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]

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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.

Government elicited the testimony of a DI and Ms. Yanira Santiago-Soto, Respondent's owner and pharmacist in charge; Respondent also elicited the testimony of Ms. Santiago-Soto. Both parties also introduced documentary evidence into the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On September 26, 2013, the ALJ issued his Recommended Decision (hereinafter, cited as R.D.) Therein, the ALJ found that the Government had established a *prima facie* case that granting Respondent's application ''would be inconsistent with the public interest.'' R.D. 36. The ALJ further found that Respondent had ''failed to rebut'' the Government's case. *Id.* The ALJ thus recommended that Respondent's application be denied.

Respondent filed Exceptions to the Recommended Decision. Having reviewed Respondent's Exceptions along with the entire record, I find that several of them are well taken and that the ALJ committed multiple prejudicial errors. These include:

(1) Barring Respondent from using a document, which, according to Respondent's offer, was from DEA's Web site, to impeach a Government witness, because it was not submitted in advance of the hearing;

(2) barring Respondent from introducing evidence of an email its principal sent to an Agency Investigator the day after she submitted the application, which according to Respondent's offer, memorialized a phone conversation in which she asked if she had correctly answered an application question, also on the ground that it was not submitted in advance of the hearing, notwithstanding that the Government did not even disclose that it was pursuing the material falsification allegation until one week before the hearing; and

(3) finding that Respondent's principal materially falsified its application based on the answer she gave to Question Four when the Government never provided notice that the answer to this question was at issue in the Show Cause Order, its pre-hearing statements, or its opening statement, nor even questioned her about her answer to this question, even though it called her to testify in its case-in-chief.

Because I reject the ALJ's legal conclusions that Respondent's principal materially falsified its application and that Respondent violated its corresponding responsibility under 21 CFR 1306.04(a) when it dispensed prescriptions issued by a physician whose registration had expired, and these errors solely affect these two allegations, I conclude that a remand is not warranted. While I agree with the ALJ's legal conclusion that Respondent violated federal law when it dispensed Suboxone prescriptions, which were issued to provide maintenance or detoxification treatment and the prescribers lacked the requisite authority to prescribe the drug for this purpose, I do not find that the record as a whole supports the proposed outright denial of the Application. Accordingly, I will order that Respondent be granted a registration subject to conditions set forth in this decision. I make the following findings of fact.

Findings

Respondent's License and Registration Status

Respondent is a corporation which owns a retail pharmacy located at Carretera 109, Kilometer 26.7, Barrio Culebrina, San Sebastian, Puerto Rico. Tr. 9; GX 1. Ms. Yanira Santiago-Soto is the owner of Respondent and its pharmacist-in-charge. Tr. 106.

Respondent is licensed as a pharmacy by the Commonwealth of Puerto Rico Department of Health; this license does not expire until June 26, 2015. RX D1, at 3. Respondent also holds a controlled substance registration, which was also issued by the Commonwealth's Department of Health.[2] RX E4.

Respondent previously held DEA Certificate of Registration FF1070894, pursuant to which it was authorized to dispense controlled substances in schedules II through V. GX 5, at 1. While this registration was not due to expire until September 30, 2014, on November 30, 2011, Ms. Santiago-Soto surrendered Respondent's registration.[3] *Id.; see also* RX I. On March 26, 2012, Ms. Santiago-Soto applied on Respondent's behalf for a new registration. GX 1, at 1–2. It is this application which is at issue in this proceeding.

On the application, Respondent was required to answer four questions. *Id.* at 1. The second of these asked: ''Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?'' GX 1, at 1. Ms. Santiago-Soto answered the question by checking the ''no'' box. *Id.* The fourth question asked, in relevant part:

> If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?

Id. Respondent also answered this question, by checking the ''no'' box. *Id.*

The Investigation of Respondent

Following Ms. Santiago-Soto's submission of Respondent's application, a Diversion Investigator with the Ponce, Puerto Rico DEA Office was assigned to investigate the application. Tr. 40–41. Upon doing so, the DI determined that on November 30, 2011, a search warrant had been executed at Respondent during which various items of evidence, including prescriptions, were seized. *Id.* at 43. Some of the evidence was sent to the DEA digital evidence laboratory for further analysis; according to the DI, the lab extracted various data and sent a CD containing the data to his office. *Id.* at 44. In addition, prescriptions were seized from Respondent and scanned by the Ponce DEA office. *Id.*

Upon reviewing the data provide by the digital evidence lab, the DI determined that ''there were two main violations.'' *Id.* at 46. According to the DI, the first set of violations involved Respondent's having ''illegally filled'' some ''241 prescriptions'' which were issued by a Doctor Hector J. Aguilar-Amieva after the latter's registration was retired by DEA on January 31, 2009 and ''he was no longer authorized to prescribe any controlled substances. *Id.* at 46–47; *see also* GX 6 (affidavit of Chief, Registration and Program Support Section, Drug Enforcement Administration, stating that Dr. Aguilar-Amieva's registration expired on June 30, 2008 and was retired from the DEA computer system on January 31, 2009).

As for the second set of violations, the DI stated that they involved

[2] According to the certificate, the registration was due to expire on September 30, 2013. RX E, at 4.

[3] The day before, Ms. Santiago-Soto had been indicted along with thirty-two other defendants, on two felony counts of violating the Controlled Substances Act. The charges were: (1) Conspiring to possess and dispense, with intent to distribute, various controlled substances, in violation of 21 U.S.C. 841(a)(1), 846, and 860; and (2) aiding and abetting each other and ''knowingly and intentionally possess[ing] and dispens[ing] with intent to distribute various'' schedule II through IV controlled substances, ''outside the scope of professional practice and not for a legitimate medical purpose,'' in violation of 21 U.S.C. 841(a)(1) and 18 U.S.C. 2. RX B, at 1–13. Several months later, the Government moved to dismiss the charges with prejudice, and on March 23, 2012, the District Court entered a Judgment of Dismissal. RX C.

Respondent's having filled twenty-nine prescriptions issued by both Dr. Aguilar-Amieva and Dr. Cesar Vargas-Quinones for Suboxone (buprenorphine). Tr. 47, 49. According to the DI, the prescriptions were unlawful because the doctors ''were not authorized to'' prescribe Suboxone (buprenorphine) ''because they were not DATA-waived [4] practitioners.'' *Id.* at 48. The DI further explained that a DATA-waived practitioner is a physician who is approved by ''the Center of Substance Abuse'' (actually, the Center for Substance Abuse Treatment, a component of the Substance Abuse and Mental Health Services Administration) to prescribe Suboxone (buprenorphine) to treat narcotic addiction and that these physicians are issued ''a specific registration that is distinguished with an X number,'' which ''should be on the prescription[s]'' they issued for these drugs. *Id.* at 49. However, none of these prescriptions bore an X number (even though seventeen of the twenty-nine prescriptions listed a diagnosis of opiate addiction or dependence). *Id.* at 49–50; *see also* GX 3, at 410–56.

The DI further testified that Respondent's application contained a falsification because in answering ''[q]uestion [n]umber 3,'' Ms. Santiago-Soto failed to disclose that the pharmacy had previously surrendered its registration. Tr. 45. While the DI was not present when Ms. Santiago-Soto surrendered Respondent's registration, he testified that he had read a report that stated that she ''voluntarily surrendered the pharmacy's license'' and that he had also seen the document that she signed, and that the document said that she ''voluntarily surrendered'' the registration. *Id.* at 60–61. The DI further explained that based on the inconsistencies between what he read in the report and the answers to the application's questions, he concluded that Ms. Santiago-Soto had falsified the application. *Id.* at 62–63.

Later, on cross-examination, the DI conceded that the criminal charges which were filed against Ms. Santiago-Soto were voluntarily dismissed with prejudice. *Id.* at 72. Moreover, when asked whether Ms. Santiago-Soto had violated any federal law or regulation, the DI answered:

> The conclusion, once again, is based on our records, what I see in the records, and it's based on the evidence. Whenever an application is submitted to the DEA, and we are required to analyze this application, and based on the pharmacy's, for example, that the applicant is dispensing controlled substances.

Id. at 72–73. Respondent's counsel then asked if anyone had found that Ms. Santiago-Soto ''has violated any federal law in dispensing those prescriptions that are part of the evidence here today?'' *Id.* at 73. The Government objected on the ground that the question ''ha[d] been asked and answered'' and the ALJ sustained the objection, noting that he knew that the charges were dismissed and that there was no evidence that Ms. Santiago-Soto had been convicted of any federal offense.[5] *Id.*

Respondent's counsel then asked the DI if there was any official Web site or registry where a pharmacist can verify if a DEA number is active. *Id.* at 74. The DI testified that there is such a registry, that he ''believe[d]'' that the registry was available in 2009 through 2011 and was located at the DEA Diversion Web site, and that he believed that if a person was registered, they could access the Web site. *Id.* Subsequently, the DI testified that he could confirm that the registry has been available since 2009, but ''[t]o [his] knowledge . . . physicians have been informed at least from 2010, [and] that she should have been able to do that.'' *Id.* at 75–76. However, later in his testimony, Government counsel raised the possibility that this service had been discontinued, when he asked the DI: ''But you're not aware of when it started, and when it stopped?'' and the DI answered: ''That is correct.'' *Id.* at 92.

Respondent's counsel then asked the DI ''why the DEA site, as of today, states that you cannot verify a DEA number online?'' *Id.* at 76. The DI replied: ''[t]hat is new to me.'' *Id.* Respondent's counsel then asked if he could show a document to the DI which, according to the proffer, was from the Agency's Web site and was contrary to the DI's testimony. *Id.* at 76–78. The ALJ barred Respondent's counsel from doing so even for the purpose of impeachment, explaining that his prehearing orders were clear that if documents ''were not presented to the Government, in advance of the hearing,'' he would not ''allow it.'' *Id.* at 77.

Respondent's counsel then asked the DI if, in order to verify a DEA number, one had to pay for a program. *Id.* at 78–79. The DI answered that this was correct but that that ''if there are [sic] any reason to verify, you can call our office at any time, and you can ask for a verification.'' *Id.; see also id.* at 92. Next, when asked if ''the law requires that any dispensing pharmacist calls the DEA to verify if a physician's license is active,'' the DI answered ''yes.'' *Id.* at 79. When then asked what statute or agency regulation requires this, the DI could not identify one. *Id.* at 79–80. Moreover, the DI then testified that there is no law or regulation that requires a pharmacy to subscribe to the database provided by the National Technical Information Service. *Id.* at 80.

Still later, when asked if ''it is the responsibility of the doctor [to have] a valid DEA license when prescribing a controlled substance,'' the DI answered: ''It is the responsibility of both the doctor and the pharmacist. The pharmacy has the responsibility.'' *Id.* at 86–87. The DI then acknowledged that the prescriptions in Government Exhibit 3 contained the required information and that he could not identify a prescription that was ''suspicious or irregular without knowing that the physician's license has been revoked or expired.'' *Id.* at 87–88. However, on re-direct examination, the DI explained that the Suboxone prescriptions were suspicious because they did not include an X number for the physician. *Id.* at 90–91.

