therefore the opportunity to present evidence to refute the Government's showing that he/she has committed acts which render his/her registration ''inconsistent with the public interest,'' 21 U.S.C. 823(f), and the only evidence in the record relevant to these issues is Reynolds' letter to the DI.

Therein, Reynolds stated that he has closed his practice and would not re-open it; that he has taken 55 hours of continuing education in ethics, boundaries, pharmacology and pain; and offered to take ''other training'' to ensure the public safety and his ''compliance with DEA standards.'' GX 42, at 2. Even were I to give weight to Reynolds's unsworn statement regarding the remedial measures he has undertaken, I would still deny his application because he has presented no evidence that he acknowledges his misconduct. To the contrary, the multiple material false statements Reynolds made in his letter establish that he does not accept responsibility for his misconduct in prescribing to N.S. and others. Thus, I conclude that Reynolds has not refuted the Government's *prima facie* showing that granting his application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). So too, because there is no evidence that either Stout or Killebrew has accepted responsibility for his/her misconduct, nor any evidence that either Stout or Killebrew has undertaken remedial measures to ensure that he/she will not re-offend in the future, I also conclude that neither one has refuted the Government's *prima facie* showing. Accordingly, I will order that the registration issued to Stout be revoked, and that the applications of Reynolds, Stout, and Killebrew [24] be denied.

Orders

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration MS0443046 issued to David R. Stout, N.P., be, and it hereby is, revoked. I further order that the application of David R. Stout, N.P., to renew his registration, be, and it hereby is, denied. This Order is effective June 18, 2015.

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 Bobby D. Reynolds II, F.N.P., for a DEA Certificate of Registration as an MLP—Nurse Practitioner, be, and it hereby is, denied. This Order is effective June 18, 2015.

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 Tina L. Killebrew, F.N.P., for a DEA Certificate of Registration as an MLP—Nurse Practitioner, be, and it hereby is, denied. This Order is effective June 18, 2015.

Dated: April 30, 2015.

Michele M. Leonhart,

Administrator.

[FR Doc. 2015–12038 Filed 5–18–15; 8:45 am]

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[24] While compared to Reynolds and Stout, Killebrew issued substantially fewer illegal prescriptions, her misconduct still involved the knowing diversion of controlled substances, and as such, is sufficiently egregious to support the denial of her application. *See Jayam Krishna-Iyer,* 74 FR at 464 (''[E]ven where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant [an application for] registration unless [she] accepts responsibility for [her] misconduct.''); *see also MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011) (sustaining agency order revoking practitioner's registration based on proof physician knowingly diverted drugs to two patients).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–35]

JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp; Decision and Order

On October 24, 2013, Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, ALJ), issued the attached Recommended Decision. Neither the Government nor the Respondents filed exceptions to the Recommended Decision.[1]

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact including his credibility determinations except as discussed below.[2] I also adopt the ALJ's

[1] All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

[2] In the Recommended Decision, the ALJ observed that his factual findings ''are entitled to significant deference.'' R.D. at 34 (citing *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951)). To make clear, the Agency is the ultimate factfinder and considers an ALJ's factual findings ''along with the consistency and inherent probability of testimony. The significance of [the ALJ's] report, of course, depends largely on the importance of credibility in the particular case.'' *Universal Camera,* 340 U.S. at 496. *See also Reckitt & Colman, Ltd.,* v. *Administrator,* 788 F.2d 22, 26–27 (D.C. Cir. 1986).

For reasons I have previously explained, *see Top Rx Pharmacy,* 78 FR 26069, 26069 n.1 (2013), I do not adopt the parenthetical following the ALJ's citation to *Paul Weir Battershell,* 76 FR 44359, 44368 n.27 (2011). *See* R.D. at 36.

In his discussion of factor two (''the applicant's experience in . . . dispensing controlled substances''), the ALJ explained that this factor manifests Congress's ''acknowledgment that the qualitative manner and *the quantitative volume* in which an applicant has engaged in the dispensing of controlled substances may be [a] significant factor'' in determining ''whether an applicant should be (or continue to be) entrusted with a DEA'' registration. R.D. at 37 (emphasis added).

It is certainly true that evidence as to the volume of dispensings (whether by a prescriber or a pharmacy) has been admitted in these proceedings, by both the Government to show the extent of practitioner's unlawful activities, and by practitioners to show the extent of their lawful activities. That being said, neither the text of factor two, nor the legislative history of the 1984 amendments which gave the Agency authority to consider the public interest in determining whether to grant an application or revoke (or suspend) an existing registration, compel the conclusion that Congress considered ''the quantitative volume'' of an applicant's or registrant's dispensings to be a significant factor in the public interest analysis.

The word ''experience'' has multiple meanings. Among those most relevant in assessing its meaning as used in the context of factor two are: (1) The ''direct observation of or participation in events as a basis for knowledge,'' (2) ''the fact or state of having been affected by or gained knowledge through direct observation or participation,'' (3) ''practical knowledge, skill, or practice derived from direct observation of or participation in events or in a particular activity,'' and (4) ''the length of such participation.'' *See Merriam-Webster's Collegiate Dictionary* 409 (10th ed. 1998); *see also The Random House Dictionary of the English Language* 681 (2d ed. 1987) (defining experience to include ''the process or fact of personally observing encountering, or undergoing something,'' ''the observing, encountering, or undergoing of things generally as they occur in the course of time,'' ''knowledge or practical wisdom gained from what one has observed, encountered, or undergone'').

None of these meanings compels the conclusion that Congress acknowledged that ''the quantitative volume'' of a practitioner's dispensing activity may be a significant consideration under this factor, and certainly none suggest that the Agency is required to count up the number of times an applicant or registrant has dispensed controlled substances in making factual findings under this factor as suggested by another ALJ. *See Clair L. Pettinger,* 78 FR 61592, 61597 (2013) (rejecting reasoning in ALJ's recommended decision that factor two ''requires evidence of both the qualitative and quantitative volume of the Respondent's experience'' and that ''[w]here evidence of the Respondent's experience . . . is silent with respect to the quantitative volume of the Respondent's experience, and requires speculation to support an adverse finding under Factor Two, this Factor should not be used to determine whether the Respondent's continued registration is inconsistent with public interest.'').

Prior to the 1984 amendment of section 823(f), the Agency's authority to deny an application or revoke a registration was limited to cases in which a practitioner: (1) Had materially falsified an application, (2) had been convicted of a State or Federal felony offense related to controlled substances, or (3) had his State license or registration suspended, revoked, or denied. *See* S. Rep. No. 98–225, at 266 (1983), *as reprinted in* 1984 U.S.C.C.A.N. 3182, 3448. Finding that the ''[i]mproper diversion of controlled substances'' was ''one of the most serious aspects of the drug abuse problem,'' and yet ''effective Federal action against practitioners ha[d] been severely inhibited by the [then] limited authority to deny or revoke practitioner registrations,'' *id.,* Congress concluded that ''the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest.'' *Id.*

The Senate Report thus explained that ''the bill would amend 21 U.S.C. 824(f) [sic] to expand the authority of the Attorney General to deny a practitioner's registration application.'' *Id.* The

Continued

conclusions of law that: (1) Respondents' principal (Mr. Moro Perez) materially falsified each pharmacy's application by failing to disclose that he had previously surrendered for cause each pharmacy's DEA registration, and (2) that Respondents failed to demonstrate that they can be entrusted with a new registration.[3] However, for reasons explained below, I do not adopt the ALJ's conclusions that Respondents and their pharmacists violated their corresponding responsibility when they dispensed controlled substance prescriptions issued by a physician whose registration had expired.

The Material Falsification Allegations

As explained in the ALJ's decision, Mr. Moro Perez asserted that he did not materially falsify the applications because he did not believe that the surrenders were for cause.[4] With respect to this allegation, the evidence showed that on November 30, 2011, the Government executed a search warrant at the two pharmacies and that Mr. Moro Perez, who had been arrested at his residence, was taken to Best Pharmacy, where he was presented with a voluntary surrender form (DEA From 104), and that while the form was in English, its purpose and contents were explained to Mr. Moro Perez by a Special Agent who spoke Spanish. Tr. 175–77.

The evidence further showed that the DI (through the Special Agent who translated for him) explained to Mr. Moro Perez that the form ''dealt with the regulatory matter'' and ''his DEA registration number,'' and that it was ''separate from any criminal allegations that may be levied.'' *Id.* at 177. The DI also told Mr. Moro Perez that ''[i]f he chose not to sign the form, then we would move for an order to show cause proceeding.'' *Id.* Mr. Moro Perez did not dispute this testimony.

The evidence further showed that the DEA Form 104, which was used by the DI to memorialize the surrender, contains two boxes which can be checked with an accompanying statement. The first of these states, in relevant part: ''In 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[.]'' GX 14, at 1. According to the DI, this box had been checked prior to the form's presentation to Mr. Moro Perez. Tr. 176. Mr. Moro Perez signed the form. *Id.; see also* GX 14, at 1.

Thereafter, Mr. Moro Perez was criminally charged with several violations of the Controlled Substances Act including possession with intent to distribute, *see* 21 U.S.C. 841(a)(1), and conspiracy to possess with intent to distribute. *See id.* § 860. However, on March 23, 2012, the charges, on motion of the Government, were dismissed with prejudice. RX 3.

The ALJ took official notice that Respondents were previously the subject of an Order to Show Cause Proceeding, and that either one or both Respondents in this matter requested a hearing on the allegations, which was deemed filed with the Office of Administrative Law Judges on December 6, 2011, and assigned Docket No. 12–16. *See* R.D. at 10. The ALJ also took official notice that the aforesaid proceeding was terminated on June 29, 2012. *Id.*

The evidence further showed that Respondent Farmacia Nueva did not complete a DEA Form 104. Tr. 72–74. However, the Government submitted various emails, which were exchanged between Farmacia Nueva's counsel in proceeding No. 12–16 (and who also represented Respondents in this proceeding) and a DEA attorney, whom the ALJ found, upon taking official notice of the Agency's records, served as the Agency's counsel of record in that proceeding.[5] GX 14, at 2–3; R.D. at 10.

