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).[35] 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, 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.[36] 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

[35] 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.

[36] 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.[1] 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 Abalihi, and that while Mrs. Abalihi 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. Abalihi responded by stating, in essence, that those matters would be addressed by the pharmacist she would retain. Tr. 143–46. In her testimony, Mrs. Abalihi 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. Abalihi ''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

[1] 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.

some two years later.[2] While neither the Controlled Substances Act (CSA), nor the Agency's regulations, prohibits a pharmacy, which is owned by a non-pharmacist, from holding a DEA registration, the holder of the registration is ultimately accountable for ensuring compliance by its pharmacists with the requirements of the CSA and the Agency's regulations. *See United States* v. *Southern Union Co.,* 630 F.3d 17, 31 (1st Cir. 2010), *rev'd on other grounds,* 132 S.Ct. 2344 (2012) (quoted in *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62315, 62317 (2012) (''[T]hose who manage companies in highly regulated industries are not unsophisticated. . . . It is part of [a company's] business to keep abreast of government regulation.'')).

It is indisputable that absent knowledge of the CSA and the Agency's regulations, a registrant cannot properly supervise its pharmacists to protect against the diversion of controlled substances.[3] Thus, Mrs. Abalihi's admitted lack of knowledge of these requirements provides reason alone to conclude that granting Respondent's application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

I further adopt the ALJ's conclusion that the evidence with respect to factor five—such other conduct which may threaten public health and safety—supports the denial of Respondent's application. More specifically, the ALJ found that both Mrs. Abalihi and Ms. Taylor, who purportedly was to be Respondent's pharmacist-in-charge, made materially false statements to the Investigators when they were questioned regarding who would act as Respondent's pharmacist. However, upon review of the record, including the pleadings, I adopt the ALJ's conclusion only with respect to Ms. Taylor.

The evidence showed that when DEA Diversion Investigators (DI or DIs) asked Mrs. Abalihi who would manage the pharmacy, she stated that Ms. Jacinta Taylor would do so. Tr. 34. Subsequently, the DIs interviewed Ms. Taylor, who is a licensed pharmacist (and the owner of ten percent of Respondent) and who stated that she would be the pharmacist-in-charge at Respondent. *Id.* at 38. Ms. Taylor also told the DIs that she would order the controlled substances and that the pharmacy would be open from nine to six on weekdays and nine to one on Saturday. *Id.* at 38–39.

However, during the interview, Ms. Taylor told the DIs that she had a full time position at a Sweetbay Pharmacy in Tampa, and worked between the hours of ten to eight. *Id.* at 39. A DI further testified that according to the State Pharmacy Board, Ms. Taylor was not listed as Respondent's supervising pharmacist. *Id.* When the DI asked Ms. Taylor ''about that,'' she replied that ''she would leave Sweetbay if and when [Respondent] started to make money.'' *Id.* at 40.

The DIs then asked Ms. Taylor who would be Respondent's pharmacist-in-charge given her full time position at Sweetbay and intent to continue working there until Respondent became profitable; Ms. Taylor identified a Ms. Mustafa, a co-worker at Sweetbay. *Id.* However, when the DIs told Ms. Taylor that they wanted to talk to Ms. Mustafa, Ms. Taylor stated that she did not think that Ms. Mustafa would want to be interviewed and added, ''[w]ell, perhaps she won't work there.'' *Id.* at 41. Subsequently, one of the DIs called Mrs. Abalihi and ''asked her to put [him] in touch with Ms. Mustafa.'' *Id.* at 42. While Mrs. Abalihi stated that she would contact Ms. Mustafa and either get her phone number for the DI ''or have her call'' him, he never received a call from Ms. Mustafa. *Id.*

Ms. Taylor did not testify at the hearing. However, in an affidavit, Ms. Taylor stated that she ''was caught 'flat footed' '' by the question and ''thought'' that Ms. Mustafa, ''another pharmacist who worked at Sweetbay, . . . might be willing to serve such role.'' RX 7, at 2. Ms. Taylor further acknowledged that at the time of the interview, she ''had not made formal arrangements for [a] replacement and had not yet asked Ms. Mustafa whether she would be willing to fulfill such role, but thought that Ms. Mustafa would be so willing.'' *Id.* Moreover, in her testimony, Ms. Abalihi stated that she did not know Ms. Mustafa, that she had never spoken with her, and that there was ''no plan'' to have her work at Respondent. Tr. 138–39. And when asked by the ALJ whether in March 2011, Ms. Taylor had told her ''that she would be relying on Ms. Mustafa,'' Mrs. Abalihi answered that Taylor ''did not say she would be relying on Ms. Mustafa, no. She said the name came to her when this question was thrown to her. She wasn't expecting it, but the name came to her.'' *Id.* at 161.

Notwithstanding her assertion that she was caught flatfooted, Ms. Taylor's affidavit, as well as Ms. Abalihi's testimony, establishes that Taylor had no basis in fact for her statement to the Investigators that Ms. Mustafa would be Respondent's pharmacist-in-charge until Ms. Taylor decided to start working there. Accordingly, Ms. Taylor's statement was false. Moreover, her statement was materially false in that it had the capacity to influence the Agency's decision to grant Respondent's application, because of the obvious need to determine whether those who will actually engage in dispensing activities on behalf of a proposed pharmacy registrant, hold the necessary state license and have not previously violated federal or state laws related to controlled substances. *See* 21 U.S.C. 823(f)(2) & (4) (directing Agency to consider the applicant's experience in dispensing controlled substances and compliance with applicable laws related to controlled substances); *see also* 21 CFR 1301.76(a) (''The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause.'').

I do not, however, adopt the ALJ's legal conclusion that Mrs. Abalihi made a material misrepresentation when she subsequently agreed to provide Ms. Mustafa's contact information rather than disclose that she knew nothing about Ms. Mustafa's role with the pharmacy. R.D. at 32. In support of his reasoning, the ALJ explained that ''[i]f Ms. Abalihi intended on using contract pharmacists at the start of Allwell's operation, she had an affirmative duty to say so when DEA investigators asked her about the role Ms. Mustafa was to play. By her silence, and by promising to provide contact information for Ms. Mustafa, Ms. Abalihi misled the investigators.'' *Id.*

It may be that Ms. Abalihi misled the investigators, but the record is far from clear on this point. More specifically, while the record establishes that the DI called Ms. Abalihi and asked her about getting contact information for Ms. Mustafa, the record does not establish that the Investigator ever specifically ''asked her about the role Ms. Mustafa

[2] While Ms. Abalihi testified that she was not told prior to her interview with the DIs that ''she needed to study anything,'' Tr. 136, the Show Cause Order clearly provided notice that her lack of knowledge of DEA regulations was at issue.

[3] Pharmacies which handle controlled substances are subject to extensive recordkeeping and security requirements. *See* 21 CFR 1301.75–1301.76 (security requirements); *id.* §§ 1304.03–1304.06; 1304.21–1304.22 (recordkeeping and reporting requirements). In addition, as the ALJ explained, their pharmacists are charged with the responsibility of dispensing only those prescriptions which are ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). *See also generally* 21 CFR part 1306 (setting forth various other requirements pertaining to prescriptions and the dispensing of controlled substances by pharmacies).

was to play.'' Most significantly, the Government never alleged in either the Show Cause Order or its pre-hearing statements that Ms. Abalihi made a materially false statement or materially misled the DIs when she promised to get Ms. Mustafa's contact information. Nor did the Government make any such argument in its post-hearing brief.[4] Accordingly, because the Government never provided notice in the charging documents that it intended to litigate the issue and makes no claim that the issue was litigated by consent, I reject the ALJ's conclusion that Mrs. Abalihi materially misled the Investigators.[5] *See Kenneth Harold Bull,* 78 FR 62666, 62674 (2013); *CBS Wholesale Distributors,* 74 FR 36746, 36749–50 (2009). That being said, the material misrepresentation of Ms. Taylor, who owned ten percent of Respondent and who was designated by Respondent's majority owner as its pharmacist-in-charge, is properly charged to Respondent and supports the denial of its application under factor five.

Moreover, even as of the date of the hearing, the Agency still does not know who will be Respondent's pharmacist-in-charge. Beyond Ms. Taylor's statement that she did not intend to leave her job at Sweetbay Pharmacy until Respondent is profitable, the evidence further showed that at the time of the hearing, Ms. Taylor had left the Tampa area and was working at a pharmacy in Orlando. RX E; Tr. 156–57. Moreover, Ms. Taylor did not testify at the hearing. Because Respondent has failed to provide material information as to who will be its pharmacist-in-charge and oversee the dispensing of the controlled substances and compliance with the Agency's various regulations, I hold that the Agency had demonstrated that granting its application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

* * * * *

In the Show Cause Order, the Government also alleged as a basis for denial of the application that ''Mrs. Abalihi's husband participated in [the] unlawful dispensing of controlled substances that were prescribed over the Internet by physicians who did not personally examine the patients'' and that ''[t]his dispensing occurred while he was a pharmacist at a pharmacy that surrendered its DEA registration in December 2007 because of these illicit dispensing practices.'' ALJ Ex. 1, at 1. The Show Cause Order further alleged that Mrs. Abalihi's husband told the Agency's Investigators ''that these dispensing practices were lawful and that he intended to apply for a DEA registration to open his own retail pharmacy.'' *Id.* at 1–2.

The parties stipulated that Mrs. Abilihi's husband, Alfred Abilihi ''is a registered pharmacist, [and] was a pharmacist at Moon Lake pharmacy who dispensed controlled substances based on unlawful internet prescriptions prior to Moon Lake Pharmacy surrendering its DEA registration on December 17th, 2007.'' Tr. 11–12. The evidence shows that on November 29, 2007, a DEA Investigator received an anonymous phone call from a pharmacist who had worked at Moon Lake for one day, GX 6C, at 1; the pharmacist alleged that ''the pharmacy was engaging in internet drug trafficking of [h]ydrocodone.'' Tr. 74. Accordingly, on December 7, two DIs went to the pharmacy, which was located in New Port Richey, and ''after several minutes of examination . . . found that the pharmacy was solely engaged in internet drug trafficking of [h]ydrocodone and some [s]chedule IV drugs such as Xanax and Valium,'' in violation of 21 CFR 1306.04(a). *Id.* at 75.

The DI further testified that after ''a few minutes of investigation,'' he and another DI ''discovered that there were two physicians,'' one located in Virginia and one located in New York City, ''who had sent . . . hundreds of prescriptions for [h]ydrocodone to Moon Lake Pharmacy for filling'' and that the purported patients were located ''throughout the 50 states of the United States.'' *Id.* at 77–78. The DI further explained that ''there was no contact between the patients and the so-called physicians'' and ''[e]verything was based on the submission of a credit card number,'' with the ''payment of several hundred dollars to a company that used [Moon Lake] to fill the prescriptions'' and that ''Moon Lake . . . was getting $75 per filled [h]ydrocodone prescription.'' *Id.* at 78.

According to the DI, the pharmacy was not open to the public and it ''was extremely small, it looked like 600 square feet'' with ''no seating area for walk-ins.'' *Id.* at 79. Also, ''[t]here was no over-the-counter merchandise'' and ''no merchandise . . . other than the controlled substances.'' *Id.* Continuing, the DI explained that ''[t]here was essentially nothing except the compounding equipment, a fax machine, a scale, the counter, [and] little else.'' *Id.*

The DI identified one Vivian Alberto as the owner of the pharmacy. *Id.* at 78. However, Ms. Alberto was not a licensed pharmacist. *Id.* Indeed, the only pharmacist the Investigators encountered at Moon Lake was Mr. Alfred Abalihi. *Id.* at 80. According to the DI, he and his partner approached Mr. Abalihi and stated that they had found ''hundreds of prescriptions being filled for people that have no contact with two physicians, one in Virginia [and] one in New York.'' *Id.* at 84. After telling Mr. Abalihi that he was ''creating these labels, [and] you know what's going on,'' the DI asked him if he thought ''it's legal that the patients are far removed from the doctors with no contact and they're getting [h]ydrocodone.'' *Id.* at 85. Mr. Abalihi replied that he did not see a problem with filling the prescriptions and that ''it was legal and . . . ethical to do so.'' *Id.* at 80. The DI further testified that while interviewing Mr. Abalihi, the latter stated that ''he would like to open up his own pharmacy.'' *Id.* at 81.[6]

Mr. Abalihi testified that he worked for Moon Lake for only ''a few days,'' before the Investigators showed up and that he had obtained the job through a temporary staffing agency. Tr. 98–99. He further maintained that he did not know that Ms. Alberto was the owner because ''she speaks only Spanish'' and he does not. *Id.* at 102. He then claimed that prior to the Investigators' inspection of Moon Lake, no one at the pharmacy had explained how the prescriptions arrived there and that he had ''no'' idea how the patients obtained the prescriptions and that a Web site was used as part of the prescribing process. *Id.* at 102–03. And when asked whether he had any recollection that there was anything wrong with the prescriptions he filled for Moon Lake, Mr. Abalihi answered: ''No, I can't recollect.'' *Id.* at 103–04.

In his testimony, Mr. Abalihi denied telling the Investigators that what he was doing was legal, as well as that he intended to open his own pharmacy. *Id.* at 104. He also claimed that the DIs ''didn't even tell me why they were there,'' although he also asserted that they told him that ''we didn't come here for you. If the pharmacy manager did what we told him to do the last time we came we wouldn't have been here.'' *Id.*

[4] For the same reason, I need not decide whether, even assuming that Ms. Abalihi lacked the intent to deceive when she told the Investigators that she would obtain Ms. Mustafa's contact information, she had a duty to correct any erroneous information she provided the Investigators upon being told by Ms. Taylor that there was no plan for Ms. Mustafa to work at Respondent.

[5] I reject ALJ Finding of Fact number 5 and Conclusion of Law number 5 only to the extent they are based on the statements of Ms. Abalihi.

[6] Six days later, Ms. Alberto voluntarily surrendered Moon Lake's DEA registration. Tr. 82. As the DI explained, he requested that Ms. Alberto surrender Moon Lakes' registration ''because everything [Ms. Alberto] was doing was criminal.'' Tr. 83.

at 100–01.[7] Yet, the evidence establishes that the DIs encountered Mr. Abalihi on their first visit to Moon Lake Pharmacy. GX 6C, at 2 (¶ 4).