Respondent's counsel then asked whether he had ''any evidence'' that Ms. Santiago-Soto ''ha[d] acted with the intention or knowledge'' in dispensing either Dr. Aguilar's or Dr. Vargas' prescriptions. *Id.* at 88. The DI answered that he did not ''base [his] evaluations on intentions'' but ''on the documents'' that he had ''seen.'' *Id.*

Also on redirect, the DI was asked whether part of the process of granting the applications of pharmacies involves ''explaining to the pharmacies that they have the burden to verify all prescriptions.'' *Id.* at 91. The DI answered ''that is correct,'' and agreed

[4] *See* Drug Addiction Treatment Act of 2000, Pub. L. 106–310, Div. B, Title XXXV, § 3502(a), 114 Stat. 1222 (2000) (codified at 21 U.S.C. 823(g)(2)).

[5] Contrary to the ALJ's understanding, this was an undue restriction on Respondent's right of cross-examination, especially given that the answer was not responsive.

Later in the proceedings, the Government called Respondent's owner in its case-in-chief. *Id.* at 106. During cross-examination, the Government objected to Ms. Santiago-Soto's testimony (well after the question was asked and well into her answer) regarding a conversation she had in April 2012 with the group supervisor on the ground that it was ''[o]utside the scope of the pre-hearing statement'' and ''[t]here [was] no proffer that they were going to be introducing testimony from DEA agents.'' Tr. 134. The ALJ sustained the objection on the ground that ''it goes beyond the scope of what you informed in the amended pre-hearing statement.'' *Id.*

Here again, the ALJ erred in sustaining the objection. Even if Respondent's pre-hearing statements did not disclose that Ms. Santiago-Soto would testify regarding this issue, its pre-hearing statement only limited the scope of what she could testify to on direct examination in Respondent's case-in-chief and had no bearing on the appropriate scope of cross-examination given that Ms. Santiago-Soto was still testifying as a Government witness. Moreover, the Government did not argue that the testimony was beyond the scope of its direct examination.

that this is a requirement for maintaining a DEA registration ''under the code of regulations.'' *Id.*

Still later in his testimony, when no question was pending, the DI proceeded to state that even aside from the Suboxone prescriptions, the 241 prescriptions at issue were suspicious because they were for oxycodone and alprazolam, which are highly abused drugs. *Id.* at 95–96. The DI then explained that ''if physicians regularly prescribe those drugs only, those should be of concern to any pharmacist who is . . . trying to ensure the public health and safety.'' *Id.* at 96. The Government did not produce any evidence, however, to show that these were the only drugs which were being prescribed by Dr. Aguilar-Amieva and being filled by Respondent.

The Government also called Ms. Santiago-Soto as a witness. Tr. 105. Ms. Santiago-Soto acknowledged that she has been Respondent's owner and pharmacist-in-charge since she opened the pharmacy.[6] *Id.* at 106. Asked by the Government whether the pharmacy had filled ''241 prescriptions for Dr. Aguilar-Amieva from February 2009 to October 2009,'' Ms. Santiago-Soto answered ''yes.'' *Id.* However, when asked whether she knew ''that his registration had been revoked in January of 2009,'' Ms. Santiago-Soto answered that she ''didn't know'' at the time.[7] *Id.* at 106–07.

Next, the Government asked Ms. Santiago-Soto whether she ''believe[d] that it's your duty to verify all prescriptions''; she replied: ''That's what I do all the time.'' *Id.* at 107. The Government then asked Ms. Santiago-Soto why she had filled Dr. Aguilar-Amieva's prescriptions ''if that's what you do all the time?'' *Id.* Ms. Santiago-Soto replied:

> Well to start with, I'm a pharmacist. And I revise [sic] prescriptions, and I make sure that the indications are correct, are the adequate ones, that they meet all standards and legal requirement [sic], whether they be federal or state laws.
>
> Once all those standards are met, and there is no question surrounding the prescription that might prompt me to call the physician for whatever reasons, then we proceed to dispense it.

Id. at 107–8.

Ms. Santiago-Soto then acknowledged that Respondent filled the twenty-nine Suboxone prescriptions issued by Drs. Aguilar-Amieva and Vargas-Quinones and that she was not aware that neither doctor was a DATA-waiver physician. *Id.* at 108. When asked whether Respondent had ever contacted the two doctors to verify the purpose of these prescriptions, Ms. Santiago-Soto answered:

> I verified the exhibit that you . . . gave me. . . . And if you take a look at the Suboxone prescriptions, in their majority, they have a diagnosis that is related to the abuse of opioids, or opiates.
>
> Therefore, it was my understanding that these physicians had their license current, including some prescriptions that were invoiced to health insurance plans, and they were paid by these, even after they were reviewed.
>
> So, supposedly, that if the health insurance plan hires a physician, all the credentials should be up to date. And if they didn't come to notice this, and with them being the health insurance plan, when they are usually up to date on everything, then it was my understanding that the prescriptions were okay.

Id. at 109. When then asked what her understanding was of who could prescribe Suboxone to treat substance-abuse patients, Ms. Santiago-Soto answered that she ''was aware of the use given to the medication'' and that ''[i]f you go prescription by prescription . . . the amounts are not such that would raise my suspicions that something is running amok.'' *Id.* at 109–10. She then reiterated that, at the time, she ''was not aware of the X DEA number'' that is required to prescribe Suboxone and buprenorphine to treat narcotic-dependent patients. *Id.* at 110.

Upon questioning by the Government, Ms. Santiago-Soto acknowledged that a DATA-waiver physician must meet certain requirements and that ''not all physicians may prescribe'' Suboxone, and that a physician who prescribes Suboxone for this purpose must have an X-number. *Id.* The Government then asked Ms. Santiago-Soto why she did not know this when she ''became accredited as a pharmacist?'' *Id.* Ms. Santiago-Soto explained that she graduated in 1995, that the DATA was enacted in 2000, and that Suboxone and buprenorphine were not approved for this purpose until 2002. *Id.* She then contended that ''the DEA in Puerto Rico never has provided any guidance to her whether through an orientation or conference, online guidance, or by letters.'' *Id.* She further asserted that in none of the continuing education classes that she was required to take to maintain her pharmacist license was there any training offered by DEA on the DATA's requirements. *Id.* at 111.

Ms. Santiago-Soto testified that she did not become aware of the DATA's requirements until Respondent was audited by a health insurance plan and the buprenorphine prescriptions were discussed with her.[8] *Id.* at 112. However, she acknowledged that she should have learned of these requirements earlier. *Id.* at 114. After describing what she was taught at pharmacy school about spotting diversion, *id.* at 114–16, the Government asked Ms. Santiago-Soto whether she found ''anything suspicious with Dr. Aguilar-Amieva's prescriptions?'' *Id.* at 116. She replied:

> The prescriptions met all legal parameters. The patients would come over to the drug store, and the ones that I did dispense, their reputation wasn't in doubt, in my judgment, because many of them would also bring me prescriptions of their medications that they took for continuous use.

Id.

The Government then asked Ms. Santiago-Soto whether she analyzed the prescribing practices of a physician for signs of diversion when filling a prescription. *Id.* at 117. Ms. Santiago-Soto replied:

> I don't speak with the doctors. There is a confidentiality law between doctor and patient. I review that the prescription meets the law and that it shouldn't raise the least suspicion possible in me, that this medication is not intended, particularly intended for this patient, for medical use.

Id. at 117. When then asked whether she ''went through [Respondent's] computer system looking for patterns,'' Ms. Santiago-Soto answered that she ''kept a manual inventory and . . . from it I couldn't necessarily discern that something was out of place.'' *Id.* at 119. She then explained that in 2009, she dispensed a total of 30,000 prescriptions (including 27,000 for non-controlled drugs), of which 66 had been written by

[6] Ms. Santiago-Soto testified that she had worked at four other pharmacies prior to opening Respondent. Tr. 139–40. She also testified that Respondent had been inspected by the Commonwealth's Health Department and the AMSCA, which is the Commonwealth agency that regulates controlled substances, and that she held the licenses required by the Commonwealth. Tr. 141–42. She further testified that Respondent had been inspected twice by DEA and had provided the DIs with both prescriptions and a list of various controlled medications that it had dispensed; according to Ms. Santiago-Soto, she was never notified that her pharmacy had engaged in any wrongdoing. *Id.* at 143.

[7] The Government's evidence does not establish that Dr. Aguilar-Amieva's registration had been revoked, in which case a Decision and Order would have been published in the **Federal Register**. *See* GX 6. Rather, the Government's evidence shows that Dr. Aguilar-Amieva's registration expired on June 30, 2008 and was retired from the DEA computer system on January 31, 2009. *See id.*

[8] Ms. Santiago-Soto denied that she had not learned about the DATA's requirements until after being served with the Show Cause Order. Tr. 112. Ms. Santiago-Soto testified that the insurance plan audit occurred several months before the search warrant was executed at her pharmacy. *Id.* at 113. It is noted that the Government's evidence shows that Respondent did not dispense any Suboxone prescriptions after July 3, 2011. GX 4, at 23–24.

Dr. Aguilar-Amieva.[9] *Id.* She further stated that Dr. Aguilar-Amieva's prescriptions did not raise any suspicion. *Id.* at 122.

Turning to the application, Ms. Santiago-Soto acknowledged that she understood both questions two and three.[10] *Id.* at 123–24. When then asked whether she had surrendered her DEA registration for cause in November 2011, Ms. Santiago-Soto replied: ''In my judgment, I surrendered the license, but not with cause.'' *Id.* at 124. She then explained that:

> . . . . In my judgment, this is simple. When I surrendered my license, it was in a situation where I was under arrest, and I had no other choice but to sign the document that was placed in front of me.
>
> Moreover, at the moment of having to sign the document, an agent came out speaking or yelling, ''was her rights read to Yanira Santiago, was her Miranda rights''—and just before I signed that paper that said ''surrender,'' I had my Miranda rights read. And I was practically signing simultaneously.
>
> Agent [P.N.], from the Ponce DEA, explained to me that I had to sign that surrender because of the criminal charges against me. And not because of what I'm being told of here.
>
> * * * * *
>
> I'm handcuffed, and I had to sign a document that they demand from me to sign because I had no other option. Because, according to what they were saying, I was part of a scheme.
>
> When I proceed to answer this questions [sic] that is posed in the new application and quote/unquote, it puts the words ''with cause.''
>
> It's my understanding, as of this day, that I surrendered the license without cause, because it was taken away from me because of my criminal case [an]d not because of what I'm being told here.

Id. at 124–26. *See also id.* at 132 (''I signed the document, because he told me that I had to surrender the license because of a criminal charge against me.'').

Ms. Santiago-Soto then explained that when she filled out the application ''that question raised doubts in my mind.'' *Id.* at 126. Accordingly, the next day, she called ''the regional director for the DEA in Ponce[11] . . . and . . . told her . . . that I was unsure if I had answered the question correctly'' and that she had ''answered 'no,' because, quote/unquote, it said 'with cause.' '' *Id.* Ms. Santiago-Soto further testified that the official said ''that she would look into it and verify if that was answered correctly, because she didn't know. And she also told me that, since I had informed her about it, eventually, if any situation came up, she could appear as a witness and say that I had that doubt, and I had asked her about it, and that she had answered me.'' *Id.* at 126–27. Ms. Santiago-Soto testified that she memorialized the conversation in an email. *Id.* at 127. However, as of the date of the hearing, the official had not replied to the email. *Id.* at 136.