The emails include a June 27, 2012 email, which was sent at 8:52 a.m., by DEA's counsel to Respondent's counsel stating: ''Wondering if you've discussed the surrender issue with your client yet. Please let me know if you have any other questions, thanks.'' GX 14, at 2. Later that day (after exchanging emails as to when they could discuss the matter), Respondent's counsel wrote to DEA counsel: ''Ok, anyway, I discussed the case with my client. I think he will surrender it voluntarily. Let me know where to find a form, or send it to me if you have one.'' *Id.*

DEA counsel then replied: ''We can do it without the form if you'd like, just send me an email stating your client agrees to surrender his registration. I'll then file a joint motion to dismiss the proceeding.'' *Id.*

The next day, Respondent's counsel emailed the following to DEA counsel: ''My client, Farmacia Nueva, has decided to voluntarily surrender its DEA registration at issue in the case Docket No. 12–16. Please prepare a joint motion to dismiss the pending case. Thank you.'' *Id.*

In his testimony, Mr. Moro Perez denied that he had knowingly or intentionally falsified both applications. He testified that he did not believe that the surrenders of either pharmacy's registration were for cause, maintaining that upon the dismissal of the criminal case against him, he believed ''that there was no cause against'' him. Tr. 211. Throughout his testimony he repeatedly adhered to this position. However, as the ALJ explained, at the time he surrendered the Best Pharma registration, the criminal case would not be dismissed for another four months.[6]

Moreover, in signing the voluntary surrender form, Mr. Moro Perez clearly acknowledged that he was doing so ''[i]n view of my alleged failure to

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Report further explained that ''in those cases in which registration is clearly contrary to the public interest, the amendment would allow a swift and sure response to the danger posed to the public health and safety by the registration of the practitioner in question.'' *Id.* at 267, *as reprinted in* 1984 U.S.C.C.A.N. at 3449. Accordingly, section 823(f) was amended to provide the Agency with authority to deny an application based upon a finding that the issuance of a registration ''would be inconsistent with the public interest,'' upon consideration of the five public interest factors, including the experience factor. *Id. See also* 21 U.S.C. 824(a)(4). Nowhere in the Report's discussion of the amendments to sections 823 and 824 is there any support for the notion that Congress deemed the quantitative volume of a practitioner's dispensings to be a significant consideration in making findings under the experience factor.

As in past cases, the parties may continue to introduce evidence as to the extent of both a practitioner's lawful or unlawful dispensing activities. However, under Agency precedent, proof of a single act of intentional or knowing diversion remains sufficient to satisfy the Government's *prima facie* burden and to impose on a respondent, the obligation to produce evidence to show that it can be entrusted with a registration. *See Jayam Krishna-Iyer,* 74 FR 459, 463 (2009); *see also MacKay* v. *DEA,* 664 F.3d 808, 819 (10th Cir. 2011) (''Although Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to K.D. and M.R. is sufficient to support her determination that his continued registration is inconsistent with the public interest.''). I therefore do not adopt the ALJ's statement that Congress acknowledged ''the quantitative volume'' of a practitioner's dispensings to be a ''significant factor'' in assessing a practitioner's experience.

[3] I also adopt the ALJ's legal conclusion that the Government did not sustain the record keeping allegation.

[4] Question 2 on the DEA Application 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?'' On each application, Mr. Moro Perez answered no. GX 1 & 8.

Question 4 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 . . . ever surrendered or had a federal control substance registration revoked, suspended, restricted, or denied . . . .? GX 1, at 1.

[5] While the ALJ provided Respondent with the opportunity to refute the various facts of which he took official notice, Respondent did not do so. *See* R.D. at 9 n.29.

[6] The record does not establish the date on which the criminal case against Mr. Moro Perez was filed.

comply with the Federal requirements pertaining to controlled substances'' and that he was consenting to the termination and revocation of the Best Pharma ''registration without an order to show cause, a hearing, or any other proceedings.'' GX 14, at 1. Also, as the ALJ found, Mr. Moro Perez was specifically told by the Diversion Investigator that the voluntary surrender form involved his pharmacy's registration and was separate from any criminal allegations that could be levied against him. And most significantly, the Diversion Investigator then told Mr. Moro Perez that if he did not sign the voluntary surrender form, he would seek an Order to Show Cause.

Mr. Moro Perez thus knew that the DI was pursuing the voluntary surrender based on the latter's belief that Best Pharma was engaged in unlawful practices. And finally, in addition to the DI's testimony (which the ALJ found credible) that he repeatedly explained to Mr. Moro Perez that the voluntary surrender form addressed a regulatory matter and was separate from any criminal charges that might be filed, it is noted that the CSA explicitly provides that ''[p]roceedings to deny, revoke, or suspend . . . shall be independent of, and not in lieu of, criminal prosecutions . . . under this subchapter or any other law of the United States.'' 21 U.S.C. 824(c).

As the ALJ recognized, DEA regulations do not define the meaning of the term ''for cause'' as used on the various application for registration forms. Moreover, the application does not define the term. Nonetheless, persons of ordinary intelligence cannot dispute that a surrender which occurs in response to allegations of misconduct raised by the Agency's Special Agents and Diversion Investigators is ''for cause,'' especially when those Agents and Investigators further advise the registrant's principal that if he/she declines to surrender a registration, the Agency will nonetheless initiate proceedings to revoke it.[7]

Beyond this, as the ALJ recognized, if the dismissal of the criminal proceeding transformed the earlier surrender of Best Pharma's registration into a surrender which was no longer ''for cause,'' given that the same allegations were raised with respect to both pharmacies, there would have been no reason for the Agency to continue its pursuit of the Show Cause Proceeding against the registration Mr. Moro Perez held for Farmacia Nueva. Yet the Agency did pursue the Show Cause Proceeding against Farmacia Nueva's registration until its principal agreed to surrender its registration some three months after the dismissal of the criminal case against Mr. Moro Perez. In his testimony, Mr. Moro Perez offered no explanation as to why, if the dismissal of the criminal case against him rendered the surrender of Best Pharma's registration not ''for cause,'' he subsequently agreed to surrender Farmacia Nueva's registration.[8]

In his testimony, Mr. Moro Perez also denied that he knowingly or intentionally falsified the applications because he completed them, ''knowing and recognizing that you, the DEA office, are aware of, [and] had knowledge and everything about me,'' Tr. 218, including his arrest. However, whether Investigators at the local DEA office were aware of Mr. Moro Perez is irrelevant in assessing his scienter; having answered the liability question ''no,'' the only issues that are relevant are whether he knew that he had surrendered his registrations and had done so ''for cause.'' Because Mr. Moro Perez clearly knew that he: (1) Had surrendered his registrations, (2) had done so in response to allegations that his pharmacies had committed violations of the CSA, and (3) did so to avoid proceedings to revoke the registrations, he also clearly knew that he had surrendered ''for cause.''

I thus agree with the ALJ's conclusion that Mr. Moro Perez knowingly and materially falsified[9] the applications he submitted for both Best Pharma and Farmacia Nueva. *Id.* These findings provide reason alone to support the denial of his applications, especially when coupled with the ALJ's findings that Mr. Moro Perez's testimony as to why he falsified the applications ''is simply not credible.'' R.D. at 67.

The Corresponding Responsibility Allegations

The ALJ also found that Respondents' pharmacists violated their corresponding responsibility under 21 CFR 1306.04, when, over the course of some thirty-four months, they filled numerous controlled substance prescriptions which were written by a physician who no longer possessed a valid DEA registration. While I adopt the ALJ's finding that Respondents dispensed the prescriptions at issue when the physician no longer possessed a DEA registration, I reject his legal conclusion that Respondents violated 21 CFR 1306.04(a) because the Government failed to prove that the pharmacists acted with the requisite scienter. However, based on Respondents' admissions, I find that they committed acts inconsistent with the public interest when they failed to verify that the physician remained registered at any time for some thirty-four months.

With respect to this allegation, the evidence showed that a physician named Dr. Hector J. Aguilar-Amieva (hereinafter, Dr. Aguilar) had allowed his registration to expire and that his registration had been retired by the Agency since January 31, 2009.[10] The evidence further shows that between January 30, 2009 and November 30, 2011 (when the search warrants were executed at Respondents), Farmacia Nueva filled 143 controlled substance prescriptions which were purportedly issued by Dr. Aguilar (and which used his DEA registration) and that Best Pharmacy filled thirty-two controlled substance prescriptions. GXs 5 & 10.

Under 21 CFR 1306.03, a controlled substance prescription ''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

[7] In its post-hearing brief, Respondents note that on the application, the phrase ''for cause'' is in parentheses. Resp. Br. 22–23. Respondents then argue that ''[i]t must be in parenthesis [sic] for some reason [and] [t]he idea cannot be and should not be that any time an applicant who had surrendered his registration for some reason answers 'no' to this question, that applicant is automatically falsifying facts.'' *Id.* at 23.

That is certainly true, as a pharmacy registrant may have surrendered its registration previously because it went out of business but has since reopened, just as a physician registrant may have done so because he/she ceased professional practice but has since resumed practicing medicine. The argument ultimately takes Respondents nowhere because Mr. Moro Perez surrendered Best Pharmacy's registration after he was accused of having violated the CSA and was told that if he did not surrender the registration, the Agency would pursue a proceeding to revoke its registration; as for Farmacia Nueva's registration, the Agency was continuing to pursue a Show Cause Proceeding to revoke its registration when Mr. Moro Perez agreed to surrender its registration.

[8] Respondent makes no claim that Mr. Moro Perez was unaware that its attorney had surrendered Farmacia Nueva's registration. Even if it had, '' 'a principal is chargeable with the knowledge of, or notice to, his agent that is received by the agent in the due course of his employment and is related to the matters within his authority.' '' *McMillan* v. *LTV Steel, Inc.,* 555 F.3d 218, 230 (6th Cir. 2009) (quoting *Aetna Cas. & Sur. Co.* v. *Leahey Constr. Co.,* 219 F.3d 519, 541 (6th Cir. 2000)).