On cross-examination, Mr. Abalihi repeatedly maintained that he could not remember if he had dispensed prescriptions for hydrocodone or if hydrocodone was the main drug that was being dispensed at Moon Lake. *Id.* at 110–11. Indeed, Abalihi maintained that he could not recall having looked at any of the prescriptions he filled, did not know the size of the pharmacy, and could not recall whether Moon Lake was ''set up as a typical retail pharmacy'' and was ''selling other merchandise.'' *Id.* at 112. He also maintained that he did not discuss with anybody ''how they operate[d]'' and that ''[t]he only thing is that prescriptions were filled and brought to me to check, and I checked.'' *Id.*[8] Moreover, when asked if he ''knew [that] what was going on at Moon Lake Pharmacy; that the operation was illegal with what they were doing with hydrocodone,'' Mr. Abalihi answered: ''I didn't say, sir.'' *Id.* at 120.

Mr. Abalihi also testified that he had tried to subsequently open his own pharmacy, but had withdrawn his application for a DEA registration after his then-attorney advised him that DEA intended to deny his application. *Id.* at 106. Moreover, Mr. Abalihi testified that he does not intend to work or otherwise operate Respondent and that he ''just wanted . . . to advise my wife how to do things,'' and he ''would have loved to work there, but the DEA wouldn't allow me to.'' *Id.* at 108. He further maintained that during the week, he works full time as a pharmacist at a Miami area pharmacy, and comes home to Tampa on the weekends. *Id.* at 109.

Mr. Abalihi acknowledged that his wife had filed her application after he had withdrawn his application. *Id.* at 122. When asked if he had advised his wife regarding her application, he answered: ''I'm her husband. I knew she was going to apply to open a pharmacy.'' *Id.* After testifying that he did not have an ownership interest in Respondent and was neither a director nor officer of it, Mr. Abalihi further asserted he does not ''have any hand in running'' the pharmacy. *Id.* at 123.

Likewise, Mrs. Abalihi asserted that she did not make her husband a co-owner of Respondent because he ''had tried in the past'' to ''open a pharmacy'' and was told by his counsel to withdraw his DEA application. Tr. 133. She further asserted that DEA has ''blacklisted'' her husband. *Id.* Mrs. Abalihi offered no testimony that her husband would not work at the pharmacy.

According to Respondent's Exhibit C, which is a License Verification printout from the Florida Department of Health, Mr. Abalihi has a clear and active pharmacist license in the State of Florida, and has not been subject to discipline or a public complaint. RX C, at 1. Yet the License Verification printout also lists Mr. Abalihi's address of record as 1947 W. Dr. Martin Luther King Jr. Blvd. in Tampa, Florida. *Id.* This is the same address as Respondent. *See* RX B. Moreover, the License Verification printout does not list any secondary locations for Mr. Abalihi. *Id.* at 2.

The ALJ rejected the Government's contention that Respondent's application should be denied because Mr. Abalihi's ''past negative history'' in dispensing controlled substances ''has a clear nexus'' to his wife's application. R.D. at 28–30 (citing Govt's Proposed Findings of Fact, Conclusions of Law, and Argument in Respondent to Respondent's Brief, at 10 (citing *Matthew D. Graham,* 67 FR 10229 (2002)). The ALJ rejected the Government's argument, noting that in *Graham,* the Agency had denied the application based on the misconduct of the applicant's business partner, who had previously surrendered a DEA registration for distributing large quantities of list I chemicals while having reasonable cause to believe they would be used to manufacture a controlled substance. *See id.* at 29.

The ALJ thus reasoned that *Graham* was distinguishable because ''unlike the business plan presented by Ms. Abalihi, the registrant in *Graham* was economically tied to the third party'' but ''Ms. Abalihi presented a business plan that expressly removed Mr. Abalihi from all phases of the proposed pharmacy's operation'' and he ''would not directly participate as an officer or owner of'' Respondent. *Id.* While noting that Ms. Abalihi offered no testimony that ''she would prohibit her husband from working in the pharmacy,'' the ALJ credited her statement ''that she would keep her husband 'apart from ownership and management' of the pharmacy.'' *Id.* The ALJ further reasoned that ''having considered the affidavit of Mr. Abalihi,[9] and having considered the testimony from both Mr. and Mr. [sic] Abilihi, I find sufficient credible and unrebutted evidence to conclude Mr. Abalihi does not intend to perform a significant role in the operation of'' Respondent. *Id.*

As for Mr. Abalihi's involvement at Moon Lake Pharmacy, the ALJ noted that he shared the same sense as the DIs ''that anyone in Mr. Abalihi's position would have had reason to question the legitimacy of the operation'' as well as the DIs' ''sense of incredulity that Mr. Abalihi would have failed to recognize the illegal nature of what was going on at Moon Lake, even though his stay there was brief.'' *Id.* at 29–30. After noting that Mr. Abalihi ''was not charged with any misconduct arising out of his service at Moon Lake,'' the ALJ explained that while ''Mr. Abalihi may have unwisely told the DEA investigators that Moon Lake's operations were legal . . . I cannot conclude from that piece of evidence that [he] was knowingly advancing Moon Lake's criminal enterprise when the DEA arrived.'' *Id.* at 30. Notwithstanding ''that the parties . . . stipulated that Mr. Abalihi dispensed controlled substances based on unlawful Internet prescriptions during his short tenure at Moon Lake,'' the ALJ explained that ''the most we can say for certain is that Mr. Abalihi was the pharmacist who was present when the DEA agents arrived at Moon Lake and brought its operation to an end.'' *Id.* And noting that Mr. Abalihi's record ''since then is unblemished,'' the ALJ reasoned that ''his plan to avoid direct involvement with [Respondent] adequately attenuates the link between him and the proposed pharmacy.'' *Id.*

I reject the ALJ's conclusion that Mr. Abalihi was not knowingly advancing Moon Lake's criminal enterprise when DEA arrived. Indeed, this conclusion is irreconcilable with the ALJ's finding that there is ''sufficient credible evidence to conclude Mr. Abalihi was aware that the practices[10] in this pharmacy were illegal.'' R.D. at 28. Moreover, as the ALJ found, the evidence shows that Mr. Abalihi committed criminal conduct by knowingly dispensing controlled substance prescriptions which were issued outside of the usual course of

[7] It is undisputed that Mr. Abalihi was never subjected to discipline by the Florida Board of Pharmacy.

[8] When asked on cross-examination, whether as a Florida-based pharmacist, he would not fill a prescription issued by a New York doctor for a patient who lives in Georgia, Mr. Abalihi answered:

It depends. If I see a prescription—and I call the doctor and verify that that prescription came there. I don't know if the doctor has met the patient. The onus lies on the doctor to make sure that he sees his patient, and my own is to make sure that the prescription is authentic.

Tr. 114. However, Mr. Abalihi then testified that he did not recall that he ever called and asked a physician if he/she had contact with the patient when he worked at Moon Lake. *Id.* at 114–15.

[9] Having reviewed Mr. Abalihi's affidavit, I am at a loss as to what statement it contained that the ALJ found so persuasive on this issue.

[10] While I agree with the ALJ's finding, I do not rely on the DI's assertion that the pharmacy's compounding activities were illegal.

professional practice and lacked a legitimate medical purpose. *See* 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a).

Here, in addition to the stipulation that Mr. Abalihi dispensed controlled substances based on unlawful internet prescriptions, a DI testified that upon arriving at the pharmacy and reviewing the prescriptions, he found that the prescriptions were solely for hydrocodone, a schedule III controlled substance, and drugs such as Xanax and Valium, which are schedule IV benzodiazepines. Tr. 75. Most significantly, the evidence showed that the Investigators found that hundreds of prescriptions were being filled that had been written for controlled substances by two physicians, one of whom was located in Virginia and the other New York, and that the patients were located throughout the fifty States of the U.S. *Id.* at 77–78; 84. Moreover, the pharmacy did not have an area for walk-in patients, had no over-the-counter merchandise, and indeed, sold no merchandise other than controlled substances. *Id.* at 79.

Under 21 CFR 1306.04(a), ''[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of . . . professional practice.'' Moreover, while ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* Accordingly, ''[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*[11]

As held in numerous Agency decisions, under the Controlled Substances Act, ''it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act 'in the usual course of . . . professional practice' and to issue a prescription for a 'legitimate medical purpose.' '' *See, e.g., David A. Ruben, M.D.,* 78 FR 38363, 38380 (2013) (citing *United States* v. *Moore,* 423 U.S. 122, 142–43 (1975); other citations omitted). So too, DEA has held that a physician who engages in the unauthorized practice of medicine, such as by prescribing controlled substances to patients who reside in a State where he/she is not licensed to practice, acts outside of the usual course of professional practice and therefore violates the CSA for this reason as well. *United Prescription Services,* 72 FR 50397, 50407 (2007) (''A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA.''). As the Supreme Court has explained: ''In the case of a physician, [the CSA] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice.'' *Moore,* 423 U.S. at 140–41 (emphasis added).

Thus, I reject the ALJ's portrayal of Mr. Abalihi as a hapless bystander who was in the wrong place at the wrong time when the DIs arrived at Moon Lake. To the contrary, as the ALJ found, there was ''sufficient credible evidence to conclude [that he] was aware that the practices in this pharmacy were illegal.'' R.D. at 28. Indeed, the respective locations of the two prescribing physicians and the patients, who were located through the country, made it clear to Mr. Abilihi that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a). Moreover, even if it was not immediately apparent to Mr. Abalihi that he was aiding and abetting a criminal enterprise, surely at some point during his first day at Moon Lake a reasonable pharmacist would have reached this conclusion, and in any event, Mr. Abalihi went back to the pharmacy a second day.[12]

In short, the evidence shows that Mr. Abalihi violated his corresponding responsibility and the CSA by filling prescriptions which lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. *Id.; see also* 21 U.S.C. 841(a)(1). Moreover, Mr. Abalihi's testimony makes clear that he still does not understand the scope of his obligations in dispensing controlled substances. As found above, when asked if he would not fill a prescription written by a New York physician for a patient who lives in Georgia, he testified, in essence, that if he called the doctor and the doctor verified the prescription, he wouldn't ''know if the doctor ha[d] met the patient'' and that ''[t]he onus lies on the doctor to make sure that he sees his patient.'' Tr. 114.

Not only did Mr. Abalihi offer no testimony that he had called either of the doctors whose prescriptions he filled while at Moon Lake, his understanding of the scope of his obligations under federal law has been repeatedly rejected by both this Agency and multiple United States Courts of Appeal. As the Fifth Circuit has explained, ''[v]erification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact-finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification.'' *United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979). Thus, simply calling a physician to verify a prescription is not enough because a pharmacist has ''the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows [or has reason to know] that the issuing practitioner issued it outside the scope of medical practice.'' *Id.* (quoted in *East Main Street Pharmacy,* 75 FR 66149, 66164 (2010)); *see also United States* v. *Henry,* 727 F.2d 1373, 1379 (5th Cir. 1984); *Medic-Aid Pharmacy,* 55 FR 30043,

[11] Well before Mr. Abalihi filled prescriptions for Moon Lake, several federal appeals courts had upheld the convictions of pharmacists under 21 U.S.C. 841(a)(1) for filling prescriptions which were issued over the internet by physicians, who did not practice in the same State where the patients resided, and who did not physically examine the patients, because the physician did not establish a legitimate doctor-patient relationship with the patient. *See United States* v. *Nelson,* 383 F.3d 1227, 1231–32 (10th Cir. 2004); *United States* v. *Fuchs,* 467 F.3d 889, 899–900 (5th Cir. 2006). So too, DEA had issued numerous decisions holding that both the act of prescribing over the internet, as well as the act of dispensing a prescription issued over the internet, by a physician who has either engaged in the unlicensed practice of medicine or failed to establish a legitimate doctor-patient relationship, violates 21 CFR 1306.04(a) and constitutes an unlawful distribution under 21 U.S.C. 841(a)(1). *See United Prescription Services, Inc.,* 72 FR 50397, 50407–09 (2007); *Trinity Health Care Corp., d/b/a Oviedo Discount Pharmacy,* 72 FR 30849, 30855 (2007); *EZRX, LLC,* 69 FR 63178, 63181 (2004); *see also William R. Lockridge, M.D.,* 71 FR 77791 (2006); *Marvin L. Gibbs, Jr., M.D.,* 69 FR 11658 (2004); *Rick Joe Nelson, M.D.,* 66 FR 30752 (2001).

Moreover, in 2001, DEA issued a Guidance Document warning of the potential illegality of dispensing controlled substances based on prescriptions which were obtained through the internet and telephone consultations. DEA, *Dispensing and Purchasing Controlled Substances over the Internet,* 66 FR 21181, 21182–83 (2001).

[12] The ALJ ''note[d] that Mr. Abalihi was not charged with any misconduct arising out of his service at Moon Lake.'' R.D. at 30. As has been repeatedly explained, this is totally irrelevant because there are any number of reasons why neither a prosecutor nor a state licensing body may bring charges. *See Robert L. Dougherty, M.D.,* 76 FR 16823, 16833n.13 (2013). Rather, what matters is his underlying misconduct.

30044 (1990); *Frank J. Bertolino,* 55 FR 4729, 4730 (1990).

Nor—notwithstanding that it is couched as being based on credibility findings—do I find persuasive the ALJ's conclusion that the link between Mr. Abalihi and Respondent is adequately attenuated because Mrs. Abalihi has kept her husband ''apart from [the] ownership and management of'' Respondent and Mr. Abalihi ''plan[s] to avoid direct involvement with'' the pharmacy. R.D. at 29–30. While *Graham* is undoubtedly distinguishable from this case, it does not reflect the limits of the Agency's authority to deny an application or revoke an existing registration based on the misconduct of a third party, particularly where that third party is a family relation of the applicant's principal. Indeed, in numerous cases—none of which are discussed in the Recommended Decision—the Agency has either revoked existing registrations or denied applications of pharmacies based on the closeness of the relationship between a person who diverted controlled substances or committed other serious CSA violations and another party who is either the applicant or new owner of a pharmacy.

Accordingly, the Agency has held that it ''may look to who exerts influence over the registrant'' in determining whether to deny an application or revoke a registration. *See, e.g., City Drug Co.,* 64 FR 59212, 59214 (1999). As the Agency explained in *City Drug:* ''sometimes the bonds linking the former owner to the new owner are too close to ensure that the former owner will have no influence over the operation of the pharmacy.'' *Id.* (citing *Monk's Pharmacy,* 52 FR 8988, 8989 (1987) and *Carriage Apothecary, Inc.,* 52 FR 27599, 27599 (1987)).