The Government then asked Ms. Santiago-Soto ''if you had to fill this application out again today, what would you put for the Question No. 3?'' *Id.* at 128. Ms. Santiago-Soto replied:

> I would answer it the same way. I would answer the same thing. Because of the statement ''with cause,'' if that statement wouldn't have been there, I would have no reason to answer ''no.'' I would've answered ''yes.'' Because I surrendered.
>
> But since it stated, in parentheses, ''with cause,'' that's not my issue. Because I surrendered my DEA license because of the criminal case against me. Not because of this intervention right now, that we're having today.

Id.

Throughout her testimony, Ms. Santiago-Soto maintained that she did not voluntarily surrender Respondent's registration, but rather was coerced into surrendering it. *Id.* at 132. She also testified that the various prescriptions which form the basis of the allegations regarding the dispensing violations were taken from Respondent on the date she was arrested. *Id.* at 135–36.

Upon the conclusion of Respondent's cross-examination of Ms. Santiago-Soto, Respondent's counsel attempted to move into evidence a copy of the email which she had sent to the group supervisor and explained that he had shown a copy of the email to the Government. *Id.* at 137. The ALJ denied the motion, explaining: ''That may be true, Counsel, but I don't have it. It's not evidence before me. I don't have any reason to understand why it wasn't presented ahead of time, so I could evaluate it.'' *Id.* at 137–38.

As found above, the email appears to have been relevant to the issue of whether Ms. Santiago-Soto falsified Respondent's application. And contrary to the ALJ's on the record explanation for denying the motion, there was ample reason for why the document was not ''presented ahead of time.'' Specifically, the ALJ ignored that the Government did not provide any notice that it intended to litigate the issue of material falsification until its supplemental pre-hearing statement, which it filed one week before the hearing, and on which date Respondent was also required to file its supplemental pre-hearing statement. Moreover, the ALJ's June 18 order did not address what procedure Respondent was required to follow in the event the Government raised an entirely new allegation at this stage of the proceeding. *See* ALJ Ex. 7. Finally, the document was not included with the transmitted record as a rejected exhibit as it should have been. *See* 21 CFR 1316.60.

Ms. Santiago-Soto also testified in Respondent's case-in-chief. Ms. Santiago-Soto testified that prior to her arrest on November 30, 2011, she had been inspected twice by DEA. Tr. 142–43. The first of these inspections occurred on September 2, 2010; the second on September 7, 2011. RXs G & H. While Agency Investigators apparently reviewed the controlled-substance prescriptions and her dispensing records, they never notified her of ''any findings or wrongdoings on'' the part of Respondent. Tr. 143. Nor did they advise that Dr. Aguilar-Amieva or any other doctor was under investigation. *Id.* at 144.

Ms. Santiago-Soto further testified that there is a ''question and answer section'' on the DEA diversion Web site which includes a question regarding whether the Agency can verify a DEA registration. *Id.* at 145–46. According to Ms. Santiago-Soto, ''the answer that the DEA gives . . . is 'no' '' and that she has to buy a program from the National Technical Information Service ''to be able to have access on several occasions to that registry.'' *Id.* at 146. Ms. Santiago-Soto further testified that it ''costs over $2,000 on an annual basis . . . for one user.'' *Id.* However, she then explained that she would buy the program if she is issued a registration. *Id.* at 146–47. Still later, she testified that the NTIS is ''costly for a drugstore that's just starting out'' and that she did not ''know of any small community pharmacy that has purchased'' a subscription to the NTIS database, ''because the law does not require that it be purchased.'' *Id.* at 149. However, she reiterated that she would purchase the database. *Id.; see also id.* at 154–55. Moreover, Ms. Santiago-Soto testified that if she was granted a registration, she would be willing to consider any

[9] In Respondent's case in chief, Ms. Santiago-Soto testified that Respondent dispensed 104 prescriptions in 2010 and 63 prescriptions in 2011 which were issued by Dr. Aguilar-Amieva. Tr. 151.

[10] Question three asks whether ''the applicant [has] ever surrendered (for cause) or had a state professional license or controlled substances registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' GX 1, at 1. There is no evidence, however, that the Commonwealth took any of these actions against Respondent's (or Ms. Santiago-Soto's) professional license or controlled substance registration. Thus, it is unclear why Ms. Santiago-Soto was asked about this question rather than question four.

[11] I have taken official notice that the official is actually a group supervisor.

recommendations made by the Agency. *Id.* at 155.

Regarding the allegation that she dispensed prescriptions written by Dr. Aguilar-Amieva, whose registration had expired, Ms. Santiago-Soto explained that she had reviewed the DEA Pharmacist's Manual, and that while the Manual contains extensive information as to what must be provided on a prescription, ''[n]owhere in the law am I told that I have to be checking each one of the licenses at every moment.'' *Id.* at 148. She also testified that during the period at issue, she ''would check the list of those physicians that had been criminally charged because of their prescriptions,'' *id.,* and that if the name of a doctor was not on the list, she ''proceeded to dispense the prescription.'' *Id.* at 161.

However, neither Dr. Aguilar-Amieva nor Dr. Vargas-Quinones appeared on the various lists for the years 2008 through 2013.[12] *Id.* at 148–49. Finally, Ms. Santiago-Soto denied that she had ever knowingly dispensed a prescription which had not been lawfully issued. *Id.* at 154.

Following the conclusion of Ms. Santiago-Soto's testimony, Respondent's counsel requested that the ALJ take official notice of various documents, including the Web page containing various questions and answers which Respondent's counsel had previously sought to use to impeach the testimony of the DI to the effect that Ms. Santiago-Soto could have verified whether the physicians were registered by calling DEA. Tr. 162–67. After the ALJ asserted that the document's ''relationship to the narrative . . . attributed to'' Respondent should have been clear to its counsel when she filed its amended pre-hearing statements, Respondent's counsel again argued that it had no ''knowledge that the witness for the DEA would provide testimony . . . under oath, that contradicts the information the DEA provided on that Web page.'' *Id.* at 167. However, the ALJ again rejected Respondent's request. *Id.*

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied upon a determination ''that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the CSA requires the consideration of the following factors:

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

(2) The applicant's experience in dispensing . . . 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.

Id.

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied.'' *Id.* Moreover, I am not required to make findings as to all of the factors.[13] *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005).

Under Section 304(a)(1), a registration may be revoked or suspended ''upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.'' 21 U.S.C. 824(a)(1). Under agency precedent, the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See The Lawsons, Inc.,* 72 FR 74334, 74337 (2007); *Anthony D. Funches,* 64 FR 14267, 14268 (1999); *Alan R. Schankman,* 63 FR 45260 (1998); *Kuen H. Chen,* 58 FR 65401, 65402 (1993). Thus, the allegation that Respondent materially falsified its application is properly considered in this proceeding. *See The Lawsons,* 72 FR at 74337; *Samuel S. Jackson,* 72 FR 23848, 23852 (2007). Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *The Lawsons,* 72 FR at 74338; *cf. Bobby Watts, M.D.,* 58 FR 46995 (1993).

In this matter, the Government alleged that Ms. Santiago-Soto materially falsified Respondent's application for registration by failing to disclose that it had previously surrendered its prior registration for cause. Gov. Post-Hearing Br., at 6–9. It also alleged that Respondent's registration is inconsistent with the public interest because it violated 21 U.S.C. 843(a)(2), as well as 21 CFR 1306.04 and 1306.06, when: (1) Between February 2009 and October 2009, it filled 241 prescriptions which were issued by Dr. Aguilar-Amieva, whose registration had been retired by the Agency; and (2) it filled Suboxone prescriptions issued by Dr. Aguilar-Amieva and Dr. Vargas-Quinones to treat narcotic addiction, when neither doctor was authorized under Federal law to do so. *See* Gov. Post-Hearing Br., at 11–12.

The Material Falsification Allegation

The Government argues that Ms. Santiago-Soto materially falsified Respondent's application for registration because she failed to disclose the November 30, 2011 surrender of its registration. More specifically, the Government contends that Ms. Santiago-Soto materially falsified the application, when she provided a ''no'' answer to question two, which asked: ''Has the applicant ever surrendered (for cause) or had a federal controlled substances registration revoked, suspended,

[12] On cross-examination by the Government, Ms. Santiago-Soto acknowledged that these lists may actually have been of those physicians who were subjected to administrative proceedings. Tr. 158. When the Government suggested that her review of these lists was inadequate because they were lists of final agency actions and would not ''contain the names of doctors that voluntarily surrendered'' their registrations, Ms. Santiago-Soto replied that ''I can't make any supposition, as you've been telling me. You're asking me to suppose something, and I'm not here to suppose anything. I'm here with facts. I'm being shown facts. So I have to answer with facts.'' *Id.*

However, upon questioning by the ALJ, Ms. Santiago-Soto admitted that if a doctor who voluntarily surrendered his registration was not identified on the Web site, she ''wouldn't know'' that the doctor did not have the requisite authority. *Id.* at 161–62.

[13] I have considered Respondent's evidence that it is currently licensed by the Commonwealth of Puerto Rico as a pharmacy and holds a registration from the Commonwealth which authorizes it to dispense controlled substances. I have also considered Respondent's evidence that the Pharmaceutical Board took no action against Ms. Santiago-Soto's pharmacist's license. However, none of these documents constitute a recommendation from the state licensing board as to whether DEA should grant the application, *see* 21 U.S.C. 823(f)(1), and while Respondent clearly possesses authority to dispense controlled substances under the laws of the Commonwealth and thus meets a prerequisite for obtaining a registration, this finding is not dispositive of the public interest inquiry.

So too, I acknowledge that neither Respondent, nor Ms. Santiago-Soto, has been convicted of an offense under either federal or Puerto Rico law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, while the charges against Ms. Santiago-Soto were dismissed, this finding is not dispositive of the allegations that Respondent filled unlawful prescriptions because this proceeding involves different allegations than those brought in the criminal proceeding and is subject to a lower standard of proof (the preponderance standard) than that applied in a criminal proceeding.

restricted or denied, or is any such action pending?'' Gov. Br. at 7 (citing GX 1, at 1). Moreover, in its post-hearing brief, the Government contends—for the first time in the proceeding—that Ms. Santiago-Soto also materially falsified the application when she provided a ''no'' answer to question four, which asked: ''If the applicant is a corporation . . . or pharmacy . . . has any officer, partner, stockholder or proprietor . . . ever surrendered or had a federal controlled substances registration revoked, suspended, restricted, or denied . . . .?'' *Id.* at 8. I reject the allegations.

One of the fundamental tenets of Due Process is that an Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB* v. *I.W.G., Inc.* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc.* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990). Because the Government did not allege in the Order to Show Cause that Respondent had materially falsified its application, before proceeding to address whether the evidence supports the Government's contention, it is necessary determine whether the Government otherwise provided adequate notice of its intent to litigate the issue. *See* 5 U.S.C. 554(b) (''Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.'').