[9] Respondents do not contend that the falsifications were immaterial.

[10] According to the DI, Dr. Aguilar's registration expired after he was convicted of a federal criminal offense; the record does not, however, establish the offense of which he was convicted nor the date of his conviction. Moreover, while there was evidence that Dr. Aguilar's office was only a three to four minute walk from Farmacia Nueva, Tr. 250, and that it was the closest pharmacy to his office, the Government provided no evidence that Respondents' pharmacists were aware of any enforcement actions that were brought against Dr. Aguilar.

exempted from registration [under] this chapter.'' Thus, Dr. Aguilar's prescriptions were unlawful.[11]

Mr. Moro Perez testified that there were ''many times'' when Respondents' pharmacists refused to fill Dr. Aguilar's controlled substances prescriptions because ''we knew that that patient didn't require the use of the medication.'' Tr. 252; *see also id.* at 254. When questioned by the ALJ as to whether he thought it was suspicious that many of Dr. Aguilar's patients were presenting controlled substance prescriptions that he (and his pharmacists) would not fill, Mr. Moro Perez testified that ''we have been very careful with the dispensing'' and ''the amount of medications that were dispensed, the percentage [was] very low.'' *Id.* at 253. Mr. Moro Perez then testified that he never called Dr. Aguilar, and when asked why, claimed that he and his pharmacists reviewed the patient's history and used their professional judgment to evaluate whether a particular prescription was legitimate. *Id.*

When questioned further as to why he did not call Dr. Aguilar, Mr. Moro Perez testified: ''Because I understood, I was aware that the doctor's license were [sic] up-to-date.'' [12] *Id.* at 254. Mr. Moro-Perez and his pharmacists never attempted to verify whether Dr. Aguilar held a registration, *id.* at 193–94, even though, according to the DI, they could have done so simply by calling the local DEA office.[13] *Id.* at 20.

Instead, Mr. Moro-Perez testified that he and his pharmacists relied on the patients' insurance carriers (to which they submitted claims for payment of medications) to determine whether a physician had valid licenses and registrations by seeing if the claim was paid. *Id.* at 200–1. Mr. Moro-Perez conceded that the insurance companies continued to pay claims for prescriptions issued by Dr. Aguilar until the date on which the search warrant was executed, which was nearly three years after the latter's registration had been retired. *Id.* at 202. However, no evidence was adduced as to whether any claim for payment was rejected by a patient's insurer, and there was obviously no evidence as to whether in the event an insurer rejected a claim, it would disclose the reason it did so.[14]

As the ALJ recognized, under DEA's longstanding regulation, a pharmacist has a corresponding responsibility to fill only those prescriptions which are ''issued for a legitimate medical purpose by [a] practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Continuing, the regulation states that ''the person *knowingly* filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*[15] (emphasis added).

DEA has long interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ''knows or *has reason to know* that the prescription was not written for a legitimate medical purpose.'' *Medic-Aid Pharmacy,* 55 FR 30043, 30044 (1990) (emphasis added); *see also Frank's Corner Pharmacy,* 60 FR 17574, 17576 (1995); *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990); *United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980). Thus, proof of actual knowledge is not necessary to establish that a pharmacist has violated his/her corresponding responsibility to dispense only lawful prescriptions.

However, in finding violations of the corresponding responsibility where actual knowledge has not been proved, the Agency has explained that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid positive knowledge of the real purpose of the prescription,'' and thereafter fill the prescription ''with impunity.'' *Bertolino,* 55 FR at 4730 (citing *United States* v. *Kershmann,* 555 F.2d 198 (8th Cir. 1977); *United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979)); *accord Liberty Discount Drugs, Inc.,* 54 FR 30116, 30117 (1989). *See also Medic-Aid Pharmacy,* 55 FR at 30044 (''The administrative law judge concluded that it is not necessary to find that [the pharmacist] in fact knew that many prescriptions presented to him were not written for a legitimate medical purpose, for there is no question that a conscientious pharmacist would have been suspicious of these prescriptions and would have refused to fill them.''). Thus, both *Bertolino* and *Medic Aid Pharmacy* applied the standard of deliberate ignorance or willful blindness in assessing whether a pharmacist acted with the requisite scienter. *See Seelig,* 622 F.2d at 213 (''the element of knowledge may be inferred from proof that appellants deliberately closed their eyes to what would otherwise be obvious to them''); *Kershmann,* 555 F.3d at 200 (''the element of knowledge may be shown by deliberate ignorance'').

In addition to the obligation imposed by 21 CFR 1306.04(a), ''[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 (emphasis added). Thus, the Agency has also repeatedly held that ''a pharmacist must exercise professional judgment [and common sense] when filling a prescription.'' *Bertolino,* 55 FR at 4730; *see also Medicine Shoppe-Jonesborough,* 73 FR 363, 381, *pet. for rev. denied, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. App'x 409, 412 (6th Cir. 2008); *Trinity Health Care Corp.,* 72 FR 30849, 30854 (2007); 21 CFR 1306.06. Accordingly, the Agency has held that ''when a customer presents a suspicious prescription, at a minimum, a pharmacist has a duty to verify the prescription with the prescriber.'' *Medicine Shoppe-Jonesborough,* 73 FR 364, 381; *see also Medicine Shoppe,* 300 Fed. App'x at 412.

Moreover, even if a prescriber tells a pharmacist that a prescription has been issued for a legitimate medical purpose, a pharmacist cannot ignore other evidence that the prescription has not been issued for a legitimate medical purpose or that the prescriber acted outside of the usual course of his or her

[11] Respondents do not claim that Dr. Aguilar was exempt from registration, and under the CSA, had they claimed as much, they (and not the Government) would have had the burden of proof on the issue. *See* 21 U.S.C. 885(a) (1).

[12] The ALJ was not impressed by this testimony, finding it to be ''the obvious fruit of intentional equivocation.'' R.D. at 20. That being said, the ALJ's finding does not establish that Moro-Perez knew that Dr. Aguilar was no longer registered (as opposed to simply being unaware of the status of Aguilar's license) when his pharmacies filled the prescriptions and the ALJ made no such finding. Moreover, it is not even clear on the record whether Moro-Perez was testifying regarding Dr. Aguilar's DEA registration rather than his state license.

[13] The evidence also showed that since 2008, DEA has provided a Web page, at which a DEA registrant can verify the registration status of another person or entity. Tr. 22. However, other than vague testimony suggesting that during an inspection an investigator would tell a registrant that the Web site is available, *id.* at 90, no evidence was put forward that this information was conveyed to Respondents. Nor did the Government provide any evidence as to what efforts have been made to notify the community of registrants as to the Web page's availability.

It is noted that in publishing its Interim Final Rule on Electronic Prescriptions for Controlled Substances, the Agency explained that ''[i]f a pharmacy has doubts about a particular DEA registration, it can now check the registration through DEA's Registration Validation Tool'' which is available at the Agency's Web site. *See* 75 FR 16236, 16266 (2010).

[14] Nor was any evidence put forward as to how many of the Aguilar prescriptions were actually paid for with cash.

[15] As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135 (1975)).

professional practice and dispense the prescription. As one court of appeals has explained:

> Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification. . . . What is required by [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.

United States v. *Hayes,* 595 F.2d 258, 260 (5th Cir. 1979). *See also Medicine Shoppe,* 300 Fed. App'x at 412 (quoting *Bertolino,* 55 FR at 4730) (''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.' ''); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 FR 62316, 62341 (2012); *East Main Street Pharmacy,* 75 FR 66149, 66163–64 (2010).

Under an Agency regulation, every controlled substance prescription must contain ''the name, address and registration number of the practitioner'' who issued it. 21 CFR 1306.05(a). However, the Agency's regulation does not require that a practitioner provide the expiration date of his registration on a prescription. *See id.*

Moreover, 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. Indeed, the Agency recognized this much 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.*

As this pronouncement makes clear, a pharmacist is not obligated to verify whether every prescription he fills has been issued by a practitioner who holds a valid DEA registration. Of course, if a pharmacist has actual knowledge that a prescriber does not hold a valid registration, or acts with willful blindness to this fact, a pharmacist violates the Controlled Substances Act if he proceeds to dispense that prescription. 21 U.S.C. 843(a)(2). Thus, in *United Prescription Services,* I held that a pharmacy violated its corresponding responsibility by dispensing prescriptions issued by a physician, whose registration had expired, where the pharmacy had on file a copy of the physician's registration and thus, its pharmacists clearly knew, or were willfully blind to the fact, that the physician was issuing prescriptions on an expired registration and that the prescriptions were therefore illegal.[16] 72 FR at 50408.

More recently, in *Holiday CVS, L.L.C.,* 77 FR 62316 (2012), two pharmacies continued to fill prescriptions written by two physicians whose registrations had expired. Moreover, the registration of one of the physicians had been revoked following a proceeding under 21 U.S.C. 824(a)(4) and the Agency's Decision and Order had been published in the **Federal Register** (as well as on the DEA Office of Diversion Control's public Web site) approximately one month before the Order became effective. *Id.* Yet both pharmacies continued to dispense prescriptions issued by this physician, including some which were issued more than five months after the Order became effective. *Id.* Finally, the evidence also showed that the pharmacies used a company wide information management system which obtained updated registration data from a third party aggregator (which obtained it from DEA) on a weekly basis and that a prescribing physician's registration status was displayed to the pharmacist when entering the prescription into the pharmacy's dispensing software. *Id.* Thus, the pharmacists at each store had knowledge that the physicians' registrations had expired at the time they filled most of the prescriptions.[17] *Id.* Here again, liability was imposed on the pharmacies consistent with the corresponding responsibility imposed on their pharmacists.[18]

As the ALJ found, the Government put forward no evidence that Mr. Moro-Perez or any of his pharmacists had actual knowledge that Dr. Aguilar's registration was no longer valid at any point during the thirty-four month period in which they filled his prescriptions. R.D. 51 n.86. The ALJ nonetheless concluded that the requisite knowledge could be imputed to Respondents because their pharmacists entirely failed to investigate whether Dr. Aguilar held a valid registration and thus were willfully blind to the fact that Aguilar was no longer registered and could not write a controlled substance prescription. R.D. at 53 (citing *United*

[16] In *United Prescription Services,* this particular physician's registration had expired on February 28, 2003, and yet the pharmacy was still dispensing prescriptions written by him in September and October 2004. *See* 72 FR at 50408.