In *Monk's Pharmacy,* the Agency denied an application of a pharmacy, noting that the former owner, who had been convicted of a felony relating to controlled substances, had transferred ownership to his children and to a third-party, who was a registered pharmacist. 52 FR at 8988. The Agency denied the application, noting ''that the bonds linking the convicted [former pharmacy owner] with his children and the subject pharmacy are too close to permit a reasonable certainty that he will have no authoritative voice in its operation.'' *Id.* at 8989.

So too, in *Carriage Apothecary,* the pharmacy's owner, who had committed recordkeeping violations, had transferred the stock of the corporation which owned the pharmacy to his children. 52 FR at 27599. Noting that ''[t]he Administrator has long held that he can look behind a corporate façade to determine who makes the decisions concerning the controlled substance business of a pharmacy,'' the Agency revoked the pharmacy's registration, holding that while the pharmacy was now owned by the children of the former owner, neither child was a pharmacist, and the former owner ''continues to exert influence or control over [the pharmacy] through the family-held corporation.'' *Id.*

Moreover, in *Unarex of Plymouth Road, d/b/a Motor City Prescription and Unarex of Dearborn, d/b/a/Motor City Prescription Center,* 50 FR 6077 (1985), two pharmacists, who had been convicted of CSA violations (conspiracy and unlawful distribution), had transferred both their ownership interests and their respective office or directorship to their spouses. Noting that both pharmacists ''share[d] indirectly in the profits of'' the two pharmacies, the Agency revoked the registration of both pharmacies, holding that ''[i]t is appropriate that both registrations be revoked in light of this continued benefit'' received by the pharmacists.[13] *Id.* at 6079.

Lawsons & Sons Pharmacy and Fenwick Pharmacy, 48 FR 16140 (1983), involved two pharmacies whose pharmacist was convicted of unlawfully distributing controlled substances. At the time of the proceeding, the pharmacist's wife owned 100 percent of one of the pharmacies and fifty percent of the other.[14] Therein, the registrants provided an affidavit from the pharmacist's wife ''stat[ing] that she is an active and knowledgeable officer of each of the corporations and has come to understand the operation of the pharmacies,'' and that ''she ha[d] great trust in the two pharmacists she ha[d] hired to run these pharmacies and that her husband has withdrawn from [his] involvement in the pharmacies''; the registrants also provided an affidavit from one of the registrant's managing pharmacists stating that he understood that the convicted pharmacist's wife would ''discourage'' her husband ''from entering the store'' upon his release from incarceration. *Id.* at 16141. The Agency nonetheless rejected the registrants' evidence and revoked both registrations, holding that while the convicted pharmacist's wife ''has always had some administrative duties in the store, she is not a trained pharmacist and relies on the advice of the managing pharmacists at both stores. In light of [the convicted pharmacist's] past activities, the Acting Administrator cannot conclude that he will not attempt to exert some form of control over one or both of the pharmacies.'' *Id.*

Here, the totality of the circumstances leads me to reject the ALJ's conclusion that the link between Mr. Abalihi and Respondent is too attenuated to support (in addition to the other bases set forth above) the denial of the latter's application.[15] Notably, Mrs. Abalihi submitted the application only after Mr. Abalihi was informed (by his attorney) that the local DEA field office intended to deny his application and he withdrew it.[16]

Indeed, Mrs. Abalihi admitted that the reason she did not make her husband a co-owner was because of his prior failed attempt to obtain a DEA registration. Tr. 133. So too, while Mr. Alabihi was not made a shareholder of Respondent, he is married to Respondent's principal owner and would thus share, at least indirectly, in any of Respondent's profits. *See Unarex,* 50 FR at 6079. Mr. Abalihi would thus have a strong economic incentive to exercise influence over Respondent's operation.[17] *See id.*

[13] While the Administrator noted that one of the pharmacists continued to work in one of the stores, and thus declined to believe that this pharmacist ''no longer exerts influence over the operation'' of the pharmacy, no such evidence was presented as to the second store. 50 FR at 6079.

[14] The Agency's decision does not state who owned the other fifty percent of this pharmacy.

[15] The ALJ ''question[ed] whether there is a sufficient link established between Mr. Abalihi's past work at Moon Lake Pharmacy and Cove, Inc.'s proposal to operate'' Respondent. R.D. at 28; *see also id.* at 31 (''[T]he facts shown here do not establish the kind of ties that link Mr. Abalihi's past brief involvement with Moon Lake's illegal operation to the operation proposed by the Respondent here.'').

To the extent the ALJ was suggesting that to the deny the application on this basis, the Government must show that Mrs. Abalihi intended to operate Respondent as a pharmacy which filled prescriptions obtained by soliciting customers over the internet and which were issued by physicians who did not establish a valid doctor-patient relationship with the customers, the Government was not required to make such a showing. Rather, it was only required to show that Mr. Abalihi had committed violations of the CSA and that there was reason to believe that he would exert influence or control over Respondent's operation.

[16] While the Abalihis maintain that they have been ''blacklisted'' by DEA, Tr. 98 & 133; instead of withdrawing his application, Mr. Abalihi could have challenged the proposed denial of his application and would have been entitled to a hearing. *See* 21 U.S.C. 824(c). At that hearing, he could have challenged the Government's evidence as well as put forward evidence relevant to the issue of whether his registration would be consistent with the public interest. *See id.* § 823(f).

[17] While in *Graham,* there clearly was a business arrangement between the applicant and his partner (who had diverted list I chemicals), consistent with the cases discussed above, I reject the ALJ's reasoning that *Graham* is distinguishable on ground that ''unlike the business plan presented by Ms. Abalihi, the registrant in *Graham* was economically tied to the third party.'' R.D. at 29. Contrary to the ALJ's understanding, the Abalihi's marriage

Moreover, notwithstanding that Mr. Abalihi was not made a shareholder or officer, Mrs. Abalihi offered no testimony that he would not work at the pharmacy. R.D. at 29. Indeed, Respondent's own evidence shows that Mr. Abalihi listed Respondent as his address of record for his pharmacist license with the Florida Department of Health.[18] RX C. Thus, while Mr. Abalihi claimed that he had no intention of working at Respondent, he offered no explanation for the inconsistency between his testimony and his action in listing Respondent as his address of record. Moreover, given Mr. Abalihi's claim, it is strange that he signed the return receipt card, manifesting service of the Show Cause Order, which was mailed to Respondent at its physical location of 1947 W. Dr. Martin Luther King Blvd. *See* GX 1, at 2. Thus, while the ALJ found credible Mr. Abalihi's testimony that he did not intend to work at Respondent, the ALJ never reconciled his finding with this evidence.

Finally, Ms. Taylor, who Mrs. Abalihi represented as being Respondent's pharmacist-in-charge, told the DIs that she did not intend to leave her then-position at Sweetbay Pharmacy until Respondent was profitable. Moreover, when questioned as to who would be the pharmacist during the interim period, Ms. Taylor gave the name of a person she had never asked. Ms. Taylor, who has since taken a position in Orlando, did not testify in the proceeding, and while she did submit an affidavit, the affidavit contains no statement that she still intends to become Respondent's pharmacist-in-charge. Indeed, Mrs. Abalihi still has not disclosed who will be Respondent's pharmacist-in-charge.[19] The evidence thus suggests that the plan all along was for Mr. Abalihi to be Respondent's pharmacist-in-charge.

Accordingly, based on the record as a whole, I reject the ALJ's conclusion that the links between the applicant and Mr. Abalihi are sufficiently attenuated to conclude that he will exercise no influence or control over Respondent.[20] I further conclude that the record supports a finding that Mrs. Abalihi submitted the application as part of a ruse to obtain a registration after her husband withdrew his application. This finding provides additional reason to reject the application.[21]

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Cove, Incorporated, doing business as Allwell Pharmacy, for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. This order is effective immediately.

Dated: May 11, 2015.

Michele M. Leonhart,

Administrator.

Brian Bayly, Esq., for the Government
Daniel G. Musca, Esq., and *Brian C. Chase, Esq.,* for the Respondent

establishes that Mr. and Mrs. Abalihi are economically tied. *Cf. Califano* v. *Jobst,* 434 U.S. 47, 54 (1977) (''Both tradition and common experience support the conclusion that marriage is an event which normally marks an important change in economic status.''); *Women Involved in Farm Economics* v. *USDA,* 876 F.2d 994, 1005 (D.C. Cir. 1989) (noting with approval the assumption that ''whatever their roles, married men and women constitute one economic unit'').

While I conclude that Mrs. Abalihi submitted the pending application as part of a ruse by the Abalihis to obtain a registration after Mr. Abalihi withdrew his application, and that the Abalihis planned all along for Mr. Abalihi to be Respondent's pharmacist-in-charge, contrary to the ALJ's understanding, the Agency's case law does not require that the Government prove that Mr. Abalihi ''intend[ed] to perform a significant role in the operation of'' Respondent. R.D. at 29.

[18] Mr. Abalihi also testified that he was working full time at a pharmacy in Miami. Tr. 109. Yet he did not list this pharmacy as either his address of record or as a secondary location with the Florida Department of Health, *see* RX C, and I find it implausible that he would continue working full time in Miami if Respondent obtained a registration given the expense of hiring a pharmacist.

[19] Notwithstanding that many of the Agency cases have involved pharmacies whose prior owners were convicted of criminal offenses, a criminal conviction of either the pharmacy or its pharmacist/owner is not required to sustain the denial of an application or the revocation of a registration. For example, in *Carriage Apothecary,* the pharmacy and pharmacist were not convicted of any offense but agreed to pay a civil penalty. 52 FR at 27599.

[20] I therefore reject the ALJ's finding of fact number seven. *See* R.D. at 34. I also reject the ALJ's conclusion of law number four. *See id.* at 35–36.

[21] In one of Respondent's filings, it asserts that its case is ''most analogous'' to the Agency's decision in *Terese, Inc., D/B/A Peach Orchard Drugs,* 76 FR 46843 (2011). It's not. In *Terese,* the Government sought the revocation of the registration of a pharmacy, which was owned by the wife of a pharmacist, who along with his pharmacy, had been convicted of health care fraud and required to surrender his DEA registration as part of his sentence. While the Government argued that the pharmacy was simply the alter ego of a previous pharmacy, which had been subject to mandatory exclusion from federal health care programs by virtue of its conviction, *see* 21 U.S.C. 824(a)(5) and 42 U.S.C. 1320a–7(a), I noted that the respondent was not subject to mandatory exclusion but rather only permissive exclusion, and that Congress had not granted the Agency authority to revoke a registration on the latter basis. 76 FR at 46846–48.

While the Government also alleged that the former pharmacy and its pharmacist had diverted controlled substances, I rejected the allegation for lack of substantial evidence. *Id.* at 46846 & n.9. However, I also explained that ''had the evidence established that [the owner's husband or the former pharmacy had] violated the CSA or state controlled substance laws, the Agency case law on piercing the corporate veil would authorize the revocation of [the] [r]espondent's registration.'' *Id.*

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

Nature of the Proceeding

Christopher B. McNeil, Administrative Law Judge. On March 3, 2011, Ogechi E. Abalihi submitted a request on behalf of Cove, Inc., seeking a new retail pharmacy DEA Certificate of Registration, allowing it to dispense controlled substances through a business that would be known as Allwell Pharmacy in Tampa, Florida. On July 26, 2011, finding cause to believe this registration would be inconsistent with the public interest, the Drug Enforcement Administrator, through the Deputy Assistant Administrator, issued an order to show cause why the Administrator should not deny the application. In response, on August 22, 2011, the Respondent requested an extension of the time permitted to file a response, which was granted by DEA Administrative Law Judge Timothy J. Wing. Judge Wing thereafter received what he found to be a waiver of Cove, Inc.'s right to a hearing on the matter and terminated the administrative review Cove had requested.

In her review of the record, the Administrator concluded there were factual disputes that warranted further development and remanded the matter to the Office of Administrative Law Judges, with instructions to permit the parties to present evidence at a hearing to be conducted in Tampa, Florida. At this point, Judge Wing was no longer with the DEA Office of Administrative Law Judges, so Administrative Law Judge Gail Randall issued an order for prehearing statements. On December 3, 2012, prior to the submission of prehearing statements, Chief Administrative Law Judge John J. Mulrooney II reassigned the case from ALJ Randall to the undersigned, and I presided over an evidentiary hearing conducted in Tampa, Florida, on February 13, 2013.

Issue

The general issue to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes, by substantial evidence, that Cove, Inc.'s application for a Certificate of Registration with the DEA should be denied as inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f).

The issue arose after DEA investigators completed an evaluation of the evidence supporting Cove, Inc.'s application. In this evaluation, investigators learned that the 90 percent owner of Cove, Inc., Ogechi Abalihi, R.N., had no experience as a pharmacist and limited knowledge about DEA regulations pertaining to the retail distribution of controlled substances. Investigators also found that the ten percent owner of Cove, Inc., pharmacist Jacinta Taylor, was not planning on being present at the pharmacy until after it became profitable. The investigators noted that Ms. Taylor gave them conflicting information regarding who would serve as Allwell's pharmacist up to the time when Ms. Taylor would participate in the operation of the pharmacy. Investigators also

were concerned that Ms. Abalihi's husband, Alfred Abalihi, R. Ph., although not a Cove, Inc. shareholder or manager of Allwell, had been associated with a different pharmacy that had been compelled to surrender its DEA Certificate in 2007 due to illegal dispensing operations.

Based on the information presented to them in the course of Cove, Inc.'s application, the Diversion Investigators concluded that granting Cove, Inc. a Certificate of Registration would be inconsistent with the public interest, prompting the show cause order that would deny this application. The specific issue thus is whether by at least a preponderance of the evidence the Government has established that granting a DEA Certificate of Registration to Cove, Inc. would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f)

After carefully considering the testimony elicited at the hearing, examining the admitted exhibits, evaluating the arguments of counsel, and weighing the record as a whole, I have set forth my recommended findings of fact, conclusions of law, and analysis below, recommending that the DEA deny Cove, Inc.'s Application for a Certificate of Registration.