'' 'Pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law.' '' *Aloha Airlines* v. *Civil Aeronautics Bd.,* 598 F.2d 250, 262 (D.C. Cir. 1979) (quoted in *CBS Wholesale Distributors,* 74 FR 36746, 36749 (2009)); *accord Citizens State Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984). Accordingly, ''the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive and an issue can be litigated if the Government otherwise timely notifies a [r]espondent of its intent to litigate the issue.'' *CBS Wholesale,* 74 FR at 36570. Thus, while the Agency has held that ''the parameters of the hearing are determined by the prehearing statements,'' consistent with numerous court decisions, it has also recognized that even where an allegation was not raised in either the Show Cause Order or the pre-hearing statements, the parties may nonetheless litigate an issue by consent. *Pergament United Sales,* 920 F.2d at 135–37; *see also Duane* v. *Department of Defense,* 275 F.3d 988, 995 (10th Cir. 2002) (discussing *Facet Enterprises, Inc.* v. *NLRB,* 907 F.2d 963, 974 (10th Cir. 1990); ''we held that defendant had constructive notice of an alternate theory of liability not described in the formal charge when the agency detailed that theory during its opening argument and at other points during the hearing and when the defendant's conduct revealed that it understood and attempted to defend against that theory'').[14]

''The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.'' *Pergament United Sales,* 920 F.2d at 135 (citation omitted). While the issue of whether an allegation ''has been fully and fairly litigated [by consent] is so peculiarly fact-bound as to make every case unique,'' *id.* at 136, ''the simple presentation of evidence important to an alternative [allegation] does not satisfy the requirement'' that a respondent be afforded with a full and fair opportunity to litigate the alternative allegation. *I.W.G.,* 144 F.3d at 688 (quoting *NLRB* v. *Quality C.A.T.V., Inc.,* 824 F.2d 542, 547 (7th Cir. 1987) (other citation omitted)).

''An agency may not base its decision upon an issue the parties tried inadvertently. Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue.'' *Yellow Freight System, Inc.* v. *Martin,* 954 F.2d 353, 358 (6th Cir. 1992) (citation omitted). Accordingly, where the Government's case ''focus[es] on another issue and [the] evidence of [an] uncharged violation [is] 'at most incidental,' '' the Government has not satisfied its constitutional obligation to provide a full and fair opportunity to litigate the issue and it cannot rely on the incidental issue as the basis for imposing a sanction. *Pergament,* 920 F.2d at 136 (quoting *NLRB* v. *Majestic Weaving Co.,* 355 F.2d 854, 861–62 (2d Cir. 1966)).

In its initial Pre-Hearing Statement, the Government again failed to allege that the application was materially false. Nor, in summarizing the testimony of its proposed witnesses therein, did the Government provide notice that it intended to put forward any evidence which would lead Respondent to conclude that the material falsification of its application was an issue in the case.

Instead, the Government did not provide notice that it intended to litigate the issue of whether the application contained a material falsification until its Supplemental Pre-Hearing Statement, which was not filed until one week before the evidence-taking phase of the proceeding convened. Even then, the Supplemental Pre-Hearing Statement did not identify which specific statements on the applications were allegedly false. Rather, the Supplemental Pre-Hearing Statement merely stated that ''Ms. Soto will be asked about the circumstances of the pharmacy's prior surrender of its DEA certificate of registration, and about her failure to note the previous surrender on Respondent's new application for registration.'' ALJ Ex. 7, at 3. Because the Government's Supplemental Pre-Hearing Statement did not specifically identify which of the various application statements it was alleging to be materially false, only those issues which the record shows were litigated by consent can support a finding (if proved by substantial evidence) that Ms. Santiago-Soto materially falsified the application and the imposition of a sanction.

Notably, while at the evidentiary phase of the hearing the Government made an opening statement, here again, it did not identify the specific statements which were allegedly false. Rather, it confined its opening statement to the following: ''Your Honor, the Government seeks a recommendation of a denial of application based on Sections 823 and 824 of the Controlled Substances Act, on the basis of a material falsification on the application, and the fact that Respondent's registration would be inconsistent with the public interest.'' Tr. 39.

Moreover, in questioning both the DI and Ms. Santiago-Soto, the Government did not elicit any testimony regarding Question Four. Rather, it focused entirely on the answers Ms. Santiago-Soto had given to Question Two, and, notwithstanding that there was no evidence that the Commonwealth of Puerto Rico had taken any action against either Respondent or Ms. Santiago-Soto, Question Three. *See* Tr. 45 (testimony of DI that Respondent's application

[14] *See also Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44077 n.23 (2012) (holding that while the Government did not provide adequate notice of its intent to litigate an allegation in either the Show Cause Order or its pre-hearing statements, where respondents ''did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it'' and ''fully litigated the issue,'' the allegation was litigated by consent) (citing *Citizens State Bank,* 751 F.2d at 213; *Kuhn* v. *Civil Aeronautics Bd.,* 183 F.2d 839, 841–42 (D.C. Cir. 1950); and *Yellow Freight System, Inc.* v. *Martin,* 954 F.2d 353, 358 (6th Cir. 1992)).

contained a falsification at ''Question Number 3''); *id.* at 123–24 (Government's questioning of Ms. Santiago-Soto regarding Questions Two and Three). Indeed, it was not until its post-hearing brief that the Government finally argued that Ms. Santiago-Soto had provided a materially false answer to Question Four. This, however, is simply too late in the day to provide a meaningful opportunity to refute the allegation. *See Pergament United Sales,* 920 F.2d at 135.[15]

Thus, I hold that the Government provided adequate notice to support a finding that the parties litigated by consent the issue of whether Ms. Santiago-Soto's answer to Question Two was materially false. However, I further hold that the record does not support a finding that the parties litigated by consent whether her answer to Question Four was also materially false.

Turning to the merits of the allegation pertaining to Question Two, the evidence showed that on November 29, 2011, Ms. Santiago-Soto was indicted (along with thirty-two other persons) on two felony counts of violating the Controlled Substance Act, including: (1) By conspiring to possess and dispense, with intent to distribute, various controlled substances, in violation of 21 U.S.C. 841(a)(1), 846, and 860; and (2) by aiding and abetting each other and ''knowingly and intentionally possess[ing] and dispens[ing] with intent to distribute various'' schedule II through IV controlled substances, ''outside the scope of professional practice and not for a legitimate medical purpose,'' in violation of 21 U.S.C. 841(a)(1) and 18 U.S.C. 2. RX B, at 1–13.

On November 30, 2011, Ms. Santiago-Soto was arrested early in the morning and taken to her pharmacy where, after receiving the Miranda warnings, she was told by P.N., a DI,[16] that she had to surrender her registration ''because of the criminal charges against'' her and that she ''had no other options'' because she was ''part of a scheme.'' Tr. 125–26. The evidence further showed that Ms. Santiago-Soto executed a Voluntary Surrender form, which was witnessed by P.N. (as well as another DI). RX I. This form stated that she had been ''fully advised of my rights, and understood that I am not required to surrender my controlled substance privileges,'' and that ''[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part'' she was ''voluntarily surrender[ing] my . . . Certificate of Registration.'' *Id.*

As found above, the DI who testified for the Government did not personally participate in the arrest of Ms. Santiago-Soto and did not witness the events surrounding her execution of the Voluntary Surrender form. Tr. 60–61. Nor did the Government call as a witness any other person who witnessed the execution of the surrender form. Thus, there is no evidence that, at the time she surrendered Respondent's registration, Ms. Santiago-Soto was confronted with any allegations of misconduct aside from those which comprised the criminal case.

Subsequently, the U.S. Attorney moved to dismiss *with prejudice* both of the charges against Ms. Santiago-Soto. RX C. On March 23, 2012, the District Court granted the Government's motion and entered a Judgment of Dismissal and discharged her. *Id.* The consequence of this was that the charges could not be refiled against her.

The Government nonetheless argues that Ms. Santiago-Soto ''could not under any reasonable circumstances have answered the relevant liability questions . . . in the negative'' and that she ''placed undue emphasis on the words 'for cause' in liability question #2.'' Gov. Post-Hrng. Br., at 7. The Government further notes Ms. Santiago-Soto's claim that she signed the surrender form ''under duress.'' *Id.*

I need not decide whether surrendering a registration under duress constitutes a valid defense to a charge of material falsification of Question Two or whether the facts here would support such a defense.[17] This is so because I find unpersuasive the Government's contentions that Ms. Santiago-Soto could not have reasonably answered Question Two in the negative and that she ''placed undue emphasis on the words 'for cause.' ''

As for the latter contention, Ms. Santiago-Soto was only required to answer Question Two as it was written on the application and not as it otherwise could have been written (such as without those words). Indeed, the Government does not explain how Ms. Santiago-Soto could have ''placed undue emphasis on the words 'for cause,' '' when those words were part of the question and the application contains no explanation of what the term ''surrender for cause'' means.

There is no Agency regulation which defines the term ''for cause'' as it is applied in the context of an application for registration. However, two regulations do define the term in the context of imposing requirements on practitioners in the employment of persons who handle or have access to controlled substances, *see* 21 CFR 1301.76(a), as well as on manufacturers and distributors (among others) in the employment of persons who will have access to listed chemicals. *See* 21 CFR 1309.72(a). Under these provisions, ''the term 'for cause' means a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal actions resulting from an investigation of the handling of controlled substances or listed chemicals.'' 21 CFR 1301.76(a); *id.* at 1309.72(a).

However, even if this definition was applied to Respondent's application, it would offer no support to the Government. Here, there is no evidence that Ms. Santiago-Soto was advised that if she did not surrender the registration, Respondent would face an Order to Show Cause. Thus, she did not surrender the registration ''in lieu of'' a hearing. Moreover, while she had been indicted prior to the surrender, there is no evidence that she surrendered the registration in lieu of facing the criminal charges, which were not dismissed until several months later.[18]

Notably, Ms. Santiago-Soto's testimony that she was told that she had to surrender her registration because of her involvement in a criminal scheme stands unrefuted, and there is no evidence that, at the time of the surrender, she was told by Agency personnel that the Agency was alleging additional violations of the CSA or DEA

[15] Indeed, even if an allegation could be refuted without further factual development because it involves a matter of law, because DEA proceedings customarily require the parties to file their post-hearing briefs simultaneously (as was done here), there is no meaningful opportunity to respond prior to the issuance of an ALJ's recommended decision.

[16] In her testimony, Ms. Santiago-Soto referred to this person as an Agent; however, on the Voluntary Surrender form, this person signed as a witness and listed his title as ''Diversion Investigator.'' RX I.

[17] Of consequence, Question Two did not ask whether Respondent had ''ever voluntarily surrendered (for cause)'' but only if it had ''ever surrendered (for cause)'' its registration. GX 1, at 1. Moreover, notwithstanding that Ms. Santiago-Soto was under arrest at the time she surrendered Respondent's registration, in signing the Voluntary Form, she acknowledged that she had been ''fully advised of [her] rights'' and understood that she was ''not required to surrender my controlled substances privileges''; she then acknowledged that she was ''freely execut[ing]'' the form and ''choos[ing] to'' voluntarily surrender her registration. RX I.