[17] I also noted that as participants in a highly regulated industry, the pharmacies were required to keep abreast of regulatory developments which affect their industry and that with respect to the physician whose registration was revoked, publication of the Decision and Order in the **Federal Register** ''provided [the pharmacies] with reason to know'' that upon the effective date, the physician ''would no longer be authorized to issue controlled substance prescriptions.'' 77 FR at 62317 (citations omitted).

[18] In the Show Cause Order, the Government cited *Medicine Shoppe—Jonesborough,* 73 FR 364 (2008), as authority for the violation. In *Medicine Shoppe—Jonesborough,* a pharmacy was found to have filled over 124 controlled substances prescriptions which were written by a veterinarian who no longer possessed either a state license or a DEA registration. *Id.* at 381. However, I did not decide whether the pharmacy violated its corresponding responsibility because it dispensed the prescriptions when the veterinarian lacked either state authority or a DEA registration. *Id.* Rather, I found that even if the pharmacy's pharmacist-in-charge was unaware that the veterinarian no longer possessed a DEA registration and state license, it violated its corresponding responsibility based on the expert testimony that the pharmacy had ignored various circumstances that provided knowledge to its pharmacists that the prescriptions were not issued for legitimate medical purposes (including that the prescriptions were presented on a daily basis by the veterinarian's brother and were for drugs, which according to the expert, would be toxic for certain animals). *Id.*

However, in a footnote, I explained 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. Because of the evidence that the pharmacy had violated 21 CFR 1306.04(a), I deemed it unnecessary to decide whether the pharmacy had violated this duty. However, I 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.*

States v. *Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006)).[19]

Recently, however, the Supreme Court made clear that ''a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can *almost be said to have actually known the critical facts.*'' *Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 131 S.Ct. 2060, 2070–71 (2011) (emphasis added) (citing and quoting G. Williams, *Criminal Law* § 57, p.159 (2d ed. 1961) (''A court can properly find willful blindness only where it can almost be said that the defendant actually knew.'')); *see also id.* at 2069 (quoting with approval American Law Institute, *Model Penal Code* § 202(7) (Proposed Official Draft 1962) (''defining 'knowledge of the existence of a particular fact' to include a situation in which 'a person is aware of a high probability of [the fact's] existence, unless he actually believed that it does not exist'''')).

In *Global-Tech,* the Supreme Court further explained that even proof that a defendant was reckless in that he knew ''of a substantial and unjustified risk of wrongdoing'' does not establish willful blindness. *Id.* at 2071. Rather, to establish willful blindness, proof is required that: ''(1) the defendant must *subjectively believe* that there is high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.'' *Id.* at 2070 (emphasis added).

Here, the Government offered no evidence to establish that Mr. Moro-Perez, or any other of Respondents' pharmacists, subjectively believed that there was a high probability that Dr. Aguilar was issuing prescriptions on an expired registration. Moreover, notwithstanding that Respondents put forward no evidence that it was objectively reasonable to determine if Dr. Aguilar possessed a valid registration by relying on whether the patients' insurance companies paid for their prescriptions, there is no evidence that a claim for payment of any of Dr. Aguilar's prescriptions was ever rejected by a patient's insurer. Indeed, notwithstanding the ALJ's finding (with which I agree) that this was an ''irresponsible practice'' and ''illogical manner'' of determining a physician's registration status, he made no finding that Moro-Perez (or any other pharmacist) ''subjectively believe[d] that there was a high probability'' that Dr. Aguilar was writing on an expired registration.

To be sure, in his testimony, Mr. Moro-Perez admitted that his pharmacists had rejected controlled substance prescriptions issued by Dr. Aguilar ''many times,'' because based on the patients' histories, they did not consider the prescriptions to be legitimate for the respective patients. This admission might well have established willful blindness with respect to whether the Aguilar prescriptions which Respondents filled lacked a legitimate medical purpose—had the Government challenged the dispensing of any of the post-January 31, 2009 prescriptions on this basis. But it did not. Most importantly, it does not establish that Moro-Perez or any of his pharmacists subjectively believed that there was a high probability that Aguilar no longer had a registration.[20]

As for whether Respondents' pharmacists violated their obligation to act within the usual course of professional practice, *see* 21 CFR 1306.06, because their suspicions as to Dr. Aguilar's lack of registration should have been aroused as reasonable pharmacists and they failed to investigate, the evidence is simply insufficient to establish a violation. Notably, the Government does not cite to any statute, Board regulation, or decision of either the Board or the courts which requires a pharmacist to verify the status of a DEA registration (or medical license) upon being presented with a prescription which he/she suspects lacks a legitimate medical purpose.[21] Nor, notwithstanding the abundance of agency case law applying the reasonable pharmacist standard, did the Government call an expert to testify that the standards of professional pharmacy practice require that a pharmacist who is confronted with prescriptions from a particular physician which he/she suspects lack a legitimate medical purpose, must also determine whether the physician possesses a valid DEA registration.[22]

In its post-hearing brief, the Government argues for the first time that Respondents' pharmacists also violated their corresponding responsibility because the prescriptions they filled also lacked a legitimate medical purpose. As the Government argues, ''Mr. Moro-Perez's most egregious conduct involves filling prescriptions for Dr. Aguilar-Amieva despite the fact that he had previously flagged prior prescriptions as being illegitimate.'' Gov. Post-Hrng. Br. at 22. The Government then argues that ''Respondent[s] deliberately ignored their own internal warnings when they continued to fill other prescriptions for Dr. Aguilar-Amieva,'' that ''Moro-Perez failed to conduct any investigation to resolve this flag,'' and that ''[a]ny reasonable and prudent pharmacist would not have continued to fill prescriptions without further investigation.'' *Id.* at 23.

Even ignoring that raising this theory for the first time in its post-hearing brief is too late to provide fair notice (given that the testimony did not occur until Moro-Perez was cross-examined by his own counsel), the Government did not put on any evidence to show that any of the Aguilar prescriptions filled by

[19] *See also United States* v. *Lawson,* 682 F.2d 480, 482 (4th Cir. 1982); *United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980); *United States* v. *Kershmann,* 555 F.2d 198, 200–01 (8th Cir. 1977).

[20] Although both the Government and ALJ made much of Moro-Perez's admission, ''many'' is an indefinite term and the record does not clarify just how many prescriptions were rejected by Respondents, and as of what date their pharmacists were aware of this.

[21] The ALJ also reasoned that ''[t]he absence of Dr. Aguilar's [registration] is the most glaring of red flags that could and should have been recognized by the Respondent upon the exercise of even the most minimal due diligence. Conclusively resolving such a fundamental red flag was a mandatory condition precedent to the legal dispensing of a control substance. . . .'' R.D. at 52.

The term ''red flag'' is not defined in either the CSA or DEA regulations. However, in the context of a pharmacy, a red flag is simply a circumstance arising during the presentation of a prescription, which creates a reasonable suspicion that the prescription is not valid and which imposes on a pharmacist the obligation to conduct further inquiry into whether the prescription is valid or to not fill it all. *See Holiday CVS,* 77 FR at 62332.

Here, there was no evidence that Respondents' pharmacists ever received any information that Dr. Aguilar was no longer registered such as through a tip, the grapevine, or having seen media coverage of Aguilar's putative arrest or trial. Moreover, while a red flag includes additional facts developed during the investigation of other red flags, here, the red flag was the illegality of the prescriptions Respondents declined to fill. Because there is no regulation which required Respondents to the check the registration status of Dr. Aguilar, nor any testimony that the accepted standards of professional practice required that they do so, I do not adopt the ALJ's discussion that Dr. Aguilar's lack of a registration was ''the most glaring of red flags'' which should have been discovered.

[22] As found above, in the Interim Rule on Electronic Prescribing, the Agency noted that several commenters had objected to the proposal that the DEA registration must be verified for all electronic prescriptions, noting ''that pharmacies are not required to check DEA registrations for paper prescriptions unless they suspect something is wrong with a prescription.'' 75 FR at 16266. While this may reflect the accepted standards of professional pharmacy practice, the Interim Rule did not explain who the commenters were and whether they speak for the profession as a whole. Moreover, absent proof of either: (1) That a dispensing was simply a drug deal, or (2) that the pharmacy violated an explicit duty set forth in a statute, regulation, or case law, the standards of professional practice must generally be established on the record in any case. Accordingly, I place no weight on the statement suggesting that a pharmacist is required to check a prescriber's registration if he/she suspects there is something wrong with a prescription.

Respondents also lacked a legitimate medical purpose.[23] Indeed, there is no evidence to refute Moro-Perez's testimony (which the ALJ apparently found credible) that he and his pharmacists declined to fill many prescriptions and thus complied, (at least with respect to those prescriptions), with their corresponding responsibility.

As for its contention that no reasonable and prudent pharmacist would have filled the prescriptions, here again, there is no evidence as to what a reasonable and prudent pharmacist would have done when confronted with this information. Nor is there any expert testimony as to at what point (*i.e.,* after how many prescriptions), this information would have prompted further investigation.[24]

In their post-hearing brief, Respondents nonetheless concede that by dispensing the Aguilar prescriptions they committed acts inconsistent with the public interest, Resp. Post-Hrng. Br. 18, because ''it was wrong for him [Moro-Perez] and [the] pharmacies to rely on [an] insurance company's system to notify [them] if a doctor's license is expired, suspended, or revoked.'' *Id.* at 19. Respondents further concede that doing so constitutes ''such other conduct which may threaten public health and safety.'' *Id.* at 25.