Evidence

Allwell Pharmacy's proposed DEA-registered location is 1947 W. Dr. Martin Luther King, Jr. Blvd., Tampa, Florida 33609. The proposed DEA-registered location is not open for business or operating at this time as a pharmacy or other commercial business, but the pharmacy is licensed as a retail pharmacy in the State of Florida and retains a Florida community pharmacy license. Allwell Pharmacy's owner is Cove, Inc., and the corporation has two shareholders: Ogechi E. Abalihi, who owns 90 percent of the company, and Jacinta Taylor, who owns ten percent.[1]

Ms. Abalihi has no experience either as a pharmacist or owning a retail pharmacy, but she does have extensive experience as a Registered Nurse licensed as such since 2001, and throughout such period has worked with controlled substances. Jacinta Taylor has extensive experience working as a Florida-licensed pharmacist, working as a pharmacist and dispensing controlled substances.[2]

Testimony from the DEA Diversion Investigators

Kenneth Boggess has been a Diversion Investigator for the DEA for 26 years.[3] He graduated from the Federal Law Enforcement Training Center in 1980 and from the FBI Academy in 1986.[4] In this course of study, he has become familiar with sections of the Code of Federal Regulations, with the identification of controlled substances, and with the means and processes of illegally diverting controlled substances.[5] Throughout his tenure as a DEA Diversion Investigator, Mr. Boggess has participated in continuing education courses and has participated in numerous investigations, including those pertaining to pharmacies.[6]

Investigator Boggess explained that he was involved in evaluating the application submitted by Cove, Inc., the Respondent in this matter.[7] Part of that evaluation included meeting with one of Cove, Inc.'s two owners, Ogechi Abalihi.[8] He said his first meeting with Ms. Abalihi took place on March 22, 2011, at the DEA's Tampa office, and that DEA Diversion Investigator Ira Wald also attended this meeting.[9]

According to Investigator Boggess, Ms. Abalihi obtained her nursing degree in Lagos, Nigeria, and moved to New York in 1992.[10] He said that upon arriving in New York, Ms. Abalihi worked for a health care corporation, moving to Tampa in the early 2000s, where she began working with the Veterans Administration as a part-time nurse.[11]

As part of the application investigation, Investigator Boggess said he questioned Ms. Abalihi about her plan to manage the proposed pharmacy. He said when he asked Ms. Abalihi who would actually manage Allwell Pharmacy, she told him it would be managed by the other co-owner, Jacinta Taylor.[12] According to Investigator Boggess, Ms. Abalihi is the 90 percent owner of Cove, Inc., and Ms. Taylor is the ten percent owner.[13] Investigator Boggess said he questioned Ms. Abalihi about the business relationship between her and Ms. Taylor, and was told she met Ms. Taylor in 2010, in the course of treatment in a therapist's office.[14]

During the interview conducted on March 22, 2011, Investigator Boggess questioned Ms. Abalihi about how the proposed pharmacy would maintain its records and maintain compliance with DEA regulations concerning the dispensing of controlled substances.[15] When asked, on cross examination, whether this kind of questioning was part of his ''standard operating procedure,'' Investigator Boggess said yes, adding that Tampa ''has significant problems with applicants here, and the Internet problems and this oxycodone problem.'' [16] He explained that the questions he uses when evaluating an applicant have been generated through suggestions from DEA headquarters and from the experiences of DEA officers in Tampa, but that these questions are not published for public consumption.[17] There was, however, some indication, according to Investigator Boggess, that word of the kind of questions being asked in these applications is getting around, such that the applicants ''have a good idea what we're going to ask.'' [18]

Investigator Boggess explained that when he questions an applicant about the applicant's knowledge of DEA regulations, he ends the inquiry if it is clear the person knows nothing about those regulations, because ''there's no point in badgering someone.'' [19] That appears to have been the case here, during his interview with Ms. Abalihi. He described his questions as being ''simple,'' and gave as an example: ''How do you plan on maintaining your invoices?'' [20] Investigator Boggess said in response to the questions he posed regarding DEA regulations, Ms. Abalihi deferred all questions about controlled substances and about the security of those substances to Ms. Taylor, electing not to answer them herself.[21] When asked who would be responsible for ordering controlled substances being dispensed in the pharmacy, Ms. Abalihi told Investigator Boggess that she intended to give Ms. Taylor power of attorney, and they would use either Harvard Drug or Cardinal as their wholesale supplier.[22]

The following week, Investigator Boggess contacted Jacinta Taylor and met with her on March 30, 2011 at the DEA office in Tampa, along with Investigator Wald.[23] Investigator Boggess said after confirming her identity and her credentials as a pharmacist, he inquired about the proposed business operation.[24] He said Ms. Taylor confirmed that she met Ms. Abalihi ''socially at some type of therapy session'' in 2010.[25] He testified that Ms. Taylor initially told him she would be the pharmacist in charge of the pharmacy when it opened, and that she expected to be the person who would order controlled substances, most likely using Great Lakes Harvard Drug as the pharmacy's supplier.[26] She told him the pharmacy would be operating from 9:00 a.m. until 6:00 p.m., Mondays through Fridays, and from 9:00 a.m. until 1 p.m. on Saturdays, and would be closed on Sundays.[27]

When Investigator Boggess considered these operating hours, he asked Ms. Taylor about her current employment and the hours she was on duty with that job, as a pharmacist at Sweetbay. According to Investigator Boggess, Ms. Taylor then acknowledged working at Sweetbay on a full-time basis, with hours from 10:00 a.m. until 8:00 p.m.[28] When this scheduling conflict was brought to Ms. Taylor's attention, Investigator Boggess said Ms. Taylor amended her previous answer: rather than stating she would be the pharmacist in charge of the pharmacy when it opened, she told him that she would leave her job at Sweetbay ''if and when Allwell started to make money.''[29] Investigator Boggess pursued this inquiry, asking Ms. Taylor who would be Allwell's pharmacist in charge in the meantime. In response, Ms. Taylor told

[1] Tr. at 10–11.
[2] *Id.*
[3] Tr. at 30.
[4] *Id.*
[5] *Id.* at 32.
[6] *Id.* at 31.
[7] *Id.* at 32.
[8] *Id.*
[9] *Id.* at –32–33.
[10] *Id.* at 33.
[11] *Id.* at 33–34.
[12] *Id.* at 34.
[13] *Id.* at 36.
[14] *Id.* at 34.
[15] *Id.* at 35.
[16] *Id.* at 60.
[17] *Id.*
[18] *Id.* at 61.
[19] *Id.* at 64.
[20] *Id.*
[21] *Id.* at 36.
[22] *Id.*
[23] *Id.* at 37.
[24] *Id.* at 37–38.
[25] *Id.* at 38.
[26] *Id.*
[27] *Id.* at 38–39.
[28] *Id.* at 39.
[29] *Id.* at 40.

him the interim pharmacist in charge would be a coworker of hers, Dalya Mustafa.[30]

When he learned that Ms. Taylor intended to use Ms. Mustafa as the interim pharmacist in charge of the applicant pharmacy, Investigator Boggess told Ms. Taylor he would need to interview Ms. Mustafa, given the significant role Ms. Mustafa would be playing with the new pharmacy.[31] According to Investigator Boggess, at this point in the interview Ms. Taylor ''stuttered and said, 'Well, perhaps [Ms. Mustafa] won't work there.''' [32] At the conclusion of this interview, Investigator Boggess called Ms. Abalihi and asked if she would provide contact information so that he could call Ms. Mustafa and confirm the role she would be playing in the proposed pharmacy.[33] According to Investigator Boggess, Ms. Abalihi talked with Investigator Boggess on either the 30th or 31st of March 2011, and told him she would contact Ms. Mustafa and either have her call him or provide him with her phone number. Investigator Boggess said that despite this, Ms. Mustafa never contacted him and he heard nothing further from Ms. Abalihi regarding Ms. Mustafa.[34]

In addition to inquiring of Ms. Abalihi how Cove, Inc. would ensure compliance with DEA controlled substance regulations, Investigator Boggess said he and Investigator Wald were also concerned about the role Alfred Abalihi—Ms. Abalihi's husband—would play in the new pharmacy. Here, both Investigator Wald and Investigator Boggess described an investigation their office conducted four years earlier, involving Moon Lake Pharmacy. According to Investigator Boggess, during the initial interview on March 22, 2011 Investigator Wald told Ms. Abalihi that he had conducted an inspection of Moon Lake Pharmacy back in 2007, and that during this inspection Mr. Abalihi was the pharmacist on duty.[35] Investigator Boggess said that the inspection of Moon Lake had been prompted by information indicating it was illegally distributing controlled substances over the Internet.[36] Investigator Boggess said that during the inspection of Moon Lake, Mr. Abalihi told Investigator Wald that, while he knew nothing about the owner or operator of the pharmacy and was only working on a short-term contractual basis through his employer, HealthCare Consultants, he believed there was nothing illegal about what Moon Lake was doing and added that ''he himself . . . wouldn't mind opening a pharmacy'' of his own.[37]

The record reflects that Moon Lake surrendered its DEA Certificate of Registration shortly after this inspection, based on the investigators' charge that the operation was illegal. The record also shows that Mr. Abalihi was then dispatched to serve as a temporary pharmacist at numerous other locations, as an employee of HealthCare Consultants, all without incident or disciplinary action.

Investigator Boggess testified that at the conclusion of the investigation into Cove, Inc.'s application for DEA registration, DEA's Diversion Group Supervisor, Roberta Goralczyk determined that the application should be denied.[38] He said he then spoke to both Ms. Abalihi and Ms. Taylor, and learned that Ms. Taylor wished to withdraw the application but that Ms. Abalihi would not drop the request for the DEA Certificate.[39] Investigator Boggess told Ms. Taylor, however, that as she was not the actual applicant, she could not withdraw the application.[40] He said that after this discussion, both Ms. Taylor and Ms. Abalihi spoke with him at the end of March, 2011 and asked for a list of the DEA's objections, indicating that they both wished to have the application go forward.[41]

Investigator Boggess testified that as of January 2013, when he last drove past Allwell's proposed location, the pharmacy had not opened.[42] He added that five other pharmacies were operating within a few hundred yards of the proposed location, all in close proximity to St. Joseph's Hospital.[43] He said he recently visited these pharmacies, and confirmed they all held DEA Certificates allowing them to dispense controlled substances.[44] Through this testimony, Investigator Boggess established there is an ongoing concern by pharmacists regarding the proliferation of pain medication prescriptions, particularly regarding OxyContin 15 and 30 mg. tablets.[45] On cross examination, Investigator Boggess confirmed that it is common for health care professionals and pharmacies to cluster around a hospital.[46] He also confirmed that there is no evidence to suggest St. Joseph's Hospital is a ''pill mill hospital,'' nor did he believe there was evidence to suggest any of the pharmacies constituted problems for the DEA with respect to their dispensation practices.[47]

During his visit to David's Pharmacy on January 18, 2013, Investigator Boggess observed a sign on the divider between the pharmacy and the patients indicating that the pharmacy would not dispense oxycodone 15 or 30 mg. tablets.[48] He said he spoke with the owner, pharmacist David Cataya, and to Mr. Cataya's wife, Carmen, about concerns the pharmacist had regarding the dispensing of controlled substances in this neighborhood.[49] He learned the pharmacist saw the trend for oxycodone had gone down, but that demand for hydromorphone (Dilaudid) had gone up such that it was now the drug of choice of drug seekers in their neighborhood.[50] As a result, the pharmacist preferred to fill controlled substance prescriptions only for those individuals who could prove they lived in the neighborhood and who were his established customers.[51]

Investigator Boggess described making similar trips to and receiving similar input from four other nearby pharmacies, including Hillsborough River Compounding Pharmacy, run by Mr. Uba, Care Plus Pharmacy run by Mr. Bakari, CVS Pharmacy, run by Mr. Alicea, and Walgreens Pharmacy, run by Mr. Luu. In these interviews, Investigator Boggess learned that the nearby hospital did not generate many prescriptions for controlled substances.[52] He also learned that while some of those he interviewed felt there was a high demand for oxycodone, not all found there to be a shortage.[53] Mr. Alicea reported attempts by drug seeking customers to seek out oxycodone and to attempt to learn the price charged for the drug, prompting Mr. Alicea to refuse to fill prescriptions for more than 100 dosage units of the drug, and to post a sign in the pharmacy stating ''No Oxycodone,'' in large print on an 8 by 11 sheet of paper at the pharmacy counter.[54] At the Walgreens Pharmacy, Mr. Luu reported there was a high demand for oxycodone, and that he would not fill prescriptions for Schedule II medications.[55]

When asked on cross examination why he waited until 2013 to conduct these interviews with the nearby pharmacies, Investigator Boggess agreed that ''the two-year delay is a good question, period, for this whole process,'' but that he was working with 30 other applications at the time and the interviews were done when he ''finally got around to [them]''.[56] He added, however, that there is no regulation that requires his office to avoid saturation of a market when evaluating an application for a pharmacy.[57] He specifically denied any practice of denying an application based on over-saturation in the Tampa Bay area.[58]

DEA Diversion Investigator Ira Wald also testified. He stated he has been a Division Investigator for 38 years, having been hired in 1975 and having completed several months of initial training in DEA auditing techniques, legal procedure, and investigative techniques, with periodic refresher courses.[59] Mr. Wald stated that from this course of study, and based on his experience in investigating the application of pharmacies seeking DEA certification, he is familiar with the Code of Federal Regulations pertaining to the distribution and dispensing of controlled substances.[60]

With respect to his concerns about the role Mr. Abalihi might play in the operation of Allwell Pharmacy, Investigator Wald testified that in 2007, after receiving an anonymous call about Moon Lake Pharmacy, he visited

[30] *Id.*
[31] *Id.* at 41.
[32] *Id.*
[33] *Id.* at 41.
[34] *Id.* at 42.
[35] *Id.* at 35.
[36] *Id.* at 35.
[37] *Id.*
[38] *Id.* at 43.
[39] *Id.*
[40] *Id.* at 44.
[41] *Id.*
[42] *Id.* at 45.
[43] *Id.*
[44] *Id.* at 45–46.
[45] *Id.* at 47–59.
[46] *Id.* at 65.
[47] *Id.* at 66–67.
[48] *Id.* at 47.
[49] *Id.* at 48.
[50] *Id.*
[51] *Id.* at 50.
[52] *Id.* at 49, 51.
[53] *Id.* at 51–55.
[54] *Id.* at 56.
[55] *Id.* at 59.
[56] *Id.* at 68.
[57] *Id.* at 69.
[58] *Id.* at 70.
[59] *Id.* at 72–3.
[60] *Id.* at 73–4.

the pharmacy at its location in New Port Richey, Florida.[61] Investigator Wald said that after determining that the pharmacy was engaged in Internet trafficking of hydrocodone, Xanax, and Valium, and after determining there were violations of compounding regulations, Investigator Wald questioned the pharmacist present at the time of this visit—Alfred C. Abalihi, who is Ms. Abalihi's husband.[62]