[18] Nor does the evidence support a finding that she surrendered the registration as a consequence of the criminal action. Ms. Santiago-Soto did not surrender the registration as part of a pre-trial diversion agreement, a plea agreement, or as part of a sentence imposed by a court. Rather, the criminal case against Ms. Santiago-Soto was dismissed with prejudice.

regulations beyond the offenses for which she was indicted.[19] Moreover, the consequence of the district court's dismissal of the charges ''with prejudice,'' on motion of the Government (and apparently before trial), was that she could be not re-charged for the same offenses. Under these circumstances, a layperson could, in good faith, conclude that there was no basis for both the charges and the DI's demand that she surrender her registration, and given the absence of any definition of the limiting term, a layperson could also, in good faith, conclude that she had not surrendered her registration ''for cause.'' [20]

Even had I concluded otherwise, I would hold that there are mitigating circumstances that substantially diminish the egregiousness of the alleged misconduct. Ms. Santiago-Soto testified that the day after she submitted the application, she contacted the Diversion Group Supervisor and explained to her that she answered the question ''no'' and ''was unsure if [she] had answered the question correctly'' because the question used the words ''with cause.'' Tr. 126. Ms. Santiago-Soto also testified that the Group Supervisor told her that she did not know, but that she would look into it and get back to her. *Id.* at 126–27. Ms. Santiago-Soto further testified that she had memorialized the conversation in an email to the Group Supervisor. *Id.* at 127. However, the Group Supervisor did not respond to her. *Id.* Notably, all of this testimony was unrefuted by the Government.

While the ALJ acknowledged this testimony in his summary of the testimony, *see* R.D. at 5–6, in his discussion of whether Ms. Santiago-Soto had materially falsified the application, he entirely ignored it and offered no explanation for why he apparently rejected it even as a mitigating circumstance. *Id.* at 27–28. However, in concluding that Ms. Santiago-Soto had materially falsified the application, the ALJ repeatedly noted that Santiago-Soto had also provided a ''no'' answer to Question Four, which does not use the words ''for cause'' to modify the scope of surrenders which must be disclosed. *Id.* at 27–29. Moreover, in his earlier summary of the testimony, the ALJ noted that ''[t]here is no evidence indicating that Ms. Santiago-Soto also inquired about Question Four during her conversation with'' the Group Supervisor, *id.* at 5, and that in her testimony, she did not address her answer to Question Four. He also explained that the Group Supervisor ''did not testify at the hearing, and [that] neither party sought such testimony.'' *Id.* The ALJ further observed that ''the record before me does not include a copy of'' the email which Ms. Santiago-Soto testified she had sent to the Group Supervisor. *Id.* at 6.

Thus, it appears that the ALJ rejected Santiago-Soto's testimony regarding the phone call and email to the Group Supervisor because she did not claim to have asked about Question Four. However, to the extent this is an accurate discernment of the ALJ's unexplained reasoning, it not surprising that there is no evidence as to why Ms. Santiago-Soto answered Question Four as she did. This is so because the Government never asked her why she did, nor otherwise adequately put her on notice that her answer to this question was at issue in the proceeding.[21]

This, however, is not the only problematic aspect of the ALJ's failure to adequately explain why he gave no weight to Ms. Santiago-Soto's testimony regarding the phone call she made to the Group Supervisor. As explained above, the ALJ's decision also suggests that he gave no weight to her testimony because the Group Supervisor was not called to testify and the email was not part of the record.

As for the failure to obtain the Group Supervisor's testimony, Respondent was not required to call the Group Supervisor in order to establish that her testimony was credible. As for the ALJ's observation that the email is not part of the record, it should have been (indeed, notwithstanding the Agency's regulation, which requires that an ALJ forward a rejected exhibit to the Administrator's Office, it was not). As found above, the ALJ allowed the Government to delay filing its supplemental prehearing statement until one week before the hearing and imposed the same deadline on Respondent. Moreover, the ALJ failed to provide any direction to Respondent as to what steps it must take in the event the Government raised an entirely new allegation at this state of the proceeding and wished to present evidence to refute the allegation.

As for the ALJ's on-the-record explanation that the email had to be presented ''ahead of time, so [he] could evaluate it,'' Tr. 138, this begs the question: Evaluate it for what? Even in jury trials (where there is a manifest to need to protect the factfinder from being misled or confused), judges routinely rule from the bench on the admissibility of evidence. And here, where there is no jury, the ALJ could have evaluated this evidence at the same time he evaluated the testimony. Finally, the Government offered no objection to the email; nor could it reasonably claim prejudice given that it waited until one week before the hearing to finally make the allegation. Under these circumstances, I conclude that the ALJ's refusal to admit the email was arbitrary and capricious.

I further reject the ALJ's findings that Ms. Santiago-Soto materially falsified Respondent's application when she provided a ''no'' answer to Question Two and Four. R.D. at 29, 30–31. I further reject the ALJ's Conclusions of Law with respect to this issue. *See id.* at 35.

Factors Two and Four—The Applicant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

With respect to Factors Two and Four, the Government made two allegations. First, it alleged that ''from February 2009 to October 2009,'' Respondent ''filled approximately 241 prescriptions'' which were issued by Dr. Aguilar-Amieva, after his registration had been retired by the Agency. Gov. Post-Hrng. Br., at 11. The Government alleged that this ''conduct violated 21 U.S.C. 843(a)(2), 21 CFR 1306.04 and 1306.06.'' *Id.* Second, it alleged that Respondent filled twenty-nine Suboxone prescriptions, which were issued by both Dr. Aguilar-Amieva and Dr. Vargas-Quinones, neither of whom were authorized to prescribe this drug to

[19] It is acknowledged that on the Voluntary Surrender form the box was checked which indicates that Ms. Santiago-Soto surrendered Respondent's registration ''[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances.'' RX I. However, the Voluntary Surrender form did not list (nor is there a space to list) what those alleged failures were. *See id.* Given the absence of any evidence that at the time the surrender occurred, Ms. Santiago-Soto was told of additional allegations against her, the Voluntary Surrender form does not refute her testimony that because the criminal case was dismissed, she did not believe that she had surrendered for cause.

[20] The Government does not argue that the mere fact that she was indicted was sufficient to place her on notice that she had surrendered her registration for cause.

[21] For this reason, in testifying regarding the phone call, Ms. Santiago-Soto had no obligation to address whether she had also discussed her answer to Question Four with the Group Supervisor.

In its Post-Hearing Brief, the Government asserts that Ms. Santiago-Soto's ''failure to testify on this question supports an adverse inference that she knew the statement was false.'' Gov. Post-Hrng. Br., at 8. The Government ignores that it called Ms. Santiago-Soto to testify in its case in chief and could have—but failed to—ask her about her answer to Question Four. Nor did the Government, at any time prior to filing its Post-Hearing Brief, provide notice to Santiago-Soto that her answer to Question Four was at issue. I therefore hold that the Government is not entitled to an adverse inference regarding her answer to Question Four.

treat narcotic addiction. *See id.* at 11–12. The Government alleged that this conduct also violated 21 U.S.C. 843(a)(2), 21 CFR 1306.04 and 1306.06.

Allegation One—Respondent's Filling of Prescriptions Issued By A Physician Who Was No Longer Registered

As found above, the evidence showed that Dr. Hector J. Aguilar-Amieva's registration expired on June 30, 2008 and was retired from the DEA computer system on January 31, 2009. GX 6. The evidence, which was not objected to, further showed that Respondent filled more than two hundred controlled-substance prescriptions which were issued by Dr. Aguilar-Amieva from February 2, 2009 through August 8, 2011.[22] GX 4.

Except for in limited circumstances which are not implicated here, the Controlled Substances Act requires that ''[e]very person who dispenses . . . any controlled substance [ ] shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.'' 21 U.S.C. 822(a)(2).[23] Moreover, under a DEA regulation, ''[a] prescription for a controlled substance may be issued only by an individual practitioner who is: (1) [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) [e]ither registered or exempted from registration pursuant to 1301.22(c) and 1301.23 of this chapter.'' 21 CFR 1306.03(a). Also, it is ''unlawful for any person knowingly or intentionally . . . to use in the course of the . . . dispensing of a controlled substance . . . a registration number which is fictitious, revoked, suspended, expired, or issued to another person.'' 21 U.S.C. 843(a)(2). Thus, it is clear (and undisputed) that Dr. Aguilar-Amieva repeatedly violated the CSA by issuing controlled-substance prescriptions using his expired registration number.

The issue in this matter, however, is whether liability can be imposed on Respondent because its principal filled Dr. Aguilar-Amieva's prescriptions. As explained above, the Government contends that Respondent's conduct violated section 843(a)(2); the Agency's corresponding responsibility rule, *see* 21 CFR 1306.04(a); as well as a further regulation, 21 CFR 1304.06. Contrary to the Government's understanding, its evidence does not support a finding that Respondent violated any of the three provisions in dispensing these prescriptions.

As explained above, section 843(a)(2) imposes criminal liability on any person who uses, in the course of dispensing a controlled substance, an expired registration number. While no case has been cited by the Government where a pharmacist has been convicted of violating this provision because it filled prescriptions issued by a physician whose registration had expired, given that a prescription provides the lawful authority for a pharmacist to dispense a controlled substance, *see* 21 U.S.C. 829(a) & (b), it is clear that a pharmacist can held liable for dispensing a controlled substance prescription issued by a physician who no longer holds a registration. However, the statute imposes liability only where a pharmacist does so knowingly or intentionally. *See* 21 U.S.C. 843(a)(2).

As for 21 CFR 1306.04(a), it requires that a controlled substance prescription ''be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice'' and imposes ''a corresponding responsibility'' on the pharmacist who fills a prescription which was not issued ''in the usual course of professional treatment.'' However, here again, the regulation imposes liability only on a ''person *knowingly* filling such a purported prescription.'' *Id.* (emphasis added).

While the plain language of both of these provisions requires proof that a pharmacist dispensed a prescription knowing that the issuer lacked the requisite authority, the Government produced no evidence that Ms. Santiago-Soto knew (or was even willfully blind) to the fact that Dr. Aguilar-Amieva did not hold a DEA registration. Indeed, while in its brief the Government argues that Ms. Santiago-Soto admitted that Respondent had filled the prescriptions, Ms. Santiago-Soto expressly denied that she knew that Aguilar-Amieva's registration ''had been revoked in January 2009.'' Tr. 106–07.[24] Thus, although it is true that Ms. Santiago-Soto admitted that Respondent had filled the prescriptions, her admission satisfies the Government's evidentiary burden only with respect to showing that the dispensings occurred. Moreover, when asked whether he had any evidence that Ms. Santiago-Soto had ''acted with the intention or knowledge [of] illegal activity when dispensing Dr. Aguilar's . . . prescriptions,'' the DI gave an unresponsive answer, stating that he did not ''base [his] evaluations on intentions,'' and when asked a follow-up question, the ALJ interjected (without the DI even answering the question): ''I'll take it as a no.'' Thus, I hold that the Government did not prove that Ms. Santiago-Soto acted with the requisite knowledge to sustain a violation of either 21 U.S.C. 843(a)(2) or 21 CFR 1306.04(a), with respect to this allegation.