I agree. As the ALJ found (and given Respondent's concession), it was not objectively reasonable for Respondents' pharmacist to rely on whether insurance companies rejected a claim for payment of a prescription to determine whether a physician held a valid registration. And as explained above, more than a year prior to the conduct at issue here, I explained (albeit in a dictum) 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.'' *Medicine Shoppe-Jonesborough,* 73 FR at 381 n.45. However, because it was not necessary to decide the case, *Medicine Shoppe—Jonesborough* did not set forth the specific parameters of this duty. *See id.*

I nonetheless conclude that Respondents breached this duty because their pharmacists failed to verify that Dr. Aguilar remained registered at any time during the thirty-four month period between the expiration of his registration and the execution of the search warrants. However, I place only nominal weight on this aspect of Respondents' misconduct. The Government did not prove that Respondents' misconduct was intentional or knowing. Moreover, while Respondents do not dispute that their failure to verify Dr. Aguilar's registration at any time during the aforesaid period constitutes conduct which may threaten the public health and safety, the lack of specific guidance as to what steps are necessary to comply with this duty diminishes its egregiousness to some degree. Finally, Mr. Moro-Perez's material falsification of the applications and failure to accept responsibility for the falsifications, provide reason alone to deny the applications.

While it is indisputable that failing to verify a controlled-substance prescriber's credentials at any time during a three year period is a breach of the duty set forth in *Medicine Shoppe—Jonesborough,* I conclude that if the Agency intends to enforce this duty in other cases, it must provide the regulated community with guidance as to its scope. However, while such guidance can be announced in an adjudicatory proceeding, the process of adjudication is not well suited for doing so. *See* I Richard J. Pierce, Jr., *Administrative Law Treatise* § 6.8, at 368–74 (4th ed. 2002). Accordingly, I decline to set forth how frequently a pharmacy must verify that a prescriber is registered.

In sum, I reject the allegations that Respondents violated Federal law and DEA regulations when they dispensed controlled substance prescriptions ''issued by a medical doctor who did not possess a valid DEA registration.'' Show Cause Order (ALJ Ex. 1), at 2 ¶¶ 4 & 8 (citing 21 U.S.C. 843(a)(2); 21 CFR 1306.04).[25] However, I find that Respondents breached their duty to periodically verify Dr. Aguilar's registration status. *See Medicine Shoppe-Jonesborough,* 73 FR at 381 n.45.

Most significantly, I also adopt the ALJ's findings that Mr. Moro-Perez materially falsified the application of each Respondent by failing to disclose that he had previously surrendered each pharmacy's registration for cause, as well as the ALJ's findings that Mr. Moro-Perez has not acknowledged his misconduct in doing so. *See* R.D. at 53 (finding that Mr. Moro-Perez ''insistence that his false response to an application query regarding whether each pharmacy had ever surrendered a [registration] for cause was some sort of reasonable

[23] Notably, in this portion of its brief, the Government makes no reference to the status of Dr. Aguilar's registration. *See* Gov. Post-Hrng. Br. 22–23.

While the Government obtained the prescriptions during its investigation, it did not raise this theory in the Show Cause Order, which, with regard to Respondents' dispensings, rested entirely on the allegations that they dispensed ''prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration.'' ALJ Ex. 1, at 2. Moreover, in neither of its pre-hearing statements, did the Government provide notice that it was challenging the dispensings of the Aguilar prescriptions on the ground that they were issued for other than a legitimate medical purpose. *See* ALJ Exs. 4 & 8.

[24] Even were I to apply the ''reason to know'' standard of the common law, *see Novicki* v. *Cook,* 946 F.2d 938, 941 (D.C. Cir. 1991), which requires proof of something less than either actual knowledge or willful blindness, the Government would not prevail on its contention that Respondents violated 21 CFR 1306.04(a) because the prescriptions were issued under an expired registration. In *Novicki,* the D.C. Circuit looked to the Restatement (Second) of Agency (1958) and the Restatement (Second) of Torts (1965) to give meaning to the term. *See id.* (quoting Restatement (Second) of Agency § 9 cmt. d (1958) and citing Restatement (Second) of Torts § 12(1)). As the Restatement of Agency explains,

A person has reason to know of a fact if he has information from which a person of ordinary intelligence, or of the superior intelligence which such person may have, would infer that the fact in question exists or that there is such a substantial chance of its existence that, if exercising reasonable care with reference to the matter in question, his action would be predicated upon the assumption of its possible existence. The inference drawn need not be that the fact exists; it is sufficient that the likelihood of its existence is so great that a person of ordinary intelligence, or of the superior intelligence which the person in question has, would, if exercising ordinary prudence under the circumstances, govern his conduct as if the fact existed, until he could ascertain its existence or non-existence. . . . A person of superior intelligence or training has reason to know a fact if a person with his mental capacity and attainments would draw such an inference from the facts know to him. On the other hand, ''reason to know'' imports no duty to ascertain facts not to be deduced as inferences from facts already known; one has reason to know a fact only if a reasonable person in his position would infer such fact from other facts already known to him.

Restatement (Second) of Agency § 9 cmt. d (1958); *see also* Restatement (Second) of Torts § 12, cmt. a (''Reason to know' means that the actor has knowledge of facts from which a reasonable man of ordinary intelligence or one of the superior intelligence of the actor would either infer the existence of the fact in question or would regard its existence as so highly probable that his conduct would be predicated upon the assumption that the fact did exist.'').

Because he is a licensed pharmacist (as are presumably his other pharmacists), Mr. Moro-Perez is a ''person of superior intelligence or training.'' Thus, it would be appropriate to consider whether a person possessing the mental capacity and attainments of Mr. Moro-Perez and his pharmacists would, based on the knowledge that Dr. Aguilar was issuing prescriptions which lacked a legitimate medical purpose, draw the further inference that he was no longer registered. Here again, because the Government did not sponsor any expert testimony, there is no evidence as to whether, based on the prescriptions that he/she was rejecting, a reasonable pharmacist would have inferred that Aguilar was not registered or would have regarded the existence of this fact ''as so highly probable'' that he would have refused to dispense the prescriptions.

[25] I also do not adopt the ALJ's discussion in the Recommendation section of his decision regarding the egregiousness of Respondents' conduct in filling the Aguilar prescriptions and the Agency's interest in deterring similar misconduct. Nor do I adopt the ALJ's discussion rejecting Respondents' arguments which were offered in mitigation of this violation.

misunderstanding is simply not credible and defeats the Respondents' efforts to meet the Government's case''). Accordingly, I will deny each Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of JM Pharmacy Group Inc., d/b/a Farmacia Nueva, for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. I further order that the application of Best Pharma Corp, for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. This Order is effective immediately.

Dated: April 29, 2015.

Michele M. Leonhart,

Administrator.

Anthony Yim, Esq., for the Government.
Vladimir Mihailovich, Esq., for the Respondent.

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

Chief Administrative Law Judge John J. Mulrooney, II. On June 19, 2013, the Deputy-Assistant Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause (OSC) proposing to deny applications for two DEA Certificates of Registration (COR) submitted on behalf of two pharmacies [1] (collectively, the Respondents). In its OSC and its prehearing statements, the Government avers that the applications should be denied because they were submitted with material falsifications,[2] and because granting the applications would be inconsistent with the public interest as that term is defined under the Controlled Substances Act (CSA). 21 U.S.C. 823(f) (2006). On July 18, 2013, the Respondents, through counsel, filed a timely request for hearing, which was conducted in Arlington, Virginia, on September 3, 2013.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that the Respondents' applications for registrations with the DEA should be denied on the grounds alleged by the Government.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

[1] The two registrants were jointly captioned on a single OSC, and neither party petitioned for severance.

[2] 21 U.S.C. 824(a)(1) (2006) (providing a statutory basis for discretionary revocation).

The Allegations

In its OSC,[3] the Government alleges that the COR applications filed on behalf of both registrants should be denied as contrary to the public interest.[4] In its subsequently filed Prehearing Statement,[5] the Government supplemented its theory in support of denial with additional allegations that the COR applications filed on behalf of each Respondent contained material falsifications [6] in that each application stated that the respective registrant had never surrendered a COR for cause, when, in fact, both had.

In support of the denial it seeks regarding an application for a COR filed by JM Pharmacy Corp., d/b/a Farmacia Nueva (Farmacia Nueva or FN), based on the public interest, the Government avers that this Respondent: (1) ''filled approximately 160 prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration in violation of'' 21 U.S.C. 843(a)(2) and 21 CFR 1306.04 (2013); and (2) ''failed to keep records of approximately twenty-seven (27) prescriptions for controlled substances'' from November 2009 through November 2011 in violation of 21 U.S.C. 827(b)(1) and 21 CFR 1304.04.[7]

The Government alleges that the granting of the COR application filed by Best Pharma Corp. (Best Pharma or BP) is inconsistent with the public interest in that this Respondent: (1) ''filled approximately thirty-two (32) prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration, in violation of'' 21 U.S.C. 843(a)(2) and 21 CFR 1306.04; and (2) ''failed to keep records of approximately seven (7) prescriptions for controlled substances'' from November 2009 through November 2011 in violation of 21 U.S.C. 827(b)(1) and 21 CFR 1304.04.[8]

Additionally, the Government alleges that both Farmacia Nueva and Best Pharma ''materially falsified'' their applications for DEA CORs.[9]

The Stipulations of Fact

The Government and the Respondents, through counsel, have entered into stipulations [10] regarding the following matters:

1) The owner of Farmacia Nueva and Best Pharma is Mr. Julio E. Moro-Perez (Moro-Perez).

2) Farmacia Nueva previously held DEA COR BF9534187 as a retail pharmacy in Schedules II–V.