According to Investigator Wald, the pharmacy was small—about 600 square feet in size—and it did not appear it was open to the public, but was instead a compounding site.[63] Investigator Wald said the compounding room had thousands of hydrocodone capsules in a transparent two-gallon jug, along with 100 grams of pure hydrocodone powder.[64] According to Investigator Wald, this type of storage was a violation because ''compounding by definition requires that the compounder, the pharmacist, make up the prescription[s] one at a time pursuant to need, not thousands beforehand pursuant to projected sales possibilities.'' [65] According to Investigator Wald, when questioned about this operation, Mr. Abalihi stated he ''saw no problem with it,'' and stated ''it was legal and proper, ethical to do so''.[66] Mr. Abalihi added that ''he would like to open up his own pharmacy.'' [67]

When asked during cross examination about Moon Lake's compounding methods, Investigator Wald stated he did not know if compounding in advance based on anticipated need was permitted under Florida law, but knew that federal law forbids advanced compounding absent registration as a manufacturer.[68] Investigator Wald also acknowledged that upon his initial visit to Moon Lake Pharmacy, he did not see Mr. Abalihi actually compounding drugs, and from his review of the pharmacy records he did not see Mr. Abalihi listed as either the prescription department manager or as an officer or director of the pharmacy.[69]

Investigator Wald explained that after meeting with Mr. Abalihi at Moon Lake Pharmacy he arranged to meet with the pharmacy's owner, Vivian Alberto.[70] During this meeting and a meeting that followed shortly thereafter, Investigator Wald requested and received the surrender of the pharmacy's DEA registration, putting the pharmacy out of business ''because everything [Ms. Alberto] was doing was criminal.'' [71]

Moon Lake Pharmacy surrendered its former DEA registration number, FM0523870, on or about December 17, 2007, because the pharmacy dispensed controlled substances based on illegal Internet prescriptions. The parties have stipulated that Mr. Abalihi was a pharmacist at Moon Lake who dispensed controlled substances based on unlawful Internet prescriptions.[72] The parties also have stipulated that Mr. Abalihi was never an owner, officer, pharmacist-in-charge, or prescription department manager of Moon Lake Pharmacy.[73]

Regarding the initial investigation into Cove, Inc.'s application for a DEA Certificate of Registration for Allwell Pharmacy, Investigator Wald confirmed the testimony of Investigator Boggess regarding standard procedures in these investigations. He said it is normal for his office to quiz new DEA applications on their familiarity with DEA regulations.[74] Further, he said his office requires the applicants to meet with the investigators, to describe their operations, their backgrounds, and their professional expertise in operating a pharmacy—this because of the ''many criminal violations coming from retail pharmacies.'' [75]

Investigator Wald confirmed the salient points addressed by Investigator Boggess. He recalled that during the initial interviews with Ms. Abalihi and Ms. Taylor, he and Investigator Boggess asked about the ownership of Cove, Inc., and about Ms. Abalihi's training, education, and experience with pharmacies in the past, and about how much of her attention she was going to devote to the pharmacy.[76] The record reflects that under her proposed business plan, Ms. Abalihi would operate the retail pharmacy herself, along with a co-owner who is a registered pharmacist and who would be responsible for dispensing controlled substances. He also confirmed Investigator Boggess's observation that St. Joseph's Hospital, which is near the location of the proposed Allwell Pharmacy, is not currently regarded as a ''pill mill,'' and that while it does generate prescriptions for controlled substances, it does not dispense them—patients who are treated at the hospital but who are not actually admitted to the hospital will, for the most part, fill their prescriptions off-site.[77]

Testimony in Support of the Application

Testifying in support of Cove, Inc.'s application, Ogechi E. Abalihi stated that she has a diploma of Nursing from Lagos University Teaching Hospital as well as a diploma in Midwifery from University College Hospital. Ms. Abalihi obtained both degrees in Nigeria, where she worked between 1988 and 1992 as a Registered Nurse.[78] In addition, Ms. Abalihi has a Bachelor's Degree from City College New York, and in 2012 earned a Master's Degree in Nursing from the University of South Florida.[79] She explained that courses in the Master's program included pharmacology and advanced pharmacology, which covered the legalities of prescribing controlled substances in Florida.[80]

After moving from Nigeria to New York in 1992, Ms. Abalihi worked with the Health and Hospitals Corporation in Harlem Hospital for about ten years: [81] ''As a Registered Nurse, I worked in orthopedics, massage, I did a little bit of psychiatric nursing, I worked in [the] intensive care unit.'' [82] Ms. Abalihi said she had the knowledge and education associated with the professional standards of service as a Registered Nurse, including knowledge of medication inventorying, dispensing, and safekeeping.[83]

Ms. Abalihi said she moved to Tampa in 2001, working both at the Veterans Administration Hospital there and operating a group home, between 2007 and 2010, as the home's Director of Nursing.[84] She said in this capacity she was involved with patients who had prescriptions for controlled substances, so she was responsible for inventory, dispensing, and safe handling of the drugs.[85] She currently works as a Registered Nurse at the Veterans Administration Hospital, in the hospital's critical care unit.[86] She described this as full-time work in the intensive care unit, the cardiac unit, and the surgical unit, where she is required to make sure prescription doses are correct, and has to understand medication side effects, ''how it's going to impact my patient, and how much this patient can get at a particular time. Basically, standard nursing procedures for dispensing [and] safety [ ] of controlled substances.'' [87]

Ms. Abalihi testified that through her work as a nurse and through her formal education, she has been trained in dispensing controlled substances: ''I inventory controlled substances as a Registered Nurse, and I have knowledge of safekeeping processes with relationship to [the] nursing profession.'' [88] This experience, she said, includes ''knowledge of inventory, safety of controlled drugs [,] and dispensing.'' [89] She said she has held a nursing license from New York for over ten years, and has held her Florida license since 2001, and has never been disciplined by any governmental entity nor convicted of any crime.[90]

Ms. Abalihi said she applied for a DEA Certificate of Registration in early 2011 so that Cove, Inc. could operate Allwell Pharmacy.[91] She acknowledged she never has owned a retail pharmacy, has never worked in a pharmacy, and is not a licensed pharmacist, and as such she would not be dispensing controlled substances.[92] She said the plan was to operate a standard retail community pharmacy with a co-owner who

[61] *Id.* at 75.
[62] *Id.* at 79.
[63] *Id.*
[64] *Id.* at 76.
[65] *Id.*
[66] *Id.* at 80.
[67] *Id.* at 81.
[68] *Id.* at 86.
[69] *Id.* at 88.
[70] *Id.* at 82.
[71] *Id.* at 83.
[72] *Id.* at 11–12.
[73] *Id.*
[74] *Id.* at 89.
[75] *Id.* at 89.
[76] *Id.* at 91.
[77] *Id.* at 92, 95.
[78] *Id.* at 125–6.
[79] *Id.* at 125.
[80] *Id.* at 128.
[81] *Id.* at 126–7.
[82] *Id.* at 127.
[83] *Id.*
[84] *Id.*
[85] *Id.* at 127–28.
[86] *Id.* at 125, 128.
[87] *Id.* at 133.
[88] *Id.* at 125.
[89] *Id.* at 126.
[90] *Id.* at 140.
[91] *Id.* at 129.
[92] *Id.* at 141, 143.

was a pharmacist, and to serve as a supplier of drugs to assisted living facilities.[93] She explained that she had recently operated a group home, which she stated is ''kind of assisted living,'' and believed she could serve this kind of population.[94] She said she had no trouble obtaining a Florida state license to operate the pharmacy, and applied for a DEA Certificate of Registration shortly after obtaining a state license.[95]

According to Ms. Abalihi, she and Jacinta Taylor own Cove, Inc., with Ms. Taylor owning ten percent and Ms. Abalihi owning 90 percent. Ms. Abalihi is the sole officer and director.[96] Ms. Taylor is a pharmacist licensed in Florida. Ms. Abalihi met Ms. Taylor socially, as both have children in the autism spectrum and met each other while taking their children to autism therapy.[97]

Ms. Abalihi testified that when she was invited to the DEA to discuss her application, Investigator Wald referred to her husband, and told her ''there were issues'' with a pharmacy he had worked at.[98] Ms. Abalihi said she told Investigator Wald ''[w]ell, I don't know about that. I'm just doing this on my own.'' [99] She testified that she told the investigators that Mr. Abalihi would not have anything to do with Allwell Pharmacy, and that she was ''engaging the services of Jacinta Taylor, who is a licensed pharmacist, to be the one—the pharmacy manager or the prescriptions department manager, whichever one is being referred to.'' [100] She told the investigators that Mr. Abalihi had been ''blacklisted'' from owning or operating a pharmacy.[101]

Ms. Abalihi said that at the conclusion of the interview, Investigator Boggess asked when she planned to open the pharmacy, and offered to provide whatever help she needed, leaving her assured that she ''had a good interview.'' [102] She added, however, that she was never told that she needed to study anything about regulations pertaining to the DEA, so ''whatever questions they asked me, I answer[ed] to the best of my knowledge. The ones I could not answer I refer[red] them to my prescription manager, you know those things that I knew I didn't know anything about, for her to answer [.]'' [103]

By her own account, Ms. Abalihi recognized that she lacked the experience needed to operate a pharmacy if the pharmacy dispensed controlled substances. Recognizing this limitation, Ms. Abalihi testified that she would address this by engaging the services of a registered pharmacist to assist in the daily operation of the store. Ms. Abalihi said her familiarity and experience with controlled substances is based wholly on ''nursing professional standards''. When asked on cross-examination whether she was ''familiar with the record-keeping requirements for controlled substances for a retail pharmacy,'' she did not answer the question directly, but stated only ''[a]gain, like I said, in terms of controlled substances my experience is with nursing.'' [104] When asked about controlled substance regulations concerning biannual inventories, or concerning the different physical security requirements applicable to Schedule II controlled substances (in contrast with those applicable to Schedules III through V), Ms. Abalihi again would not answer the questions, but said questions and issues like these would have to be addressed by a pharmacist working at Allwell.[105] When asked what percentage of prescriptions she anticipated would be for controlled substances, Ms. Abalihi responded by saying that if anyone could answer that question, it would be the pharmacy manager, not herself.[106]

Ms. Abalihi described the arrangement she entered into with the prospective pharmacist, Ms. Taylor. She agreed, during cross examination, that Allwell would have to completely rely on the pharmacist working there in order to ensure compliance with DEA controlled substances regulations.[107]

Ms. Abalihi testified that the business plan for Allwell was to have it open and operational from 9:00 a.m. until 6:00 p.m. Monday through Friday, and from 9:00 a.m. to 1 p.m. on Saturdays, with the pharmacy closed on Sundays.[108] She acknowledged that when they were interviewed by the DEA investigators, Ms. Taylor was working at Sweetbay as a pharmacist, but stated that Ms. Taylor would come to work at Allwell as soon as Ms. Abalihi got the required license.[109]

Ms. Abalihi acknowledged that presently, Ms. Taylor works full time as a pharmacist in Orlando, having moved from Tampa sometime after this application was filed.[110] When asked whether she knew if Ms. Taylor was planning on moving back to Tampa if Cove, Inc. gets the Certificate it seeks for Allwell, Ms. Abalihi stated ''We can't say for sure until this whole thing is over. I mean I don't expect her to, you know, just not do something with her life with this whole thing—I mean this whole thing has to be over for her to—that is my perception, for her to make a decision what she wants to do.'' [111] She added that despite what Ms. Taylor told Investigator Boggess about the plan to use Ms. Mustafa as a second pharmacist, Ms. Abalihi did not know Ms. Mustafa, had never met her, and had never spoken with her.[112] She offered no explanation for telling the DEA investigators that she would either provide them with Ms. Mustafa's contact information or have Ms. Mustafa contact them—actions which indicate that she was complicit in Ms. Taylor's prevarication regarding the purported plan to use Ms. Mustafa when Allwell began its operation.

When pressed to explain this, Ms. Abalihi denied knowing Ms. Mustafa, denied ever speaking to Ms. Mustafa, and denied that Ms. Taylor said she would be relying on Ms. Mustafa. According to Ms. Abalihi, ''[Ms. Taylor] did not say she would be relying on Ms. Mustafa, no. She said the name came to her when this question was thrown to her. She wasn't expecting it, but the name came to her.'' [113] When asked, however, whether there was a plan in effect to actually have Ms. Mustafa work at the pharmacy, Ms. Abalihi said ''not exactly. Jacinta Taylor mentioned her after—you know, after her interview with the DEA she mentioned her to me as a possibility of coverage for her. And I know very well that you can actually get coverage. And I know very well that you can actually get coverage.'' [114]

I am thus presented with two significantly different versions of what was said when Diversion Investigators Boggess and Wald questioned Ms. Abalihi and Ms. Taylor. The Diversion Investigators testified that Ms. Taylor indicated she would leave her job at Sweetwater and join the operation of Allwell only when it started to become profitable—not at its inception. Both investigators testified that Ms. Taylor initially told them she would have a coworker, Ms. Mustafa, serve as the pharmacy's pharmacist between the time it began its operation and the time when Ms. Taylor joined the store as its pharmacist. Investigator Boggess testified that in furtherance of this representation, Ms. Abalihi committed to providing him with Ms. Mustafa's contact information—a commitment Ms. Abalihi now denies ever making.

Because the two Diversion Investigators' testimony is internally consistent, is consistent with the evidence as a whole, is consistent with a common sense understanding of the events being described, and does not appear to be tainted with bias or a motivation to prevaricate, and because I do not find other indicia of unreliability, I give substantial weight to the statements of Investigators Boggess and Wald regarding this exchange.

Further, because I find Ms. Abalihi's testimony to be internally contradictory, inconsistent with the evidence as a whole, and inconsistent with that of Ms. Taylor's statements to the investigators and her averments in the affidavit introduced as evidence, and because I find Ms. Abalihi and Ms. Taylor both had a financial interest in claiming that Allwell would have a registered pharmacist on duty in order to obtain a DEA Certificate (even if that was not going to be the case), I do not give substantial weight to Ms. Abalihi's claim that she never committed to giving the investigators contact information for Ms. Mustafa. From this contradictory account, I find Ms. Abalihi compounded the falsehood Ms. Taylor initiated, by failing to disclose the true lack of involvement of Ms. Mustafa in the planned operation of Allwell Pharmacy; and I find that Ms. Taylor falsely stated to the

[93] *Id.* at 129.
[94] *Id.* at 130.
[95] *Id.* at 130–31.
[96] *Id.* at 131.
[97] *Id.* at 131, 133.
[98] *Id.* at 134.
[99] *Id.*
[100] *Id.* at 135.
[101] *Id.*
[102] *Id.*
[103] *Id.* at 136.
[104] *Id.* at 144.
[105] *Id.* at 144, 146.
[106] *Id.* at 146.
[107] *Id.*
[108] *Id.* at 156.
[109] *Id.* at 137.
[110] *Id.* at 157.
[111] *Id.*
[112] *Id.* at 138.
[113] *Id.* at 138, 161.
[114] *Id.* at 139.

investigators that Ms. Mustafa would play a role in the pharmacy when it began its operations.