The Government also alleged that Respondent's filling of the 241prescriptions violated 21 CFR 1306.06. In relevant part, this regulation provides that ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06. Thus, on its face, this regulation does not require proof of knowledge to sustain a violation.

However, the regulation does require that the Government establish what the standards of pharmacy practice require, through either expert testimony or by reference to federal or state laws, pharmacy board or Agency regulations, or decisional law (whether of administrative bodies or the courts). Here, while the Government's evidence establishes that Respondent dispensed some 241 controlled substance prescriptions over a period of approximately thirty months, which were written by a physician who was not registered, the Government did not put on any expert testimony establishing that pharmacists have a duty to verify the registration status of the prescribers whose prescriptions they fill. Nor did the Government cite to any other rule or decision imposing such a duty.

Notwithstanding that the Government neither produced any evidence establishing that the usual course of professional practice requires that a pharmacist verify the registration status of prescribers, nor cited any law, regulation, or other authority, which imposes such a requirement, the ALJ found that when ''she filled these prescriptions[,] Ms. Santiago-Soto failed

[22] At the hearing, Respondent did not challenge the admission of this evidence on the ground of lack of foundation. Nor did it raise such a challenge in its Exceptions. Notably, the only Government witness to testify did not participate in the execution of the search warrant and did not specifically identify the prescriptions submitted by the Government as those which were seized when the warrant was issued. Moreover, the prescription labels (which were apparently affixed to the back of the prescriptions), do not identify Respondent as the dispensing pharmacy. Nor did the Government submit any documentary evidence tending to establish that the prescriptions were those which were seized from Respondent.

[23] *See* 21 U.S.C. 822(c); 21 CFR 1301.22.

[24] The quotation is from the Government's question. The Government's evidence did not establish that the Agency had revoked Dr. Aguilar-Amieva's registration, but only that Aguilar-Amieva let his registration expire after which his number was retired from the DEA registrant database. Had Aguilar-Amieva's registration been revoked, an order doing so would have been published in the **Federal Register** and on the Agency's Web site.

to conform to regulations relating to the distribution of controlled substances and failed to act in the usual course of professional pharmacy practice.'' R.D. at 34. Apparently, this was based on the ALJ's earlier conclusion that ''[o]ne way or another, pharmacists *must ensure* that they are filling only those controlled substance prescriptions that have been written by persons registered with the DEA. A pharmacy applicant who fails to appreciate the need to verify DEA credentials of prescribing doctors (either by contacting the DEA [25] or subscribing to a private verification service) demonstrates a lack of experience material to the application.'' *Id.* at 23 (emphasis added). Thus, the ALJ applied a standard of strict liability in concluding that Ms. Santiago-Soto had ''failed to act in the usual course of professional pharmacy practice.'' *Id.* at 34.

Contrary to the ALJ's understanding, no Agency regulation requires that a pharmacist ascertain that each prescription presented to him/her has been issued by a practitioner who possesses a valid DEA registration and the Agency expressly disclaimed the existence of such a duty in 2010, when it promulgated its Interim Final Rule on Electronic Prescriptions for Controlled Substances. *See* 75 FR 16236, 16266 (2010). Therein, the Agency noted that it had proposed requiring pharmacies ''to confirm that the [prescriber's] DEA registration . . . was valid at the time'' the prescription was signed. *Id.* However, several commenters objected ''that pharmacies are not required to check DEA registrations for paper prescriptions unless they suspect something is wrong with a prescription.'' *Id.*

In its response (which appears to be missing pertinent text), the Agency stated that it ''agrees with those commenters that expressed the view that, when filling a paper prescription, it is not necessary for a pharmacist who receives an electronic prescription for a controlled substance to check the CSA database in every instance to confirm that the prescribing practitioner is properly registered with DEA.'' *Id.* The Agency thus removed the requirement from the Interim Final Rule, but ''made clear that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of the [CSA] and DEA regulations, including the requirement that the prescribing practitioner be properly registered.'' *Id.* However, as explained above, the corresponding responsibility does not impose strict liability on pharmacists but rather requires proof that a pharmacist filled a controlled-substance prescription either knowing that it was unlawful or with willful blindness or deliberate ignorance of the fact that the prescription was unlawful.[26]

Accordingly, I reject the ALJ's reasoning as contrary to the published guidance of the Agency. And because the Government failed to put forward either: (1) any evidence to show that Ms. Santiago-Soto either knew or was willfully blind to the fact that Dr. Aguilar-Amieva was no longer registered, or (2) any evidence or legal authority establishing that Ms. Santiago-Soto acted outside of the usual course of professional practice, I reject the Government's contention that Respondent violated federal law and DEA regulations in filling these prescriptions.

Allegation Two—Respondent's Filling of Suboxone Prescriptions

Regarding this allegation, the evidence shows that Respondent filled twenty-nine Suboxone prescriptions, which were issued by Dr. Aguilar-Amieva and Dr. Vargas-Quinones, *see* GX 4, at 23–24; and Ms. Santiago-Soto admitted that a majority of the prescriptions (17 of the 29) listed ''a diagnosis that is related to the abuse of opioids[] or opiates.'' Tr. 108. It was undisputed that neither Dr. Aguilar-Amieva nor Dr. Vargas-Quinones was qualified to prescribe Suboxone to treat narcotic addiction. *See* GX 6, at 1 & 5.

A physician who seeks to prescribe Suboxone (or other schedule III through V drugs approved by FDA) for maintenance or detoxification treatment must meet certain conditions (including that the physician either holds various certifications or has training or experience in the management of opiate-dependent patients) and must provide a notification (which includes various certifications) to the Secretary of the Department of Health and Human Services, who must then determine (within 45 days from the date of receipt of the notification) whether the physician meets the requirements for a waiver under 21 U.S.C. 823(g)(2)(B). 21 CFR 1301.28(a)–(d). If the practitioner holds ''the appropriate registration'' and the Secretary either makes ''a positive determination'' or fails to act within the 45 day period, DEA issues an identification number, which is otherwise known as an X-number to the practitioner. *Id.* § 1301.28(d)(1); *see also* Tr. 48–49.

Moreover, under DEA's regulation:

A prescription may not be issued for ''detoxification treatment'' or ''maintenance treatment,'' unless the prescription is for a

[25] Based on the testimony of the DI, the ALJ found that ''[i]n order to determine whether a medical provider is authorized by the DEA to prescribe controlled substances, a pharmacist may contact the DEA by telephone and inquire.'' R.D. 31 (FoF #13); *see also id.* at 23 (''Although it might be a cumbersome and time-consuming verification process, the DEA does permit a pharmacist to call into a field office to confirm the status of a given prescribing source.''). However, as found above, the ALJ barred Respondent from using a Question and Answer printout from the DEA Web page to impeach the DI's testimony to this effect, reasoning that the Respondent was required to disclose this document in advance of the hearing. Tr. 164.

It is true that under the Agency's rule, a party is generally required to provide a copy of any proposed exhibit which is being offered as substantive evidence in the matter. However, contrary to the ALJ's understanding, a party is not required to disclose, in advance of the hearing, a document which is being used to impeach a witness. I therefore reject this finding.

As for the NTIS database, the ALJ acknowledged that subscribing to this service is expensive. However, he then opined that ''[i]t is no answer to complain that the NTIS program costs a lot of money; nor is it a sufficient legal response to argue that DEA regulations do not require pharmacists to purchase the program.'' R.D. at 23. To the extent this comment might be understood as creating an obligation on all pharmacies to subscribe to this service, it is rejected. While it was not fully developed on the record of this proceeding, DEA provides a web tool which allows a registrant to verify the registration of another person or entity.

[26] Notwithstanding the Agency's pronouncement in the Interim Rule, the Agency's corresponding responsibility rule is not the only potential basis for finding a violation where a pharmacist dispenses a controlled substance prescription issued by a practitioner who does not hold the requisite authority. Upon a showing that such conduct is outside of ''the usual course of professional practice,'' 21 CFR 1306.06, a pharmacist may be held to have violated DEA regulations and to have committed acts which render her pharmacy's registration inconsistent with the public interest.

Moreover, in *Medicine Shoppe—Jonesborough,* 73 FR 364, 381 (2008), the ALJ found that a pharmacist had filled a large number of controlled-substance prescriptions which were issued by a veterinarian who did not hold either a state license or DEA registration. The ALJ further found that this conduct constituted such other conduct which may threaten public health and safety, reasoning, in part, that a pharmacy has a duty to periodically verify whether a prescriber retains authority to practice medicine and dispense controlled substances. I found a violation of 21 CFR 1306.04(a), based on the evidence that the prescriptions were being presented on a daily basis by the veterinarian's brother and were for drugs that were toxic for certain animals. However, in dictum, I noted that ''[a] pharmacy has a duty to periodically check to see that a practitioner retains the authority to practice medicine and dispense a controlled substance.'' *Id.* at n.45. I also noted my agreement with the ALJ's reasoning that failing ''to do so could threaten public health and safety because there is usually a good reason for why a practitioner has lost his or her state license and DEA registration.'' *Id.*

The Government does not rely on this theory and no case (until recently) has presented the question of how frequently a pharmacy must re-verify the credentials of prescribers. Nor has the Agency published any guidance to the regulated community setting forth the parameters of this duty. What is clear, however, is that a pharmacy is not required to verify the credentials of the prescriber for every prescription it fills.

Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment *and the practitioner is in compliance with requirements in § 1301.28 of this chapter.*

21 CFR 1306.04(c) (emphasis added).

So too, pursuant to 21 CFR 1306.05(b), ''[a] prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for 'detoxification treatment' or 'maintenance treatment' *must include* the identification number issued by the Administrator under 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of [21 CFR] 1301.28(e).'' [27] (emphasis added). This information is in addition to the prescriber's DEA registration number. *See* 21 CFR 1306.05(a). Also, under 21 CFR 1306.05(f), ''[a] corresponding liability rests upon the pharmacist . . . who fills a prescription not prepared in the form prescribed by DEA regulations.'' However, none of the Suboxone prescriptions issued by either Dr. Aguilar-Amieva or Dr. Vargas-Quinones bore either an X number or a statement that the physician was ''acting under the good faith exception.'' *See* GX 3, at 410–456.

The Government contends that Respondent violated, *inter alia,* 21 CFR 1306.04 and 1306.06, because it ''does not contest that [it] acted outside the usual course of professional practice'' when it dispensed the Suboxone prescriptions. Gov. Post-Hrng. Br., at 12. Contrary to the Government's understanding, Ms. Santiago-Soto made no such admission and the Government put forward no evidence as to what the usual course of professional practice requires of a pharmacist who is presented with prescriptions that are clearly marked as being issued for the purpose of providing maintenance or detoxification treatment for narcotic-dependent patients and yet are missing the requisite X number or good faith statement.