3) Best Pharma previously held DEA COR FB1971565 as a retail pharmacy in Schedules II–V.

4) Neither Farmacia Nueva nor Best Pharma currently possesses a DEA COR.

5) On October 10, 2012, Moro-Perez applied on behalf of Farmacia Nueva for a DEA COR as a retail pharmacy in Schedules II–V at URB Raholisa #3, San Sebastian, Puerto Rico 00685.

6) On October 10, 2012, Moro-Perez applied on behalf of Best Pharma for a DEA COR as a retail pharmacy in Schedules II–V at Carr 111 KM 5.2 Bo. Pueblo, Ave La Moca 300, Moca, Puerto Rico 00685.

7) A COR previously issued to Dr. Hector J. Aguilar-Amieva, M.D. (Dr. Aguilar) was retired by DEA on January 31, 2009.

8) A criminal case against Moro-Perez, case no. 3:11–CR–00532–006, was dismissed with prejudice by the United States District Court for the District of Puerto Rico on March 23, 2012, upon petition from the United States Attorney's Office for the District of Puerto Rico.[11]

The Evidence

The Government's Evidence

The Government's case-in-chief rested on the testimony of four witnesses: DEA Diversion Investigator (DI) Ghensy Antoine, DEA Digital Forensic Examiner (DFE) Amy L. Herrmann, DI George Taylor, and Moro-Perez, the owner/president of Farmacia Nueva and Best Pharma.

DI Ghensy Antoine testified that in the course of his duties as a DI in the Ponce, Puerto Rico DEA field office, he was assigned as the lead investigator for the COR applications filed by Moro-Perez on behalf of the Respondents. Tr. 13–14, 76. Antoine explained that these COR applications were designated for investigation because the Respondents had a history of ''some issues with some minor violations.'' Tr. 15. Specifically, regarding Farmacia Nueva, Antoine stated that his application [12] investigation preliminarily revealed that on

[3] ALJ Ex. 1.

[4] 21 U.S.C. 824(a)(4).

[5] ALJ Ex. 4.

[6] 21 U.S.C. 824(a)(1).

[7] ALJ Ex. 1, at 2.

[8] *Id.*

[9] ALJ Ex. 8, at 1.

[10] On August 28, 2013 (three business days prior to the commencement of the hearing in this matter), a telephonic status conference (Status Conference) was conducted with the parties, wherein, *inter alia,* the Government concurred with Best Pharma's position that several prescription events initially alleged by the Government as involving controlled substances actually described substances that were not controlled. The next day, the Government filed a document styled ''Joint Stipulations'' (Joint Stipulations) wherein the parties mutually agreed to the substitution of previously-noticed versions of Proposed Government Exhibits 7(ID) and 12(ID), and stipulated that six prescription events purportedly detailed in Proposed Government Exhibit 7(ID) and one prescription event purportedly detailed in Proposed Government Exhibit 12(ID) do not refer to controlled substances. ALJ Ex. 11. Notwithstanding the purported exhibit substitution set forth in the Joint Stipulations, at the hearing, the Government (errantly) represented that it had withdrawn Proposed Government Exhibit 12(ID). Tr. 97–98. Regrettably, the record is further confounded by the fact that none of the seven non-controlled prescription events referenced in the Joint Stipulations are depicted in the substituted Government Exhibits 7 or 12(ID). The parties also agreed to forego objections to numerous proposed exhibits. ALJ Ex. 11.

[11] The parties stipulated to this after the issuance of the Prehearing Ruling in this matter. The Respondents, through counsel, telephonically communicated their assent to this stipulation on August 26, 2013, the business day after the Government proposed it in its Supplemental Prehearing Statement. ALJ Ex. 8.

[12] Farmacia Nueva's COR application was received into the record. Gov't Ex. 1.

November 30, 2011, the pharmacy had been the subject of a DEA-executed federal criminal search warrant,[13] which resulted in an immediate suspension order.[14] Tr. 14, 16. DI Antoine testified that he learned that, between January 30, 2009 and November 30, 2011, Farmacia Nueva had dispensed 143 controlled substances [15] based on prescription scrips issued by Dr. Aguilar,[16] and that, during that period of time, Dr. Aguilar did not possess a valid COR. Tr. 17–18. DI Antoine stated that Dr. Aguilar's registration number had been retired by DEA since January 31, 2009, following an investigation and a federal criminal conviction, and that the status of his COR would have been uploaded to the DEA Diversion Web site on the date it was retired. Tr. 53–55. According to DI Antoine, there were multiple, readily-available means for Farmacia Nueva personnel to have ascertained that Dr. Aguilar lacked federal authorization to prescribe controlled substances at the time the prescriptions were filled. Tr. 20. Antoine related that Farmacia Nueva personnel could have checked Dr. Aguilar's COR status by accessing a link that is ''clearly visible'' [17] on the DEA Diversion Web site,[18] by consulting a list of registrants updated regularly by the Department of Commerce, by contacting the local DEA field office directly, or by contracting with a private company. Tr. 20–21.

Antoine testified that he also learned that, in 2008, DEA had issued a letter admonishing Farmacia Nueva ''for failure to comply with federal requirements of the [CSA]'' (Letter of Admonition). Tr. 19. The Letter of Admonition, which was received into evidence,[19] presents as having been sent on April 3, 2008, from the DEA Caribbean Division to Moro-Perez regarding Farmacia Nueva and, on its face, purports to have been sent via certified mail. Gov't Ex. 3. The Letter of Admonition informs Moro-Perez that DEA investigators discovered numerous record-keeping discrepancies during a March 2008 investigation, *to wit:* (1) Failure to take a biennial inventory; (2) failure to record on DEA Form 222 the number of containers received and date on which such containers were received; (3) failure to record the date of receipt of controlled substances on commercial invoices; and (4) failure to submit DEA Form 41. *Id.* Each noticed violation is accompanied by a corresponding statutory and/or regulatory basis. *Id.* Although the Letter of Admonition directs Farmacia Nueva to ''[p]lease advise this office in writing within thirty (30) days, the action taken or planned, to correct [the listed] violations,'' Antoine testified that, although DEA has no record of any further correspondence related to this admonition, the matter was closed without further action. Tr. 82–86.

On the issue of Farmacia Nueva's records, DI Antoine testified that he was furnished with data from the pharmacy's computer and hard copies of prescriptions seized from Farmacia Nueva at the time of a November 30, 2011 search warrant execution. Tr. 23–24. Although Antoine's testimony was by no means a model of clarity, it appears that when the DI compared the Dr. Aguilar-authorized controlled substance dispensing events in the computer data with copies of the seized hard-copy scrips, he was unable to match twenty-two dispensing events in the data with corresponding hard-copy scrips. Tr. 23–25, 91. Antoine added that, in the course of his investigation, he also sent Moro-Perez a January 30, 2013 letter (Administrative Request for Information), over the signature of his DEA supervisor, requesting ''[c]opies of [p]rescriptions issued by [Dr. Aguilar] within the period of January 31, 2009 to November 30, 2011, including any information related to the dispensing of such prescriptions.'' Tr. 31–33; Gov't Ex. 4. Moro-Perez responded to the Administrative Request for Information in a letter,[20] dated March 4, 2013 (Response to Administrative Request for Information), which included copies of additional prescription scrips. Tr. 36. The Response to Administrative Request for Information represented that ''all of the requested prescriptions'' were included with the correspondence. Gov't Ex. 4, at 3. DI Antoine presented a document (Government FN Aguilar Scrips) that he described as copies [21] of controlled substance scrips obtained by the search warrant and later supplemented by Moro-Perez in the Response to Administrative Request for Information. Tr. 36–39; Gov't Ex. 5. Antoine testified that when he compared the Aguilar dispensing events recorded in the Farmacia Nueva computer data (FN Computer Data) to the Government FN Aguilar Scrips, he was unable to locate twenty-two Aguilar scrips that, based on the FN Computer Data, should have been there. Tr. 48. Antoine testified that he used a sorting function to create a spreadsheet from the FN Computer Data that listed every transaction from the scrips contained in the Government FN Aguilar Scrips package, or as he put it, ''exactly a mirror of what's included [in the Government FN Aguilar Scrips].'' Tr. 44–47; Gov't Ex. 6. Thus, the spreadsheet (Government FN Aguilar Scrips Spreadsheet) [22] contains every dispensing event transaction depicted in the Government FN Aguilar Scrips [23] document created by the seized scrips and supplemented by Moro-Perez pursuant to the Request for Information. DI Antoine testified that he used the sorting feature to tease out the dispensing events in the Government FN Computer Data that did not have a corresponding scrip in the Government FN Aguilar Scrips and made a spreadsheet (Government FN Aguilar No-Scrip List).[24]