During her testimony, Ms. Abalihi attempted to minimize the significance of the role Ms. Taylor or Ms. Mustafa would play in the initial stage of Allwell's operation. Ms. Abalihi said that there are agencies (like the one employing her husband) that can cover pharmacies, ''so out of the issue of Mustafa as a coverage, a substitute, I don't think it was an issue for running that pharmacy.'' [115] There is, however, no evidence that Ms. Abalihi told the DEA investigators that she intended to start Allwell's operation using temporary agency pharmacists, like the one employing her husband. She recognized, however, that DEA certification was essential to her business plan. She testified that without the DEA Certificate she could not find suppliers or insurers that would work with the pharmacy.[116]

Ms. Abalihi's husband, Alfred Abalihi, also testified in support of Cove, Inc.'s application. Mr. Abalihi stated that while he would not be part of the business operation, he did have experience in the operation of a pharmacy.[117] He holds a license to practice as a pharmacist in Florida, based on an accredited Bachelor of Pharmacy degree from the University of Ife [now Obafemi Awolowo University], in Nigeria.[118] He has held the Florida license since 2003, and has never been subject to discipline by any governmental entity with respect to that license, nor has he ever been charged with or convicted of any crime by any governmental entity.[119]

Mr. Abalihi said he was aware that his wife was attempting to secure a DEA Certificate of Registration that would permit Cove, Inc. to operate the Allwell Pharmacy but said he was never made an owner of that corporation. According to Mr. Abalihi, ''[t]o my understanding I've been made to believe that [the] DEA have [sic] blacklisted me based on the temporary work I did at Moon Lake Pharmacy in 2007.'' [120]

Mr. Abalihi explained that he did not know much about Moon Lake's operation and was working there under contract as assigned by his employer, HealthCare Consultants.[121] He said he worked at Moon Lake only a few days and that this was one of many assignments he had been dispatched to as an employee of HealthCare Consultants.[122] He said he never interviewed for the job at Moon Lake, knew nothing about who owned the pharmacy, and never spoke with anyone at the pharmacy before starting his work there—adding that the owner worked there as a technician, but spoke only Spanish, which Mr. Abalihi said he neither speaks nor understands.[123]

Mr. Abalihi said that the DEA agents visited Moon Lake on the last day on this assignment.[124] According to Mr. Abalihi, when he asked Investigator Wald whether he was in any kind of trouble, Investigator Wald told him ''No, we didn't come here for you. If the pharmacy manager did what we told him to do the last time we came, we wouldn't have been here. So it's not about you.'' [125] Mr. Abalihi testified that before working at Moon Lake Pharmacy, he knew nothing about how that pharmacy received its prescriptions—and did not know there was an Internet Web site used as part of the prescribing process.[126]

Prior to the hearing, the parties stipulated that Mr. Abalihi ''dispensed controlled substances based on unlawful Internet prescriptions'' while working at Moon Lake Pharmacy.[127] During the hearing, however, Mr. Abalihi said he now could not recall any specific prescriptions he filled during the few days that he was working at Moon Lake, and had no recollection of there being anything wrong with any of the prescriptions he filled there.[128] He said he knew Moon Lake was compounding hydrocodone into dosage units, but said the compounding was done when he was not present.[129] He denied, however, ever telling Investigator Wald that what he was doing was legal, saying ''I never made any statement like that.'' [130] Mr. Abalihi said he worked with two other people at Moon Lake—a husband and wife—both of whom ''ran away'' and escaped from the pharmacy when the DEA investigators arrived.[131] Mr. Abalihi added that his assignment at Moon Lake was to end on the day the DEA investigators visited the pharmacy, so he did not return, and that he has never been disciplined by the Florida Board of Pharmacy for his work at Moon Lake.[132]

Mr. Abalihi testified that after this experience, he attempted to open his own pharmacy through Masters Worldwide Ventures, doing business as My Master's Pharmacy.[133] He said that his business plan was to operate a community pharmacy and to dispense drugs in some assisted living facilities, apparently pursuing a business plan similar to the one described by his wife with respect to the operation of Allwell Pharmacy.[134] He said he would have no arrangements with any pain clinics, adding that he did not even know any such clinics.[135]

Mr. Abalihi said he ended this venture at the advice of an attorney, ''based on the fact that DEA has told [his lawyer] that they have made up their mind to deny me the license.'' [136] He said he personally never spoke to or met with DEA representatives when attempting to secure a Certificate to operate My Master's Pharmacy, electing instead to have his attorney meet with those agents.[137] He said he actually tried to operate My Master's Pharmacy without a DEA Certificate of Registration, but found that drug wholesalers would not supply drugs without that Certificate. Further, Mr. Abalihi realized that if he was unable to dispense controlled substances his customers would ''quickly go to the other pharmacies that have a controlled [substances] license, leaving me to lose in business.'' [138]

When asked whether he intends to work at or otherwise operate Allwell Pharmacy once it opens for business, Mr. Abalihi responded ''No. I just wanted to stay as—to advise my wife how to do things. But I would have loved to work there, but the DEA wouldn't allow me to.'' [139] When asked on cross-examination whether he gave advice to his wife about having her own application for a DEA pharmacy, Mr. Abalihi did not answer directly, but instead responded ''I'm her husband. I knew she was going to apply to open a pharmacy.'' [140]

After hearing her husband's testimony, Ms. Abalihi was asked, on cross examination, ''what is your understanding why [the] DEA 'blacklisted' Mr. Abalihi'', Ms. Abalihi said she cannot answer the question, nor could she answer the Government's question whether it is her belief that her husband violated any DEA laws.[141] When she was asked, however, why her husband withdrew his application for a DEA Certificate on behalf of My Master's Pharmacy, she stated the only reason for doing that was the advice given by counsel.[142] When asked whether either Investigator Wald or Investigator Boggess told her that her husband had been blacklisted, Ms. Abalihi stated ''[t]hey didn't tell me that.'' [143]

Analysis

The Administrator is being asked to grant a Certificate of Registration that would permit Cove, Inc., to dispense controlled substances through a pharmacy to be known as Allwell Pharmacy. When presented with such an application, the Administrator is guided by provisions in the United States Code mandating that she determine whether granting such a Certificate ''would be inconsistent with the public interest.'' [144] In determining the public interest, the following factors shall be considered:

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

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

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

[115] *Id.* at 139.
[116] *Id.* at 138.
[117] *Id.* at 108.
[118] *Id.* at 97.
[119] *Id.*
[120] *Id.* at 98.
[121] *Id.* at 99.
[122] *Id.* at 100, 102.
[123] *Id.* at 101, 102.
[124] *Id.* at 100.
[125] *Id.*
[126] *Id.* at 103.
[127] *Id.* at 11–12.
[128] *Id.* at 103.
[129] *Id.* at 111.
[130] *Id.* at 104.
[131] *Id.* at 118–19.
[132] *Id.* at 104.
[133] *Id.* at 106.
[134] *Id.* at 107.
[135] *Id.*
[136] *Id.* at 106.
[137] *Id.* at 121.
[138] *Id.* at 107.
[139] *Id.* at 108.
[140] *Id.* at 122.
[141] *Id.* at 153.
[142] *Id.* at 155.
[143] *Id.* at 163.
[144] 21 U.S.C.A. § 823 (West), current through Public Law 112–283, approved 1–15–13.

(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.[145]

As correctly noted in the Government's post-hearing brief, an application denial may be based on any one, or any combination, of the five factors cited above.[146] When exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application should be rejected.[147] Moreover, the Administrator is ''not required to make findings as to all of the factors[.]'' [148] The Administrator is not required to discuss each factor in equal detail, or even every factor in any given level of detail.[149] The balancing of the public interest factors ''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[.]'' [150]

In this case, the Government does not contend there is a history of professional discipline by a licensing board, nor did it offer evidence of a criminal conviction pertaining to any party, nor did it allege Cove, Inc., or any material party failed to comply with applicable laws relating to controlled substances. Accordingly, Factors One, Three, and Four in 21 U.S.C. 823(f) are not presented as bases for revoking this Certificate.

I would note parenthetically that there is evidence supporting the Respondent's application that neither party directly addresses. There is undisputed evidence that the Respondent obtained the required license from Florida authorities, permitting it to operate a retail pharmacy in Tampa. In a recent DEA adjudication, obtaining such a license was considered by the Administrator as evidence in support of the application under Factor One (''recommendation of the appropriate State licensing board or professional disciplinary authority'').[151] ''Although not dispositive, Respondent's possession of a valid retail pharmacy license . . . weighs against a finding that Respondent's registration would be inconsistent with the public interest.'' [152] In this case, however, neither party cites to 21 U.S.C. 823(f)(1). Given the focus on Factors Two and Five, it should suffice to note, as the ALJ did in the earlier case, that '[a]lthough not dispositive, Respondent's possession of a valid retail pharmacy license . . . weighs against a finding that Respondent's registration would be inconsistent with the public interest.'' [153]

In his Order to Show Cause, the Deputy Assistant Administrator, Office of Diversion Control, identified two factors as the bases for denying Cove, Inc.'s application. First, he referred to Factor Two, noting that Ms. Abalihi ''had no prior experience with operating or working at a retail pharmacy and had no knowledge of DEA regulations pertaining to handling of controlled substances and related security requirements.'' [154] Also under Factor Two, the Deputy Assistant Administrator charged that the role Mr. Abalihi played in the operation of Moon Lake Pharmacy and his stated intention to obtain his own Certificate of Registration to operate a pharmacy created a risk to the public interest.[155] The Order also identified Factor Five as a basis for denying the application, stating that ''[t]he only pharmacist that Mrs. Abalihi stated would work at Allwell Pharmacy gave DEA investigators evasive and conflicting information about the pharmacy's operation.'' [156]

In hearings regarding the denial of a proposed DEA Certificate of Registration, ''the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 or section 1008(c) and (d) of the Act (21 U.S.C. 823 or 958(c) and (d)) are not satisfied.'' [157] Accordingly, in order to establish cause to deny Cove, Inc.'s application, the Government must establish by at least a preponderance of the evidence that it would be inconsistent with the public interest to grant this application, given the applicant's experience in dispensing controlled substances (Factor Two), given Mr. Abalihi's past history and present association with the new pharmacy (Factor Two), and given evidence of other conduct which may threaten the public health and safety (Factor Five).

Factor Two Regarding Experience of Cove, Inc., Ms. Abalihi, and Ms. Taylor

The evidence establishes that the applicant did not have personnel with the requisite experience in dispensing controlled substances to support its application. Considering first the experience attributed to Ms. Abalihi, I find the scope of nursing practice does, to some degree, include exposure to regulations pertaining to the distribution of controlled substances. Ms. Abalihi competently testified that in the course of her nursing practice, she has had occasion to deliver controlled substances to persons in her care. Further, there is evidence that as a nurse, Ms. Abalihi has been required to account for controlled substance inventories, and to guard against improper diversion of such inventories.

The scope of this experience, however, leaves material and significant areas of expertise unmet. Pharmacists must conform to the corresponding responsibilities imposed upon them under DEA regulations. These responsibilities are unique to pharmacists, and are not likely to be recognized or met by a person whose sole function is as a Registered Nurse. DEA regulations impose upon pharmacists affirmative obligations regarding the distribution of controlled substances once a prescribing source (such as a doctor or physician's assistant) issues a prescription. Those obligations collectively are referred to as ''corresponding responsibilities,'' as they impose duties on pharmacies and pharmacists that correspond with those of treating sources.[158] There is no corollary set of obligations imposed on Registered Nurses in the course of their professional duties. ''The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.'' [159]

Driving this corresponding responsibility is the standard, also found in DEA regulations, that a prescription for a controlled substance ''must be issued for a legitimate medical purpose,'' and that it be prescribed by ''an individual practitioner acting in the usual course of his professional practice.'' [160] Although the record shows Ms. Abalihi has formal education in the fields of basic and advanced pharmacology, and has experience in administering medications including controlled substances, the record also shows that she has no experience in understanding and applying the corresponding responsibilities imposed on pharmacists who dispense controlled substances under DEA regulations. To the contrary—from her testimony and from her business plan, it is clear Ms. Abalihi disavows having such knowledge, electing to defer all questions on these regulations to her business partner, Ms. Taylor.

Such deference would create a risk of harm to the public in this case. Diversion Investigator Boggess's testimony regarding the experiences of local pharmacists, and their collective concern about drug-seeking activity involving addictive pain killers like Oxycodone, establishes that there is a clear and present danger posed by persons who present themselves to pharmacies in the area, hoping to obtain drugs by questionable

[145] 21 U.S.C.A. § 823, eff. 4/15/2009, current through Public Law 112–283, approved 1–15–13.

[146] Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to ''Respondent's Brief'' at 3 (citing *Richard J. Lanham, M.D.,* 57 FR 40475–01 (August 27, 1992), *Henry J. Schwartz, Jr., M.D.,* 54 FR 16442–01 (April 24, 1989). Also cited is *Neveille H. Williams, D.D.S.,* 51 FR 17556 (1986), but the entry at that citation corresponds to the matter of *Paul Stepak, M.D.,* 51 FR 17556 (May 13, 1986), and is inapposite here.

[147] *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945–02, 43947 (October 31, 1988); *see also David E. Trawick, D.D.S.,* 53 FR 5326–01, 5327 (February 23, 1988).

[148] *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

[149] *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988).

[150] *Jayam Krishna-Iyer, M.D.,* 74 FR 459–01, 462 (January 6, 2009).

[151] *See Physicians Pharmacy, L.L.C.,* 77 FR 47096, 47104 (August 7, 2012).

[152] *Id.* (citing *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (March 28, 2003) (state license is a necessary but not a sufficient condition for registration, and therefore, this factor is not dispositive)).

[153] *Id.*

[154] Order to Show Cause, found in ALJ Exhibit 1, at 1.

[155] *Id.*

[156] *Id.* at 2.

[157] 21 CFR 1301.44, current through April 4, 2013.