However, the evidence does establish that Ms. Santiago-Soto violated 21 CFR 1306.05(f) when she filled at least seventeen of these prescriptions.[28] With respect to the seventeen Suboxone prescriptions which contained a notation by the doctor that he had diagnosed the patient as being opioid dependent, Ms. Santiago-Soto knew that the prescriptions were issued to provide either maintenance or detoxification treatment.[29] Moreover, notwithstanding the clear requirement that the prescriptions include (in addition to the prescriber's DEA number), either his DATA-waiver identification number or the practitioner's statement that he was ''acting under the good faith exception of § 1301.28(e),'' none of the prescriptions contained either an X-number or the good faith statement.

In her testimony, Ms. Santiago-Soto maintained that she ''was not aware'' that the X number had to be on the prescription ''for that medication in particular,'' Tr. 110, and that she ''was not aware that buprenorphine [the generic name for Suboxone] fell among the medications that required the X DEA number.'' *Id.* at 112. However, Ms. Santiago-Soto did know that the purpose of most of the Suboxone prescriptions was to treat narcotic addiction. And as explained above, under the Agency's regulation, a prescription could not be issued for a Schedule III through V controlled substance such as Suboxone for this purpose unless the drug was approved by FDA for this purpose and the practitioner met the requirements for prescribing for this purpose.

Accordingly, her testimony does not establish that she made a mistake of fact but rather that she was ignorant of the regulations. This, of course is not a defense. *See United States* v. *International Minerals & Chem. Corp.,* 402 U.S. 558, 563 (1971) (''The principle that ignorance of the law is no defense applies whether the law be a statute or a duly promulgated and published regulation.'').

Indeed, Ms. Santiago-Soto's testimony regarding the allegation was most unpersuasive. More specifically, Ms. Santiago-Soto testified that she had graduated from pharmacy school in 1995, and that the DATA law was passed in 2000, but after 2002, when Suboxone was approved by FDA for the purpose of treating narcotic addiction, ''the DEA in Puerto Rico never has provided any orientation or guidance online, or by way of a conference, or through continuing education, or by letters, letting me know, or providing me these kinds of guidelines.'' Tr. 110.[30]

However, in 2003, the Agency published in the **Federal Register** a notice of proposed rulemaking, and in 2005, the Agency published its final rule, which promulgated the various provisions set forth above, including 21 CFR 1301.28 (requirements for obtaining an X-number and the good faith exception), 21 CFR 1306.04(c) (prohibiting a prescription for maintenance or detoxification treatment unless the drug has been approved by FDA for this purpose and the practitioner is in compliance with 1301.28), 21 CFR 1306.05(a) (requiring that such prescription include either the prescriber's X number or a good faith statement), and 21 CFR 1306.07 (allowing a practitioner to administer, dispense or prescribe a Schedule III through V drug specifically approved by FDA for use in maintenance or detoxification treatment if the practitioner complies with 1301.28). *See* DEA, *Authority for Practitioners to Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment,* 70 FR 36338 (2005); *see also* DEA, *Authority for Practitioners to Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment,* 68 FR 37429 (2003) (Notice of Proposed Rulemaking). Indeed, prior to the 2005 issuance of the final rule, no narcotic controlled substance *could be prescribed* by a physician (including those authorized to conduct a narcotic treatment program under 21 U.S.C. 823(g)(1)) to treat narcotic addiction and no pharmacy could have lawfully

[27] The good faith exception applies only during the period before the practitioner receives his X-number from the Agency and only if ''[t]he Secretary has not notified the registrant that he/she is not qualified'' to provide such treatment. 21 CFR 1301.28(e).

[28] While the Government alleged that Respondent violated 21 CFR 1306.04 in filling the Suboxone prescriptions, it did not identify the specific subsection which it alleges was violated. *See* Gov. Post-Hrng. Br. at 12. Notably, in contrast to subsection a of this regulation, which imposes a corresponding responsibility on a pharmacist to not knowingly fill a prescription that is issued outside of the usual course of professional practice and which lacks a legitimate medical purpose, subsection c impose duties only on the issuer of the prescription which has been issued to provide maintenance or detoxification treatment. *See* 21 U.S.C. 1306.04(c). However, as explained above, 21 CFR 1306.05(f), imposes ''[a] corresponding liability . . . upon the pharmacist . . . who fills a prescription not prepared in the form prescribed by DEA regulations.''

[29] I do not find any violations with respect to those prescriptions which did not contain a diagnosis of narcotic dependence. Under federal law, a doctor may prescribe a drug for a legitimate off-label use and absent evidence that the prescriptions, which lacked a diagnosis of narcotic dependence, were actually being issued for this purpose, I do not find a violation proved. The Government offers no argument to the effect that a doctor cannot prescribe Suboxone for any legitimate medical purpose unless they have X-number. Nor did it offer evidence that when a pharmacist is presented with a Suboxone prescription that does not list a diagnosis and lacks an X number, the standards of professional practice require the pharmacist to call the physician and determine the purpose of the prescription.

[30] The Government offered no evidence regarding the contents of the package insert for Suboxone and whether it contained any special instructions regarding the prescribing and dispensing of Suboxone following the FDA's approval of the drug for use in providing maintenance or detoxification treatment.

dispensed such a prescription. *See id.* at 37429.

As the 2003 Notice of Proposed Rulemaking explained:

> [t]he Controlled Substances Act (CSA) and current regulations requires that practitioners who want to conduct maintenance or detoxification treatment using narcotic (opioid) controlled drugs be registered with DEA as narcotic treatment programs (NTPs) in addition to the practitioners' personal registrations. The separate NTP registrations authorize the practitioners to dispense or administer, but not prescribe narcotic (opioid) controlled drugs.

Id. The Notice also observed that ''[o]n October 8, 2002, FDA approved two products containing buprenorphine, [S]ubutex and [S]uboxone, Schedule III controlled drugs, for use in maintenance and detoxification treatment,'' and that the proposed rule would ''[p]ermit pharmacies to fill prescriptions for Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.'' *Id.* at 37430.

The dispensing of controlled substances is a highly regulated industry, and as a participant in this industry, Ms. Santiago-Soto is properly charged with knowledge of the applicable regulations, including: (1) The requirement that a Suboxone prescription, which has been issued to provide treatment for opiate addiction, can only be issued by a person who meets the requirements of 21 CFR 1301.28; as well as (2) that the prescription must bear either the prescriber's X-number or the good faith statement. *See International Minerals,* 402 U.S. at 565 (where ''dangerous or deleterious . . . products . . . are involved, the probability of regulation is so great that anyone who is aware that he is in possession of them or dealing with them must be presumed to be aware of the regulation''); *United States* v. *Southern Union Co.,* 630 F.3d 17, 31 (1st Cir. 2010) (''[T]hose who manage companies in highly regulated industries are not unsophisticated. It is part of [their] business to keep abreast of government regulation.'') (citing *United States* v. *Lachman,* 387 F.3d 42, 56–57 (1st Cir. 2004)), *rev'd on other grounds,* 132 S.Ct. 2344 (2012).

I therefore find that Ms. Santiago-Soto knowingly dispensed the seventeen Suboxone prescriptions which were issued for maintenance or detoxification purposes in violation of federal law by the respective physicians and thus also violated federal law in doing so. 21 CFR 1306.04(c); *see also* 21 U.S.C. 841(a)(1). While it is true, as Ms. Santiago-Soto testified, that the amounts of most of the prescriptions were limited (most being for ten tablets or less), there were also two prescriptions for sixty tablets issued to the same patient, which contained a diagnosis of opiate dependence. Thus, I am not persuaded by her testimony ''that the amounts are not such that would raise my suspicions that something is running amok.'' Tr. 109–10.

However, Ms. Santiago-Soto testified that she had become aware of the DATA of 2000 during an audit by a health insurance plan, which occurred months before she was arrested and surrendered her registration, and that she then went online and familiarized herself with the statute's requirements. Tr. 112. Most significantly, the Government's own evidence shows that Respondent dispensed the last Suboxone prescription on July 3, 2011, nearly five months before Ms. Santiago-Soto was arrested and surrendered its registration.[31] *See* GX 4, at 23–24. Finally, in her testimony, Ms. Santiago-Soto demonstrated some degree of knowledge of the requirements pertaining to the prescribing of Suboxone to identify those prescriptions which do not comply with the DATA requirements and should not be dispensed. Tr. 110.

Thus, while I conclude that the Government has proved that Respondent committed acts which are ''inconsistent with the public interest,'' 21 US.C. § 823(f), I also find that there are several factors which mitigate the violations.

Sanction

Under Agency precedent, where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must '' 'present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration.' '' '' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

While a registrant must accept responsibility and demonstrate that it will not engage in future misconduct in order to establish that its registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2010) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009). So too, the Agency can consider the need to deter similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

As found above, the only allegation sustainable on the record is that Respondent filled seventeen Suboxone prescriptions that were issued to provide maintenance or detoxification treatment by two physicians who were not DATA-waived physicians. As explained above, I find that Ms. Santiago knowingly violated federal law by dispensing these prescriptions because the purpose of the prescriptions was clearly identified on them and none of the prescriptions had the physician's

[31] It is also noted that Respondent had stopped dispensing these prescriptions two months before a DEA inspection which occurred on September 7, 2011. *See* RX H. While DEA had also inspected Respondent on September 2, 2010, *see* RX G, as of that date, Respondent had dispensed but a single prescription (only three days earlier) for fourteen tablets. GX 4, at 23–24. No evidence was put forward by the Government as to whether this prescription was discussed with Ms. Santiago-Soto.

identification number or the requisite good faith statement. Moreover, the Government's interest in deterring pharmacists from dispensing Suboxone prescriptions, which have been issued to treat narcotic-dependent patients by physicians, who lack the requisite qualifications to treat such patients, is manifest.

Regarding these violations, Respondent's evidence of its acceptance of responsibility was less than unequivocal. While Ms. Santiago-Soto admitted that she was aware that the prescriptions were issued to treat substance abuse patients and that she should have learned about the requirements applicable to the prescribing of Suboxone for this purpose earlier than she did, she also attempted to minimize her misconduct by attributing it to the failure of the DEA office in Puerto Rico to provide any guidance to her regarding the requirements. DEA did, however, publish, in the **Federal Register**, both a Notice of Proposed Rulemaking and a Final Rule, which provided legally sufficient notice that Suboxone could only be prescribed for maintenance or detoxification purposes by a qualified physician, and that such a physician was required to either list his identification number or provide a good faith statement on the prescriptions.

Yet, while Ms. Santiago-Soto is presumed to have knowledge of the applicable regulations and thus violated federal law in dispensing those Suboxone prescriptions which bore a diagnosis indicating that they were issued to treat narcotic addiction, the egregiousness of her misconduct is diminished by two factors. First, the violations were limited in scope, as the total amount of the unlawful dispensings was 224 tablets. Second, Ms. Santiago-Soto had determined, prior to the Agency's bringing it to her attention, that the Suboxone prescriptions were illegal, and at the time she surrendered Respondent's registration, had long since ceased the offending practice.[32]

In its Exceptions, Respondent argues that the ALJ's recommended sanction of denial ''is drastic and overly broad.'' Exceptions at 15. It argues, *inter alia,* that the Agency ''could grant a license with a monetary sanction or provide in its determination that it can be issued after a determined period of additional time''; it also argues that it ''is willing to undertake and place into action any diverse measures the DEA requires as a condition for approving the'' application. *Id.* at 16.