[13] From the outset of the Government's case as detailed in the OSC and its Prehearing Statement, the Government signaled its intention to rely upon a theory of incomplete recordkeeping at Farmacia Nueva, and made known that its case in this regard would be principally established by an evaluation of records seized during the course of a search warrant executed at the pharmacy on November 30, 2011 and supplemented by an administrative request for information. ALJ Exs. 1, 4, at 4. Although it could hardly be a surprise that details surrounding the adequacy of the execution of the Farmacia Nueva search warrant could be an issue, instead of presenting testimony from anyone present when the warrant was executed, the Government elected to present hearsay testimony about the details of the operation from only DI Antoine, who was not present during the execution. Tr. 113–18. Over Respondents' timely (and ultimately correct) objection, the Government elicited details of conversations that occurred between DI Antoine and DIs Rosa Smith and Jose Rodriguez, who apparently were present at Farmacia Nueva when the search warrant was executed. DI Antoine was not certain about when the conversation(s) took place. Tr. 119–20; *see also* ALJ Ex. 24, at 7 n.1. The Government offered no indication that DIs or other personnel present at the search warrant execution were in any way unavailable and tendered no indicia of reliability that would merit consideration of this hearsay testimony in support of a substantial evidence finding. *See Mireille Lalanne, M.D.,* 78 FR 47750, 44752 (2013) (holding that the proponent of a hearsay statement in DEA administrative proceedings bears the burden to demonstrate sufficient reliability to warrant consideration as substantial evidence); *see also Kevin Dennis, M.D.,* 78 FR 52787, 52796 (2013) (''[H]earsay may be substantial evidence depending on its truthfulness, reasonableness, and credibility; hearsay statements are highly probative where declarants are disinterested witnesses, statements are essentially consistent, and counsel had access to the statements prior to the agency hearing.''). DEA applies the law in the relevant Circuit. *Lalanne,* 78 FR at 47751 & n.4. Precedent in the applicable Circuits are in accord. *Echostar Commc'ns Corp.* v. *FCC,* 292 F.3d 749, 753 (D.C. Cir. 2002) (holding that hearsay evidence at an administrative hearing may be used to support substantial evidence finding where it bears sufficient indicia of reliability and is reliable and trustworthy); *Hoska* v. *U.S. Dep't of the Army,* 677 F.2d 131, 138 (D.C. Cir. 1982) (holding that hearsay statements admitted at an administrative hearing that were tested for reliability and found wanting were thus insufficient to support a substantial evidence finding); *NLRB* v. *Serv. Wood Heel Co.,* 124 F.2d 470, 472 (1st Cir. 1941) (finding hearsay evidence adduced at an administrative hearing sufficiently trustworthy to be considered in a substantial evidence finding where corroborated and consistent with attendant circumstances). Inasmuch as the Government did not even attempt to demonstrate any indicia of reliability regarding the hearsay statements from DIs Smith and Rodriguez received through DI Antoine, those statements cannot be properly considered here, and were not considered in support of substantial evidence.

[14] An indictment issued against Moro-Perez was ultimately dismissed with prejudice. Stip. 8; Tr. 76–77.

[15] Tr. 78.

[16] DI Antoine testified that documentary references to Dr. Aguilar and Dr. Hector Aquilar refer to the same individual. Tr. 19.

[17] Tr. 87–89.

[18] DI Antoine testified that he was unable to recall the name of the database, but was sure that it was free and available to registrants and accessible as a link on the DEA Diversion Web site and that it has been up and running continuously since 2008. Tr. 21–22. A registrant must sign into the system to review the available information. *Id.*

[19] Tr. 34.

[20] The Government presented a copy of the Response to the Administrative Request for Information in a translated format as well as a copy of the original Spanish-language version. Gov't Ex. 4, at 2–3.

[21] DI Antoine testified that hard-copy scrips seized from Farmacia Nueva during the execution of the search warrant were photocopied. Tr. 37.

[22] Gov't Ex. 6.

[23] Gov't Ex. 5.

[24] Although not explained during the course of the hearing, the three pages that comprise the Government FN Aguilar No-Scrip List must be placed side-by-side and read across. Gov't Ex. 7. Needless to say, this format is not optimal.

Gov't Ex. 7. Thus, the Government FN Aguilar No-Scrip List reflects twenty-four [25] Aguilar-authorized controlled substance dispensing events at Farmacia Nueva where the combined efforts of DI Antoine's seized records and Moro-Perez's supplemented records still did not yield a copy of a scrip.

DI Antoine testified that he also conducted the COR application [26] investigation of Best Pharma. Tr. 52. According to Antoine, Best Pharma was also the subject of an executed criminal search warrant on November 30, 2011, and prescription scrips were likewise seized from its pharmacy, scanned into DEA computers, and returned. Tr. 50, 52, 60–61; Gov't Ex. 10. As was the case at Farmacia Nueva, data from the Best Pharma computers was extracted by DEA, and the data was queried by DI Antoine to yield controlled substance dispensing events on scrips authorized by Dr. Aguilar from the time his COR was retired up to and including the date the search warrant was executed. Tr. 65–69; Gov't Ex. 11. Antoine testified that an examination of the seized documents revealed that, like Farmacia Nueva, Best Pharma dispensed controlled substances on prescriptions issued by Dr. Aguilar during a time when the doctor did not possess a COR. Tr. 52–53. In his testimony, DI Antoine re-affirmed the aforementioned methods that Best Pharma staff members had at their disposal to ascertain Dr. Aguilar's COR status. Tr. 55.

Antoine also indicated that when he compared the Best Pharma computer-stored dispensing events with the controlled substance prescription scrips seized in connection with the search warrant, he was unable to identify ''four or five'' scrips that corresponded to dispensing events. Tr. 96.

Government-supplied declarations from the DEA Registration and Program Support Section Chief reflect that a COR was issued to Farmacia Nueva in 2005 and to Best Pharma in 2010. Gov't Exs. 2, 9. The DEA Best Pharma Declaration indicates that Best Pharma surrendered its COR for cause on December 14, 2011. Gov't Ex. 9. The Government also submitted a DEA Form 104 (Best Pharma Surrender Form) that indicates that Moro-Perez executed a voluntary surrender for cause on November 30, 2011.[27] Gov't Ex. 14, at 1. On the Best Pharma Surrender Form, Moro-Perez signed below a checked box, which provides: ''In 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 . . . I hereby voluntarily surrender my Drug Enforcement Administration Certificate of Registration. . . .''*Id.*

The DEA Farmacia Nueva Declaration states that Farmacia Nueva surrendered its COR for cause on June 28, 2012. Gov't Ex. 2, at 2. Also offered in support of the proposition that Farmacia Nueva surrendered for cause in 2012 was a copy of what purports to be email correspondence (printed out under DI Antoine's email header) between the Respondents' present counsel and an individual to whom counsel was seeking to surrender its COR. Gov't Ex. 14, at 2–4. Although the Government presented no explanation or context regarding the email traffic or any witness testimony regarding the participants, the exhibit (which was received in the absence of objection), on its face, includes this unambiguous statement:

> My client, Farmacia Nueva, has decided to voluntarily surrender its DEA registration at issue in the case Docket No. 12–16. Please prepare a joint motion to dismiss the pending case.

Id. at 2. Official notice is taken that the same Respondents captioned in this matter were also the subject of DEA administrative proceedings under Docket Number 2012–16 (Case 2012–16), an action that was commenced with a request for hearing filed on December 6, 2011, and which culminated in a termination order dated June 29, 2012.[28] Further notice is taken that the records of the Agency reflect that the recipient of the email served as the Government counsel of record in Case 2012–16. DEA has no record of a DEA Form 104 executed on behalf of Farmacia Nueva, but Antoine testified that it is his understanding that the email surrender occurred while the case was in active administrative enforcement proceedings. Tr. 72–74. In his testimony, DI Antoine explained that while it is his ''practice [to] always get a [DEA Form] 104,'' and that he has procured a DEA Form 104 in all but one case where he has accepted a registrant's surrender for cause, it was his understanding of the law that the email correspondence offered by the Government in this case was sufficient to memorialize the event. Tr. 73–74.

DI Antoine stated that he visited Farmacia Nueva and Best Pharma on August 14, 2013 (twenty days prior to the commencement of the hearing in this matter), and spoke with Nelson Vale and Miriam Castro Andujar, the respective pharmacists-in-charge (PICs).[29] Tr. 106–11. According to Antoine, in response to his query of them on the subject, both PICs indicated that they were aware of no written procedures issued for their respective pharmacies on the subject of the handling of controlled substances. Tr. 107. The PICs did, however, relate to DI Antoine that they believed that the owner planned to install a computer monitor in each pharmacy to facilitate some measure of access to verify the COR status of prescribing practitioners, and that there was also a plan to check prescriber statuses once per month. Tr. 112. PIC Castro told Antoine that she had recommendations for the handling of controlled substances that she would like to make to the pharmacy owner. *Id.*

DI Antoine's testimony was, at times, difficult to understand and not always clear. That said, his testimony was sufficiently detailed, plausible, and internally consistent to be deemed credible in this recommended decision.

The Government also presented the testimony of DFE Amy Herrmann, a digital forensic examiner employed by DEA. DFE Herrmann has been a DFE at the DEA Digital Evidence Laboratory since March 2008, and holds degrees in Information Technology, Network Security-Computer Forensics, and Financial Services. Tr. 122–25; Gov't Ex. 13. DFE Herrmann is certified as a Global Information Assurance Forensic Examiner and as an Information Systems Security Professional. Gov't Ex. 13. In the absence of objection, DFE Herrmann was accepted as an expert in the field of digital forensics.[30] Tr. 126.

DFE Herrmann stated that she was assigned to the investigations concerning the Respondent pharmacies that were conducted in November 2011. *Id.* She explained that another DFE who works in her office, Ryan Gladieux,[31] extracted the information from the Farmacia Nueva computer by imaging the computer to a wiped and sterile DEA hard drive. Tr. 128–29. Herrmann testified that the

[25] Although DI Antoine described twenty-two Aguilar dispensing events without corresponding scrip copies, the Government FN Aguilar No-Scrip List sets forth twenty-four dispensing events. *Id.* While no explanation regarding this disparity was offered at the hearing, the extra two entries appear to be refills of previously-filled prescriptions. In any event, the variance, whatever its genesis, was inconsequential to the resolution of the ultimate issues presented in this case.

[26] The Best Pharma COR application was received into the record. Gov't Ex. 8.

[27] Although no explanation has been tendered to explain this disparity, the anomaly does not impact any issue dispositive to a resolution of the ultimate issues in this case.

[28] The Administrative Procedure Act and the DEA regulations authorize the identification, recognition, and inclusion of material facts in the administrative record by the taking of official notice. 5 U.S.C. 556(e); 21 CFR 1316.59(e); *Attorney General's Manual on the Administrative Procedure Act* § 7(d) (1947). To the extent either party seeks to challenge the factual predicate of the official notice taken in this matter, it may file an appropriate motion no later than fifteen days from the issuance of this recommended decision.

[29] *See* Fed. R. Evid. 801(d)(2)(E).

[30] DFE Herrmann's CV was received into the record. Gov't Ex. 13.