[158] *See Sun & Lake Pharmacy,* 76 FR 24523–02, 24525 (May 2, 2011) (citing 21 CFR 1306.04(a)).

[159] 21 CFR 1306.04(a) (2005), current through February 21, 2013.

[160] *Id.*

prescriptions. Nothing in Ms. Abalihi's training suggests she is familiar with the practices of persons who present questionable prescriptions to pharmacists in the hope of securing controlled substances illegally.

Further, as a corporate entity, Cove, Inc. itself has no history of experience in the distribution of controlled substances. Allwell Pharmacy would be this corporation's first and only venture into such activity, and neither of its shareholders has ever operated a pharmacy before. The evidence calls into question whether Ms. Taylor would actually participate in the operation of Allwell Pharmacy, at least at the beginning of operations. When this application was presented to the DEA, Ms. Taylor was employed at another pharmacy on a full-time basis, during hours that would have made it impossible for her to be present when Allwell was open for business. When asked to describe her intentions in this regard, Ms. Taylor told the DEA investigators that she planned on working at Allwell only once it became profitable—not at the very beginning. Since then, Ms. Taylor has moved to Orlando, and there is no evidence indicating she has any plans to return to Tampa any time soon.

I am mindful that Ms. Abalihi now disputes the DEA investigators' reports regarding when Ms. Taylor would actually begin work. I am persuaded, however, to attribute greater weight to the testimony on this point provided by Investigator Boggess and Investigator Wald, than I attribute to Ms. Abalihi's version of what was said. It is clear from the record that Ms. Taylor had no clear investment in Cove, Inc. nor in Allwell Pharmacy. As a minority shareholder with no proven financial investment in the company, Ms. Taylor was in no way obligated to quit her job at Sweetbay in order to work at Allwell. The record offers no evidence that Ms. Taylor contributed capital or cash in exchange for receiving her ten percent shares in the corporation.

Further, there is no evidence establishing any kind of agreement between Cove, Inc. and Ms. Taylor requiring her to provide professional services. There is, for example, no evidence that Ms. Taylor faced any adverse consequence should she decide not to end her employment at Sweetbay and begin working at Allwell. Ms. Abalihi's claim that Ms. Taylor would quit her job at Sweetbay in order to accept a position at Allwell is not supported by any competent evidence, and is contradicted by what I find to be credible testimony from the two DEA investigators, to the effect that Ms. Taylor was going to take a ''wait and see'' approach before lending her expertise to this new enterprise—an approach Ms. Abalihi appears to have endorsed.[161]

This conclusion is buttressed by the evidence regarding the role of Dayla Mustafa. The need for someone to play the role attributed to Ms. Mustafa would arise only upon Ms. Taylor's absence from Allwell during the initial operation of the new pharmacy. The evidence establishes that based on Ms. Taylor's admission that she would not be present initially, and upon the investigators' query, Ms. Taylor offered Ms. Mustafa as the person who would provide the requisite experience initially. The evidence establishes that this was a falsehood—that in fact Ms. Mustafa never agreed to play such a role, and Ms. Taylor came up with the name only because she felt the need to address concerns being raised by the DEA investigators. Ms. Abalihi tacitly confirmed this false representation and compounded the problem when she offered to provide the investigators with Ms. Mustafa's contact information. Thus, the evidence establishes that no one having the requisite knowledge and experience to operate a pharmacy and to conform to DEA diversion control requirements would be present initially.

I do note the Respondent's complaint regarding the practice, attributed to Investigators Boggess and Wald, of asking applicant's questions regarding their familiarity with DEA diversion control regulations.[162] After stating that ''there is no law or regulation supporting this practice,'' the Respondent avers that ''everyone knows that the DEA does not go around interviewing Walgreens or Wal-Mart shareholders or management whenever those pharmacy chains decide to open up a new location in the area.'' [163] I cannot endorse this conclusion, as it is not supported by any evidence in the record before me. Further, I am obliged to focus on the application before me. Here, the 90 percent shareholder and sole officer of the corporation that proposes to dispense controlled substances has only limited experience handling controlled substances, and has never operated a pharmacy. Ms. Abalihi recognized the importance of this shortfall, and proposed to fill the gap by taking on a ten percent shareholder, expecting this person to bring with her the experience needed to ensure compliance with DEA diversion control regulations. That shareholder, however, was already committed to a full-time job that prevented her from working at the new pharmacy. When this gap was raised, the ten percent shareholder lied to the DEA investigators, falsely stating a co-worker, Ms. Mustafa, would be filling the gap until the new pharmacy was operational.

Given the evidence before me, I cannot endorse the Respondent's claim that ''short of being licensed as a practicing pharmacist, Mrs. Abalihi has about as much experience properly handling controlled substances as anyone is likely to have.'' [164] From her own testimony, it is clear Ms. Abalihi was unfamiliar with DEA diversion control requirements and was unwilling to answer any questions regarding the regulatory environment in which pharmacies must operate. This was true during the investigation into this application, and it was also true during the evidentiary hearing. Thus, even though Ms. Abalihi has continued her professional development by attending courses that included pharmacology, she continues to lack the knowledge and experience required to operate a pharmacy that dispenses controlled substances. She has no experience as a pharmacist, professed no knowledge of the standards of care that must be met by registered pharmacists, and proposed no concrete plan to have a pharmacist actually working at the pharmacy, at least until the enterprise was established and operational. Upon this evidence, the Government has established by at least preponderance that issuing a Certificate of Registration to the Respondent would be inconsistent with the public interest, under Factor Two.

Factor Two and the Nexus Between Cove, Inc. and Alfred Abalihi

The Government also offered evidence under Factor Two regarding Ms. Abalihi's husband, Alfred Abalihi. In the Order to Show Cause, the Deputy Assistant Administrator reports that Mr. Abalihi ''participated in unlawful dispensing of controlled substances'' while employed at a pharmacy in 2007.[165] The Government alleged that Moon Lake Pharmacy had been engaged in illegally dispensing controlled substances based on Internet prescription activity. The general premise in this part of the charge is that Mr. Abalihi told DEA investigators in 2007 that he believed the pharmacy's operations were legal, and that he hoped someday to open his own pharmacy. Further, in its post-hearing brief, the Government calls into question Mr. Abalihi's credibility in his claim that he did not know Moon Lake's operations were illegal. From this, the Government argues that Mr. Abalihi's ''negative controlled substance experience'' has a ''clear nexus with his wife's present experience'' warranting a denial of the claim under Factor Two.[166]

At the outset, I agree with the Government's skepticism regarding Mr. Abalihi's representation that he did not know Moon Lake's operations were illegal. It may be that current business practices tend to increase reliance on temporary or contract employees, including pharmacists; and that such practices increase the likelihood that the pharmacist will be unaware of the true nature of the pharmacy's operation. It is worth noting that to the extent such a practice exposes the pharmacist to the risk of working in an illegal shop, the pharmacist is not excused from his or her responsibility to act within the law, and must face the consequences of maintaining a blind eye to such an obviously illegal operation. Here, however, I need not rely on any such inference, because I have before me the parties' express stipulation that while at Moon Lake Mr. Abalihi ''dispensed controlled substances based on unlawful Internet prescriptions [.]'' [167]

Given the very small office in which this compounding and dispensing was occurring, I find sufficient credible evidence to conclude Mr. Abalihi was aware that the

[161] *See* Tr. at 157.

[162] Respondent's Post-Hearing Brief, at 12.

[163] *Id.*

[164] Respondent's Post-Hearing Brief, at 11.

[165] Order to Show Cause, at 1.

[166] Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to ''Respondent's Brief,'' at 8.

[167] Tr., at 11–12.

practices in this pharmacy were illegal. Having said that, however, I cannot conclude that this evidence supports the Government's contention that the circumstances arising from Mr. Abalihi's work at Moon Lake Pharmacy establish cause to find Cove, Inc.'s application is inconsistent with the public interest. The evidence establishes that Mr. Abalihi would not directly participate as an officer or owner of Cove, Inc. Thus, I must question whether there is a sufficient link established between Mr. Abalihi's past work at Moon Lake Pharmacy and Cove, Inc.'s proposal to operate Allwell Pharmacy.

In support of its claim that such a nexus exists and must be recognized, the Government offers as guidance the decision in *In Re Matthew D. Graham.*[168] As noted in the Government's brief, *Graham* involved the application for a List 1 Chemical Registration under 21 U.S.C. 823(h) (and not registration under 21 U.S.C. 823(f)). The DEA challenged the application because the applicant's business partner had in the past surrendered a DEA registration after the partner illegally sold pseudoephedrine. In the Final Order, Graham's application was denied, in part by applying language similar to language found in Section 832(f)'s Factor Two, which calls for the ''public interest'' inquiry to consider ''[a]ny past experience of the applicant in the manufacture and distribution of chemicals[.]'' [169] While thus not precisely on point, the discussion in *Graham* does highlight those factors that should be considered when determining whether to deny a registration based on the past misconduct of a third party.

The *Graham* opinion explained:

Regarding factor four, the applicant's past experience in the distribution of chemicals, the DEA investigation revealed that Graham has no previous experience related to handling or distributing listed chemicals. As set forth previously, however, his business partner Snodell surrendered a DEA registration because a DEA and KBI investigation revealed he was distributing large quantities of List I chemical products having reasonable cause to believe the chemical would be used to manufacture a controlled substance. Graham admitted to DEA investigators that Snodell was his source of information concerning the business of distributing listed chemicals. . . . For the above-stated reasons, the Administrator concludes that it would be inconsistent with the public interest to grant the application of Graham.[170]

The agency thus may attribute to a registrant the prior misconduct of third party. The conditions in *Graham,* however, are not well aligned to those present in Cove, Inc.'s application. In *Graham,* the registrant told the DEA he intended to enter into a wholesale business arrangement with Snodell, with whom he was co-owner of a wholesale business outlet. Thus, unlike the business plan presented by Ms. Abalihi, the registrant in Graham was economically tied to the third party. When it surfaced that Snodell had illegally sold pseudoephedrine a year earlier, and when it became clear that under Graham's business plan Snodell would be responsible for referring List I chemical orders to Graham, this nexus served as a basis for denying Graham's application.

In the case presently before the Administrator, on the other hand, Ms. Abalihi presented a business plan that expressly removed Mr. Abalihi from all phases of the proposed pharmacy's operation. The evidence establishes that Mr. Abalihi would not directly participate as an officer or owner of Cove, Inc. While it might be reasonable to be skeptical about the efficacy (or even the existence) of such a line between spouses, the evidence now in the record does not permit me to recognize the kind of nexus that existed in *Graham.*

The Government correctly notes in its brief that Ms. Abalihi has not indicated she would prohibit her husband from working in the pharmacy.[171] Ms. Abalihi's statement that she would keep her husband ''apart from ownership and management'' of the pharmacy, however, effectively distinguishes this case from *Graham.*[172] Equally important, having considered the affidavit of Mr. Abalihi, and having considered the testimony from both Mr. and Mr. Abalihi, I find sufficient credible and unrebutted evidence to conclude Mr. Abalihi does not intend to perform a significant role in the operation of Allwell Pharmacy.

I fully appreciate the Government's concern regarding the events involving Mr. Abalihi during his very short tenure at Moon Lake Pharmacy. I note the skepticism expressed by the investigators, as they recalled the nature of Moon Lake's Internet-based operation. I share their sense that anyone in Mr. Abalihi's position would have had reason to question the legitimacy of the operation, and I share their sense of incredulity that Mr. Abalihi would have failed to recognize the illegal nature of what was going on at Moon Lake, even though his stay there was brief.

The Respondent, however, correctly notes that Mr. Abalihi was not charged with any misconduct arising out of his service at Moon Lake. Mr. Abalihi may have unwisely told the DEA investigators that Moon Lake's operations were legal, but I cannot conclude from that piece of evidence that Mr. Abalihi was knowingly advancing Moon Lake's criminal enterprise when the DEA arrived. Unlike the acknowledged misconduct by Graham's business partner (leading to the partner surrendering his DEA Certificate), here the most we can say for certain is that Mr. Abalihi was the pharmacist who was present when the DEA agents arrived at Moon Lake and brought its operations to an end. While it is true that the parties have stipulated that Mr. Abalihi dispensed controlled substances based on unlawful Internet prescriptions during his short tenure at Moon Lake, Mr. Abalihi's record since then is unblemished and his plan to avoid direct involvement with Allwell and Cove, Inc. adequately attenuates the link between him and the proposed pharmacy.

Having said that, I must note that a core theme presented in support of the Respondent's application has not been established as fact. In its post-hearing brief, the Respondent states that ''[o]nce the decision had been made by the DEA that Mr. Abalihi was banned for the rest of his life from ever having an ownership stake in a pharmacy with a DEA registration, the DEA then set a course of blocking anyone relating to Mr. Abalihi from obtaining a DEA registration.'' [173] This record does not support the premise that Mr. Abalihi has been ''banned for the rest of his life'' from anything.

The record fails to establish why Mr. Abalihi withdrew his request for a DEA Certificate, other than to indicate the action was based on the advice of his attorney. The factual claims on this point appearing in the Order to Show Cause have been supported by substantial evidence, and include the parties' stipulation that Mr. Abalihi improperly dispensed controlled substances while working at Moon Lake Pharmacy. The DEA has in the past recognized the need to evaluate the circumstances that may arise when a husband and wife are involved in a new application for a retail-pharmacy DEA Certificate and when there has been a prior adverse DEA action involving one of the spouses involving another pharmacy.[174] The facts alleged in the Order to Show Cause warranted this measure of scrutiny, but the facts shown here do not establish the kind of ties that link Mr. Abalihi's past brief involvement with Moon Lake's illegal operation to the operation proposed by the Respondent here.

I reject in its entirety, however, the Respondent's assertion that the DEA's ''real motivation'' in challenging Cove, Inc.'s application, was ''Mr. Abalihi's brief employment at Moon Lake Pharmacy.'' [175] The assertion is based on an unproved premise that Mr. Abalihi has been unfairly ''blacklisted'' by the DEA, based on what he said and did on the day DEA agents visited Moon Lake Pharmacy.[176] The evidence before me does not establish that Mr. Abalihi is the subject of any bar to obtaining a DEA Certificate of Registration. Instead, the record indicates that Mr. Abalihi's former lawyer met with the DEA while he sought to start his own pharmacy, and was persuaded during that meeting to advise Mr. Abalihi to withdraw his application.