''Proceedings under sections 303 and 304 of the CSA are . . . non-punitive.'' *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (citing *Leo R. Miller,* 53 FR 21931, 21932 (1988)). As the Agency previously recognized, ''this proceeding 'is a remedial measure, based upon the public interest and the [need] to protect the public from those individuals who have misused their'' registrations and ''who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility'' attendant with holding a registration. *Id.* (quoting *Miller,* 53 FR at 21932).

I agree with Respondent that the outright denial of its application is not supported by the record and that its application can be granted ''after a determined period of additional time,'' subject to Respondent meeting various conditions. First, while I acknowledge Ms. Santiago-Soto's testimony as to the steps she took to familiarize herself with the requirements pertaining to the prescribing of Suboxone, she also testified that while she reviews a prescription to ensure that it meets legal requirements and is not suspicious, she does not ''speak with the doctors'' because ''[t]here is a confidentiality law between doctor and patient.'' Tr. 117. While the Government did not address the validity of this statement in its post-hearing brief, it is flatly inconsistent with long-standing authority setting forth the scope of a pharmacist's corresponding responsibility under the Controlled Substances Act. *See, e.g., United States* v. *Hayes,* 595 F.2d 258, 260 (5th Cir. 1979); *see also Medicine Shoppe—Jonesborough* v. *DEA,* 300 Fed. App'x 409, 412 (6th Cir. 2008) (quoting *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990) (''When [pharmacists'] suspicions are aroused as reasonable professionals,' they must at least verify the prescription's propriety, and if not satisfied by the answer they must 'refuse to dispense.' '')). Accordingly, I will order that Ms. Santiago-Soto take a course on controlled substance dispensing and the corresponding responsibility of a pharmacist under federal law. Said course must be completed and a certificate of such completion must be presented to the Agency prior to the granting of Respondent's application.

I will further order that Respondent's application be held in abeyance for six months from the date of this order (not the date of publication) at which time, its application shall be granted provided Respondent has provided evidence to DEA that Ms. Santiago-Soto has completed the above-described course and commits no violation of federal or commonwealth controlled substance laws. If, however, Ms. Santiago-Soto fails to provide evidence that she has completed such course within the six-month period, Respondent's application shall be denied.

Upon the granting of the registration, Respondent shall be placed on probation for a period of three years. During the period of the probation, Respondent and its principal shall agree to consent to unannounced inspections by DEA personnel and shall waive its right to require DEA personnel to obtain an Administrative Inspection Warrant prior to conducting an inspection. Ms. Santiago-Soto shall provide a letter to DEA manifesting Respondent's consent to unannounced inspections by DEA and waiving its right to require DEA personnel to obtain an Administrative Inspection Warrant prior to the issuance of its registration.

Respondent shall provide a copy of its controlled substance dispensing log on a quarterly basis to the DEA Ponce Office. Said quarters shall end on March 31st, June 30th, September 30th, and December 31st of each year, and the log shall be provided to the DEA Ponce Office no later than ten (10) calendar

[32] In rejecting Respondent's evidence of remediation, the ALJ faulted Ms. Santiago-Soto for testifying that DEA ''maintained information on its Web site that is contradictory to what the Diversion Investigator said during the hearing.'' R.D. at 29. Given that the ALJ improperly precluded Respondent from using a printout from the Agency's Web site to impeach the DI, there is no basis for this finding.

The ALJ further found that there is ''scant evidence that Ms. Santiago-Soto has engaged in a course of conduct that would ensure that she remains properly informed about changes in DEA controlled substance regulations.'' *Id.* at 30. Continuing, he explained that ''[t]here was no suggestion that she would accept responsibility for keeping up with changes in the DATA-waived list in the future, for example.'' *Id.* There is, however, no evidence in the record that a DATA-waived list exists, whether maintained by DEA or any other agency.

It may be that the ALJ actually meant to say that he does not believe that Ms. Santiago-Soto will properly verify that the issuers of Suboxone prescriptions for addiction treatment will have the requisite qualifications. If this was the ALJ's intent, it is refuted by his acknowledgment—one page earlier in his decision—of Ms. Santiago-Soto's testimony that she would subscribe to the NTIS service and that ''[t]his would appear to be an effective remedial step [which] possibly could lessen the risk of filling prescriptions for Suboxone if the prescribing provider was not a DATA-waived'' physician. *Id.* at 29. (Indeed, I have taken official notice that the DEA registration validation web-tool provides this information. *See* 21 CFR 1316.59(e)). Moreover, the ALJ entirely ignored Ms. Santiago-Soto's testimony (which is corroborated by the Government's evidence), that following the audit by a health plan, she reviewed the requirements applicable to prescribing Suboxone to treat narcotic addiction, and the evidence that she had ceased dispensing the Suboxone prescriptions long before DEA raised this as an issue with her. *See* R.D. at 29–30.

days following the last day of each quarter.

Respondent and Ms. Santiago-Soto shall notify the DEA Ponce Office of any disciplinary action undertaken against its pharmacy license and Puerto Rico controlled substance registration, as well as any action taken against Ms. Santiago-Soto's pharmacist license, including the initiation of any proceeding by the Commonwealth's authorities to suspend or revoke any of the licenses or registration. Such notification shall occur no later than three business days following service on Respondent or Ms. Santiago-Soto of any document initiating such a proceeding, any interim or emergency order of suspension, and any final order.

The above conditions shall terminate upon Respondent's completion of the period of probation, provided Respondent fully complies with each term of its probation. Any violation of these conditions shall constitute an act inconsistent with the public interest and grounds for the suspension or revocation of Respondent's registration.

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 Farmacia Yani be, and it hereby is, held in abeyance for a period of six months to begin on the date of this ORDER. I further order that upon the conclusion of the six-month period, the Application of Farmacia Yani shall be granted or denied as set forth above. I also order that in the event that Ms. Santiago-Soto complies with the condition that she complete a course in controlled substance dispensing and the corresponding responsibility, Farmacia Yani's Application shall be granted subject to the probationary conditions set forth above. This ORDER is effective immediately.

Dated: May 12, 2015.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–62]

Jana Marjenhoff, D.O.; Decision and Order

On June 24, 2014, Chief Administrative Law Judge (ALJ) John J. Mulrooney, Jr., issued the attached Recommended Decision.[1] Respondent filed Exceptions to the Decision.

Having reviewed the entire record, including Respondent's Exceptions, I have decided to adopt the ALJ's findings of fact,[2] conclusions of law, and recommended order, except as discussed below. A discussion of Respondent's Exceptions follows.

Exception One—Whether Respondent Was Denied Adequate Notice Because the ALJ Relied on Matters That Were Not Raised in the Order To Show Cause

Respondent argues that her rights under the Due Process Clause and the Administrative Procedure Act were violated because in the Show Cause Order, the Government alleged only that Respondent forged eight prescriptions and the ALJ proceeded to rely on ''other matters of fact to support'' his recommendation. Exceptions, at 2. Respondent does not, however, identify the specific facts of which she believes she was denied adequate notice, but rather, simply asserts that ''the matters determined by the ALJ to support findings against Respondent as to factors four and five were not previously raised in the Order to Show Cause.'' *Id.* at 3.

To the extent Respondent takes issue with the ALJ's decision because the Show Cause Order alleged only eight instances of forgery rather than the ten instances that the ALJ found proved (as well as the instance in which Respondent filled the first prescription a second time at a second pharmacy), her argument is not well taken. However, to the extent Respondent takes issue with the ALJ's finding that Respondent engaged in conduct actionable under factor five because she attempted to obstruct the pharmacist who questioned her prescription from contacting PA Francis, her argument is well taken.

One of the fundamental tenets of Due Process is that an Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc.* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990); *see also* 5 U.S.C. 554(b) (''Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact *and law* asserted.'') (emphasis added).

However, '' '[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.' '' *Aloha Airlines* v. *Civil Aeronautics Bd.,* 598 F.2d 250, 262 (D.C. Cir. 1979) (quoted in *CBS Wholesale Distributors,* 74 FR

[1] All citations to the Recommended Decision (hereinafter, cited as R.D.) are to the slip opinion as issued by the ALJ.

[2] I do not adopt the ALJ's findings that hydrocodone combined with acetaminophen is a schedule III controlled substance. *See, e.g.*, R.D. at 5 n.12; *id.* at 20 n.42. While that was correct at the time of the underlying events, as well as on the date of the issuance of the Recommended Decision, this drug has since been placed in schedule II of the Controlled Substances Act. *See Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II,* 79 FR 49661 (2014).

I also do not adopt the ALJ's finding that the dispensing event which occurred on March 15, 2011 was based on a hard copy prescription which was dated March 11, 2011, or that the March 11 prescription was presented to different pharmacies on three occasions. *See* R.D. at 22–25. Rather, I find that the March 15 prescription was based on a telephone prescription which was dated March 15, 2014. *See* GX 6, at 3; GX 8, at 5. As for the hard copy prescription which the ALJ cited as the evidence to support this finding, I find the date to be illegible. However, this finding does not alter the disposition of this matter because I adopt the ALJ's finding that PA Francis, whose prescribing authority was used to obtain the prescriptions, credibly denied having issued Respondent any controlled substance prescriptions after the initial controlled substance prescription she issued on February 14, 2011. *See* R.D. at 55.

While I adopt the ALJ's finding that the testimony of Malana Diminovich, who testified that the PA had issued the controlled substance prescriptions, was not credible, as explained in my discussion of Respondent's fourth exception, I do not rely on his reasoning to the extent it is based on the suggested inconsistency between Diminovich's testimony that ''Respondent was never observed to be under the influence of controlled substances during the time the two worked together'' and ''that she was aware that . . . Respondent was receiving controlled substance prescriptions from PA Francis.'' *Id.* at 30–31.

In his decision, the ALJ found that ''the only evidence received on the issue supports the Respondent's claim that she had an objective medical basis that could arguably have supported the prescribing of controlled substances,'' *Id.* at 62. Given the ALJ's findings, it is notable that the record is devoid of evidence as to whether patients who are taking narcotics for legitimate pain would necessarily manifest symptoms consistent with abuse or intoxication.

In any event, the Government's case primarily focused on Respondent's obtaining of controlled substances through fraud or misrepresentation such as by presenting forged prescriptions. Thus, resolution of the allegations does not require proof that Respondent was abusing the controlled substances.

Also, I do not adopt the ALJ's findings related to the dates of the phone call in which Dr. Edmonds confronted Respondent as to whether she was forging prescriptions which were purportedly authorized by PA Francis. In the decision, the ALJ referred to this phone call as occurring in July 2011, following Respondent's positive urinalysis for opiates. *See* R.D. at 39. The evidence is clear, however, that this conversation did not occur in response to the July 2011 drug test, but in September 2011, after a pharmacist had notified PA Francis about the prescriptions and the latter had presented a printout from the State Prescription Monitoring Program to the clinic's Human Resources Manager, who raised it with Dr. Edmonds. *See* Tr. 195–202; 368; 831–32.