 76 FR 19386, 19387–88 (2011) (explaining that a respondent can "argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation"); *see also Paul H. Volkman*, 73 FR 30630, 30644 (2008); *Gregory D. Owens*, 74 FR 36751, 36757 n.22 (2009).

Moreover, as I have noted in several cases, "[n]either *Jackson*, nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked," or whether an application should be denied. *Gaudio*, 74 FR at 10094 (quoting *Southwood*, 72 FR at 36503 (2007)); *see also Robert Raymond Reppy*, 76 FR 61154, 61158 (2011); *Michael S. Moore*, 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio*, 74 FR at 10095 (quoting

*Southwood*, 71 FR at 36504). Cf. *McCarthy v. SEC*, 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of "deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions").

As found above, the Government has established that Respondent: 1) committed multiple recordkeeping violations in that he did not have required inventories, was missing invoices, and his dispensing log lacked required information; 2) was engaged in the manufacture and distribution of marijuana; and 3) failed to report multiple dispensings of controlled substances to the Washington PMP. I find that the proven misconduct is sufficiently egregious to affirm the Order of Immediate Suspension and to deny his pending application to renew his registration. See, e.g., *Moore*, 76 FR at 45870 (imposing one-year suspension on physician who manufactured marijuana, notwithstanding ALJ's finding that physician accepted responsibility and demonstrated he would not engage in future misconduct).<sup>35</sup> I further find that the Agency's interest in deterring similar acts on the part of both Respondent and others supports the denial of his pending application.

Having carefully reviewed Respondent's declaration, I further find that Respondent has not accepted responsibility for his misconduct. Regarding his recordkeeping violations, Respondent entirely denied that he failed to keep the required inventories and that he was missing various invoices. Moreover, he further claimed that the reason his dispensing log was missing essential information such as patient addresses was because there was no room to make these entries. Yet in DEA's experience, thousands of other registrants who engage in dispensing have no problem complying with the latter requirements.

With respect to the marijuana allegations, Respondent offered the far-fetched story that the marijuana belonged to an acquaintance of his wife,

<sup>35</sup> In *Moore*, I agreed with the ALJ's finding that the physician's conduct in manufacturing and distributing marijuana supported revocation of his registration. 76 FR at 45868. However, I also agreed with the ALJ's finding that the physician had accepted responsibility for his misconduct and demonstrated that he would not engage in future misconduct. *Id.* By contrast, here, the record establishes that in addition to his marijuana-related misconduct, for which he disingenuously denies any responsibility, Respondent also committed multiple recordkeeping violations and violated state law by failing to report numerous dispensings to the State PMP. Also, in contrast to *Moore*, I find that Respondent has not accepted responsibility for his misconduct.

who had borrowed his car to obtain her medical marijuana but who was in such a hurry to return the car that she forgot to retrieve it even though it was her medicine. So too, Respondent's alternative explanations for why thousands of dollars of cash were found in his car defy credulity. Similarly, his claim that he was unaware of the marijuana growing activities which were being conducted at not one, not two, but three of his properties, is clearly disingenuous.<sup>36</sup> Accordingly, based on his various false statements regarding the marijuana-related activity, as well as his blatantly false assertion that he has never been subject to discipline by a state licensing authority (all of which are clearly material to the outcome of this proceeding), I further find that Respondent lacks candor.

Based on his failure to acknowledge his misconduct, his failure to offer any credible evidence of remedial efforts, and his lack of candor, I conclude that Respondent has failed to present sufficient evidence to rebut the Government's *prima facie* showing that his registration would be "inconsistent with the public interest." 21 U.S.C. 823(f); see also *id.* 824(a)(4). Therefore, I will affirm the issuance of the Order of Immediate Suspension and order that any pending application to renew Respondent's registration be denied.

## ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I affirm the Order of Immediate Suspension of DEA Certificate of Registration BL6283927, issued to Keith Ky Ly, D.O. I further order that the application of Keith Ky Ly, D.O., to renew his registration, be, and it hereby is, denied. This Order is effective June 19, 2015.

Dated: May 11, 2015.

**Michele M. Leonhart,  
Administrator.**

[FR Doc. 2015-12139 Filed 5-19-15; 8:45 am]

**BILLING CODE 4410-09-P**

<sup>36</sup> With regard to his failure to report dispensings to the Washington PMP, Respondent claimed that he was unaware of the law. However, the legislation which created the Washington PMP was enacted in 2007, more than four years earlier, and as a physician who engaged in the highly regulated activity of dispensing controlled substances, Respondent was obligated to keep abreast of legislation and regulatory developments applicable to his medical practice. Moreover, while Respondent asserted that he is now aware of the requirement and will comply in the future, his various statements regarding the events at issue (including that he had never been disciplined by a state board) support a finding that he lacks candor. Accordingly, I give no weight to his statement that he would comply with the State's PMP reporting requirement in the future.

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 11-71]

### Cove Inc., D/B/A Allwell Pharmacy; Decision and Order

On April 23, 2013, Administrative Law Judge Christopher B. McNeil (hereinafter, ALJ) issued the attached Recommended Decision.<sup>1</sup> Neither party filed exceptions to the ALJ's Recommended Decision.

Having reviewed the record in its entirety and the Recommended Decision, I have decided to adopt the ALJ's findings of fact and conclusions of law, except as discussed below. I further adopt the ALJ's recommended order that Respondent's application be denied.

As explained in the ALJ's Recommended Decision, in making the public interest determination, Congress directed the Agency to consider "the applicant's experience in dispensing . . . controlled substances." 21 U.S.C. 823(f)(2). The evidence showed that Respondent's President and majority owner is Mrs. Ogechi Abalih, and that while Mrs. Abalih is a registered nurse, she is not a pharmacist and has no experience working in a retail pharmacy. Moreover, when questioned both during the pre-registration investigation and at the hearing as to whether she was familiar with the federal controlled-substance recordkeeping and security requirements for retail pharmacies, Mrs. Abalih responded by stating, in essence, that those matters would be addressed by the pharmacist she would retain. Tr. 143–46. In her testimony, Mrs. Abalih also made clear that she lacks knowledge of these requirements as they pertain to retail pharmacies, stating that "if there's a requirement for me to do anything, know these things, study them, I will do them. But when I applied I was not made to understand that I need to know all this." *Id.* at 144.

This is truly a remarkable answer, which fully demonstrates why granting Respondent's application "would be inconsistent with the public interest." 21 U.S.C. 823(f). Notwithstanding that the Order to Show Cause specifically alleged that the Agency's investigation found Mrs. Abalih "had no knowledge of DEA regulations pertaining to the handling of controlled substances and related security requirements," ALJ Ex. 1, at 1; she still lacked knowledge of these requirements when she testified

<sup>1</sup> The ALJ's Recommended Decision is cited as R.D.; all citations to the Recommended Decision are to the slip opinion issued by the ALJ.