We do not know what was presented to this lawyer during her visits with the DEA, nor do we have the benefit of any documentary evidence supporting her reputed claim that the DEA has deemed Mr. Abalihi ineligible for a Certificate of Registration. We do not, indeed, have documentary evidence that the lawyer said or

[168] Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to ''Respondent's Brief,'' at 10, citing *In re Matthew D. Graham,* 67 FR 10229–01 (March 6, 2002).

[169] *Id.* at 10230, quoting 21 U.S.C. 823(h)(4).

[170] *Id.* at 10230.

[171] Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to ''Respondent's Brief,'' at 10.

[172] *Id.* quoting Affidavit of Ms. Abalihi, attached as Exhibit E to Respondent's Brief, ALJ Exhibit 6.

[173] Respondent's Post-Hearing Brief, at 11.

[174] See, *e.g., DePietro's Pharmacy,* 56 FR 31675–02 (July 11, 1991).

[175] *Id.* at 14.

[176] *Id.*

did anything that would justify Mr. Abalihi's decision to withdraw his 2007 application. In short, Mr. Abalihi's conclusion that he had been ''blacklisted'' has not been supported by competent evidence. Instead, I have been told that Mr. Abalihi deferred to his lawyer, electing not to speak with the DEA directly, and apparently withdrew his application solely at his lawyer's suggestion. This does not constitute evidence proving ''unfair blacklisting,'' as alleged by the Respondent.[177]

I find insufficient evidence to conclude that Mr. Abalihi's relationship with Cove, Inc., through his marriage to Ms. Abalihi, gives rise to a public threat under Factor Two, although Factor Two does serve as a basis for denying this application, given the absence of sufficient relevant experience by Ms. Abalihi, for the reasons set forth above.

Factor Five

Independent of concerns addressed under Factor Two, the evidence also forces the conclusion that conduct attributed to both Ms. Taylor and Ms. Abalihi would threaten the public health and safety, warranting a denial of the application under Factor Five. Here the evidence establishes that Ms. Taylor misled the DEA investigators when she was asked about arrangements to have a pharmacist present when Allwell began its operations. I find there is competent and credible evidence that when asked who would be working at Allwell initially, Ms. Taylor told the investigators the initial pharmacist would be her coworker, Ms. Mustafa. This was not true, and constitutes a material misrepresentation in the application process. Ms. Taylor elected not to testify (indeed there is no evidence suggesting the Respondent requested her to do so), and nothing in her affidavit [178] compels a more benign interpretation of her conduct.

Further, when the investigators requested contact information from Ms. Abalihi so they could confirm Ms. Mustafa's role, Ms. Abalihi compounded the misrepresentation and offered to get the requested information, rather than disclose that she knew nothing about Ms. Mustafa's role with the pharmacy. If Ms. Abalihi intended on using contract pharmacists at the start of Allwell's operation, she had an affirmative duty to say so when DEA investigators asked her about the role Ms. Mustafa was to play. By her silence, and by promising to provide contact information for Ms. Mustafa, Ms. Abalihi misled the investigators.

Making a material misrepresentation in the course of an investigation into the operation of the proposed pharmacy creates a risk of harm to the public health and safety. The operation of a pharmacy is a highly regulated enterprise, requiring advanced skill and technical expertise unique to the profession. Lying about who would be present with that skill and expertise casts doubt on the ability of both Ms. Abalihi and Ms. Taylor to protect the public, and suggests they will instead act only in their own self-interest. Upon such evidence, the Government has established by at least preponderance that issuing a Certificate of Registration to the Respondent would be inconsistent with the public interest, under Factor Five.

Where the Government has made out its prima facie case, the burden shifts to the Respondent to show why its continued registration would be consistent with the public interest.[179] Having considered the record as a whole and in particular the claims appearing in the Respondent's post-hearing brief, I find no substantial evidence in rebuttal of the Government's case. Ms. Abalihi continues to take the position that she is fully qualified to operate a pharmacy, based on her experience as a Registered Nurse; and continues to seek a Certificate of Registration to dispense controlled substances out of a retail pharmacy that has no pharmacist on staff.

Findings of Fact

1. On March 3, 2011 and acting on behalf of Cove, Inc., Ogechi E. Abalihi submitted a new application for a DEA retail-pharmacy Certificate of Registration, to operate a pharmacy under the name of Allwell Pharmacy, to be located at 1947 West Dr. Martin Luther King, Jr. Boulevard, Tampa, Florida 33609. This pharmacy is not open for business and has never operated as a business, although it has been issued a community pharmacy license by the state of Florida.

2. Cove, Inc. is owned by its 90 percent shareholder and sole officer, Ogechi E. Abalihi, and its ten percent shareholder, Jacinta Taylor.

3. Ms. Abalihi has no experience working in, managing, or owning a pharmacy; has no direct knowledge of DEA controlled substance regulations; has extensive experience as a Registered Nurse; has worked with controlled substances but only in the context of her service as a Registered Nurse; and has proposed a business plan for Allwell Pharmacy that requires the presence of a pharmacist throughout the pharmacy's operating hours, which were 9:00 a.m. to 6:00 p.m. Mondays through Fridays, and from 9:00 a.m. to 1:00 p.m. on Saturdays.

4. Although the Applicant's business plan called for DEA controlled substance regulations to be implemented by a registered pharmacist on duty throughout the pharmacy's operational hours, there was no provision for having a registered pharmacist present during the initial phase of the pharmacy's operation. Instead, the plan called for Ms. Abalihi to operate the pharmacy until it became profitable, at which time Ms. Taylor planned on quitting her full-time job at another pharmacy and becoming an employee at Allwell Pharmacy. Under this plan, until Ms. Taylor actually began working at Allwell Pharmacy, there would be no one with the experience, knowledge, and training needed to ensure compliance with DEA regulations.

5. During the application process and during interviews with DEA Diversion Investigators, both Ms. Abalihi and Ms. Taylor acknowledged the need to have a registered pharmacist present whenever the pharmacy was open. Both Ms. Abalihi and Ms. Taylor misled the Investigators by falsely representing that when it opened, Allwell Pharmacy's staff would include Dalya Mustafa, who is a registered pharmacist and was Ms. Taylor's co-worker. The evidence establishes that there would be no pharmacist present when Allwell Pharmacy began its operations, under the business plan created by Ms. Abalihi.

6. Without the active participation of Ms. Taylor or another person experienced in applying DEA regulations, Cove, Inc. lacked the experience required for its application to be consistent with the public interest.

7. The 90 percent owner of Cove, Inc., Ogechi E. Abalihi is married to a registered pharmacist, Alfred Abalihi. Mr. Abalihi is not an officer, shareholder, or employee of either Cove, Inc., or Allwell Pharmacy. There is insufficient evidence establishing that he would have any direct involvement with either Cove, Inc., or Allwell Pharmacy, just as there is insufficient evidence establishing that he would abstain from such involvement, should the pharmacy become operational.

8. Mr. Abalihi was a pharmacist employed in 2007 by HealthCare Consultants. In the course of his employment at HealthCare Consultants, Mr. Abalihi was directed to provide services as a registered pharmacist at Moon Lake Pharmacy. While providing services as a temporary worker through HealthCare Consultants at Moon Lake Pharmacy, Mr. Abalihi dispensed controlled substances based on unlawful Internet prescriptions prior to Moon Lake Pharmacy surrendering its DEA registration on December 17, 2007.

Conclusions of Law

1. When it proposes to deny a new application for a retail-pharmacy DEA Certificate of Registration, the Government is required to establish by at least a preponderance of the evidence that the pharmacy's initial registration is inconsistent with the public interest. 21 U.S.C. 823(f); 21 CFR 1301.44(d).

2. Five factors must be considered when determining the public interest in this case:

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

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

(3) The applicant'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).

3. In order to establish a basis for denying a new application for a retail-pharmacy Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(2) (Factor Two), the Government must present evidence establishing, by at least a preponderance, that

[177] *Id.*

[178] Respondent's Exhibit G, Affidavit of Jacinta Taylor.

[179] *See Theodore Neujahr, D.V.M.* 65 FR 5680–01, 5682 (February 4, 2000) and *Service Pharmacy, Inc.,* 61 FR 10791–01, 10795 (March 15, 1996).

the experience of the applicant in dispensing controlled substances is of such character and quality that registration is not in the public interest. This requires evidence of both the qualitative manner and quantitative volume of the applicant's experience. Where evidence of the applicant's experience, as expressed through its employees and officers, establishes that the business plan provides for the active daily involvement of no one having experience applying DEA controlled substance diversion regulations in a retail pharmacy setting, and provides only for the involvement of an employee familiar with the regulations applicable to Registered Nurses whose duties include dispensing medication, in such an application there is sufficient evidence proving, by at least a preponderance, that granting such an application would be inconsistent with the public interest.

4. When proposing to deny a retail-pharmacy application under Factor Two based on the prior association and dispensing history of a third party, the Government must demonstrate that the third party's past negative experience in dispensing controlled substances warrants a finding that his or her association with the applicant would be inconsistent with the public interest. Where, as here, the third party is the husband of the applicant's majority shareholder but has no clearly demonstrated role in either the corporation (as a shareholder or an officer), or in the retail pharmacy (as an employee or manager), and where there is insufficient evidence demonstrating the third party's past negative experience will have any impact on the operation of the retail pharmacy, the Government has not met its burden of proving a basis to deny the application under Factor Two.

5. In order to establish a basis for denying a new application for a retail-pharmacy Certificate of Registration based on the provisions of 21 U.S.C. 823 (f)(5) (Factor Five), the Government must present evidence establishing, by at least a preponderance, other conduct (*i.e.,* conduct not covered within the scope of Factors One through Four) which may threaten the public health and safety. Where, as here, the evidence establishes that when called upon by DEA investigators to identify the person or persons who would be familiar with DEA diversion control regulations and would be present at the retail pharmacy to ensure compliance with those regulations, the applicant's sole officer and both of its two shareholders made material misrepresentations about having such person or persons present, there is substantial evidence of conduct that may threaten the public health and safety. In such an application there is sufficient evidence proving, by at least a preponderance, that granting such an application would be inconsistent with the public interest.

6. Upon such evidence, the Government has met its burden and has made a prima facie case in support of the proposed order denying the Respondent's application for a retail-pharmacy Certificate of Registration.

7. Upon a review of the record as a whole, including all claims made in the Respondent's post-hearing brief, there is insufficient evidence of remediation. Accordingly, the Government has established cause to deny this application.

Recommendation

As the Government has established its prima facie case by at least a preponderance of the evidence, the Respondent's application for a retail-pharmacy DEA Certificate of Registration should be DENIED.

Dated: April 23, 2013.

Christopher B. McNeil,

Administrative Law Judge.

[FR Doc. 2015–12131 Filed 5–19–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–31]

Farmacia Yani; Decision and Order

On April 10, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Farmacia Yani (Respondent), of San Sebastian, Puerto Rico. ALJ Ex. 1. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a retail pharmacy, on the ground that its registration ''would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.* at 1.

The Show Cause Order specifically alleged that on March 27, 2012, Respondent submitted an application for a registration as a retail pharmacy, seeking authority to dispense controlled substances in schedules II through V, at a location in San Sebastian, Puerto Rico. *Id.* The Order further alleged that Respondent held a registration at the same location, which it ''had surrendered for cause on December 2, 2011,'' and that a DEA investigation found ''that from February 2009 through November 2011, [it] filled approximately 218 prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration, in violation of Federal law and regulations.'' *Id.* (citing 21 U.S.C. 843(a)(2); 21 CFR 1306.04). The Government then alleged that Respondent's ''violations of Federal law and regulations render granting its application for a [registration] inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f) and 824(a)).

On May 10, 2013, Respondent, through its counsel, requested a hearing on the allegations and the matter was placed on the docket of the Office of Administrative Law Judges. ALJ Ex. 2. Thereafter, an Administrative Law Judge (ALJ) proceeded to conduct pre-hearing procedures. ALJ Ex. 3.

In its Supplemental Prehearing Statement, the Government provided notice to Respondent that it intended to elicit testimony from an Agency Diversion Investigator (DI) that Respondent had ''filled twenty-nine (29) prescriptions for Suboxone that were written by two doctors who did not possess authority to issue these controlled substances,'' that the ''prescriptions were written by Dr. Aguilar-Amieva and Dr. Cesar I. Vargas-Quinones,'' and that a review of ''the DEA registration database . . . found that these two physicians were never registered with DEA as data-waived practitioners, in violation of 21 CFR 1301.28.'' ALJ Ex. 7, at 3. The Government also provided notice that it intended to question Respondent's owner ''about the circumstances of the pharmacy's prior surrender of its . . . registration, and about her failure to note the previous surrender on Respondent's new application for registration.'' *Id.*

On July 16, 2013, the ALJ conducted an evidentiary hearing in Guaynabo, Puerto Rico.[1] Tr. 27. At the hearing, the

[1] On June 18, 2013, the ALJ had conducted the first day of the hearing, during which he reviewed the parties' proposed stipulations and admitted several documents into the record, while holding the admission of two Government exhibits in abeyance. *See* Tr. 4–14 (June 18, 2013). After Respondent's counsel objected to the admission of some of the Government's exhibits because they contained prescriptions issued by a doctor whose prescriptions were not the basis of what it had previously alleged, the Government announced that it would be filing a supplemental prehearing statement during which it would ''outline that the Government discovered some prescriptions by Dr. Cesar Vargas-Quinones.'' *Id.* at 14. After the ALJ ruled that these exhibits would ''be held in abeyance until after we've had the opportunity to see what the Government sets forth in its supplemental prehearing statement,'' the ALJ explained that the deadline for both parties to file their supplemental prehearing statements would ''be simultaneous''; the ALJ also told Respondent's counsel that ''you really won't have a chance to reply in your—in your response in the prehearing statement,'' but that she would be able ''to object to these exhibits during the hearing itself.'' *Id.* at 15–16. Notably, during the June 18 hearing, the Government made no mention of its intent to raise the material falsification issue. Moreover, the ALJ subsequently ordered that the parties file any supplemental prehearing statements with the Office of Administrative Law Judges ''not later than 2:00 p.m. on the 9th of July 2013.'' *Id.* at 18–19.

The same day, the ALJ also issued an Order memorializing these instructions. *See* Order (June 18, 2013). Therein, the ALJ further instructed that ''[a]fter this deadline, Prehearing Statements may only be supplemented upon the filing of a motion for extension of time and after a favorable ruling by me. Any new documents identified in a supplemental prehearing statement also need to be exchanged by the parties no later than July 9, 2013.'' *Id.* at 4.