[31] During the Direct Examination of DFE Herrmann, the Government offered into evidence a declaration from DFE Ryan Gladieux. Tr. 133–37; Gov't Ex. 15. In his declaration, Gladieux states that he made complete copies of the hard drives seized during the investigations of Farmacia Nueva and Best Pharma on November 30, 2011. Gov't Ex. 15. Gladieux declares that the copies of the hard drives are complete and accurate. *Id.* In objecting to the admission of the declaration, the Respondents raised the (fair) point that in contrast to the declarant, who had actual knowledge as to how the evidence was extracted, DFE Herrmann, ''has testified only to the things she has heard from someone that that happened.'' Tr. 135–36; *see also* Tr. 149–50. In explaining its election to present a declaration in lieu of testimony from Gladieux, the Government acknowledged that Gladieux was available, but stated ''[t]he reason was that the [G]overnment felt that a declaration would have been sufficient insofar as that it was properly noticed in the prehearing statement and that an indicia of reliability would have been given during this hearing [sic].'' Tr. 135. Regarding the Government's proposed transcript errata correction (ALJ Ex. 20, at 2) in this regard, the version set forth in the official transcript is consistent with my recollection. Gladieux's declaration was received into the record over the Respondents' hearsay objection, and although all parties were granted leave to present his live testimony, none did. Tr. 136. As explained more fully, *infra,* the Respondents' objection more correctly reflected on the weight to be afforded the content of the exhibit than it did on the document's admissibility.

technique employed by Gladieux [32] for imaging the computer makes a complete copy of all data contained therein and provides an alert to indicate if certain files are unreadable.[33] Tr. 139–41. DFE Gladieux then provided the hard drive to the DEA office in Ponce where it was checked in as non-drug evidence. Tr. 131. From there it was forwarded to the DEA laboratory in Lorton, Virginia, and checked into the digital evidence vault. Tr. 122–23, 131. Herrmann stated that she then created a virtual machine with which to run Farmacia Nueva's RX30 program,[34] enabling her to access the program as if she were accessing it from Farmacia Nueva's own computer at the moment the data was extracted.[35] Tr. 141–42. Herrmann testified that she generated a report of all prescriptions dispensed by the pharmacy from January 1, 2009 to December 31, 2011, and converted the report into an Excel file. Tr. 142–43. According to Herrmann, she ran another report of the same data, but excluded any prescriptions that were noted as ''on hold'' (no-holds run). Tr. 143–44. The no-holds run generated fewer dispensing events than the first report, but she never attempted to run a report to isolate the dispensing events in the ''on hold'' status. Tr. 145–47. Some of the dispensing event transaction numbers in the no-holds run are preceded by the letter ''H.'' *See* Gov't Ex. 7. When Herrmann was queried about whether the ''H'' indicated that these events really were ''on hold,'' she conceded that she did not understand what the ''H'' meant and that she did not know why some transaction numbers bore that designator. Tr. 152–53, 161–62. Whatever ''H'' meant, DFE Herrmann testified that the report she ran on the data from the Farmacia Nueva computer excluded any dispensing event that was in an ''on hold'' status. Tr. 143–44, 151–52, 160–61.

DFE Herrmann testified that she used ''essentially the same steps'' [36] employed on the Farmacia Nueva computer data to analyze the information extracted from Best Pharma's RX30 program. Tr. 147. Regarding those matters of which she did have first-hand knowledge, her testimony was sufficiently detailed, plausible, and internally consistent to be fully credited in this recommended decision.

George Taylor, a DI stationed at the DEA Des Moines Resident Office, was called as a witness for the Government regarding his role as the team leader in charge of executing the search warrant at Best Pharma on November 30, 2011. Tr. 168–69. DI Taylor testified that his team of seven to nine federal and local agents and analysts seized all prescription records, controlled substances, and other specific items listed on the warrant. Tr. 170, 172. DI Taylor stated that the search warrant team was assisted by a Best Pharma pharmacist [37] who directed them where to find the items listed on the warrant. Tr. 170. Controlled substances were seized and inventoried on the premises, and hard copies of controlled substance scrips and other records were collected and transported back to the staging area and then to the DEA Ponce Resident Office. Tr. 170–71, 187. Taylor testified that, with the guidance of the Best Pharma pharmacist (who he assessed as cooperative), it is his opinion that the team seized all controlled substance prescription scrips that were on hand at the pharmacy, including paperwork from the prescription counter. Tr. 186–88.

DI Taylor also testified that he was with Moro-Perez at the time the latter signed the Best Pharma Surrender Form. Tr. 175; Gov't Ex. 14, at 1. On November 30, 2011, DI Taylor, accompanied by DEA Special Agent Juan Hernandez, signed the form as a witness and presented it to Moro-Perez while the latter was in custody.[38] Tr. 175; Gov't Ex. 14, at 1. DI Taylor directed Special Agent Hernandez to explain, in Spanish, to Moro-Perez that the form was a voluntary surrender of his controlled substances privileges. Tr. 176, 184. Special Agent Hernandez also read the entire form to Moro-Perez in Spanish. Tr. 178. DI Taylor testified that Moro-Perez questioned him regarding the nature of the surrender and whether it was related to the criminal charges against him. Tr. 179. DI Taylor stated that he explained that the surrender specifically related to the DEA registration number and was separate from any criminal allegations, and he testified that he dealt only with the regulatory matter. DI Taylor explained to Moro-Perez that if he did not sign the form, the DEA would move for an OSC proceeding. Tr. 176–77. DI Taylor stated that in his conversations with Moro-Perez, he never linked the voluntary surrender to the ongoing criminal investigation. Tr. 177.

Moro-Perez also testified at the hearing.[39] He stated that he is the president and original owner of both Farmacia Nueva and Best Pharma. Tr. 192, 219, 222, 238. He stated that he has been a pharmacist since he completed his training at medical school in Puerto Rico in 1999, worked as a pharmacist at another pharmacy, and served as chief pharmacist at Farmacia Nueva. Tr. 194, 202, 223–24. He acknowledged that he had received training regarding the prevention of the unauthorized distribution of controlled substances, and that he learned in his training that the pharmacy is ''ultimately responsible for ensuring the integrity and the veracity of the prescription.'' Tr. 194. He also acknowledged that, from February 2009 to October 2011, both Respondent pharmacies filled prescriptions for (the un-registered) Dr. Aguilar. Tr. 193. Farmacia Nueva filled approximately 143 prescriptions, and Best Pharma filled approximately 32 prescriptions. *Id.* Moro-Perez conceded that at no point during that time period did any of the pharmacies attempt to verify the COR status of any of the doctors for whom they filled prescriptions. Tr. 194.

During the course of Moro-Perez's testimony, he described the physical layout and operational procedures utilized at the Respondent pharmacies. Regarding Farmacia Nueva, Moro-Perez explained that the three-story establishment is manned by twenty-two employees and that Nelson Vale is and has been the pharmacist-in-charge (PIC) since 2010. Tr. 224–25. According to Moro-Perez, Best Pharma is located in a two-story building with sixteen employees. Tr. 240–41. The departments in each store are divided between the various floors. Tr. 224, 240. Moro-Perez testified that his role as a pharmacist and company president requires that he ensure that every prescription has a regular and legal use; that all administrative duties are carried out; and that each prescription is dispatched faithfully to the patient as the doctor prescribed it. Tr. 226–27. He then explained the following procedure for when a patient enters the FN pharmacy with a prescription: The patient, first, turns in his prescription at the pharmacy's receiving area. Tr. 227. Next, a pharmacy employee verifies the prescription, the name on the prescription, the address of the patient, the date, the medication, the quantity to be dispatched, the instructions on how to use the medication, the doctor's signature, and, if it is a prescription for a controlled substance, the DEA license, the AMSSCA license,[40] and the state medical registration or license as found on the pharmacy's RX30 program. Tr. 227–28, 230. The employee then verifies if the prescription and medication are bioequivalent. Tr. 228. If the patient accepts the medication, the back of the prescription is stamped and signed, and then the patient signs the document to acknowledge acceptance of the exchange of medication. *Id.* Next, pharmacy personnel enter the patient's name, phone number, address, driver's license, and medical plan information into

[32] Herrmann acknowledged that she had no personal knowledge of exactly what Gladieux did and/or how well he did it beyond reading reports he prepared. Tr. 149–50.

[33] The imaged files copy each piece of data from the original, and a DEA program creates something called a ''hash'' for every file. Tr. 128. The hash is an algorithm that uniquely fits a piece of data and creates a certain value. Tr. 132. If a piece of data is altered in any way from the original data extracted from the computer, the hash value will change, notifying the DEA of the alteration. Tr. 132, 148. Herrmann testified that she verified that all hash values matched when she commenced her analysis of the data extracted from the computer. Tr. 133. Herrmann clarified that although error is always a possibility, the software she utilized is designed to alert the examiner if the reports generated do not match the amount of records contained in the data. Tr. 154–56.

[34] RX30 appears to be a software program that enables pharmacies to manage and record their dispensing events. Tr. 91, 138, 142.

[35] Herrmann acknowledged that the reports could have been run using Farmacia Nueva's computer instead of from an image of the data extracted from the computer. Tr. 163–65.

[36] There is no indication in the record why Herrmann characterized the steps as ''essentially'' the same.

[37] DI Taylor testified that a female Best Pharma pharmacist assisted his team in the execution of the search warrant, but he was unable to recall her name. Tr. 170.

[38] It is clear from DI Taylor's testimony that Moro-Perez was in custody in the rear of a government vehicle when he signed the Best Pharma Surrender Form. Tr. 179–83. The Respondents have raised no issue related to the voluntariness of the Surrender Form execution, and no genuine issue in this regard is supported by the record evidence.

[39] Although Moro-Perez was noticed as a witness by the Respondents, his testimony was elicited by the Government as part of its case-in-chief. Tr. 190–191, 268.

[40] Regrettably, neither side provided any additional details as to what this organization is, or what the letters stand for.

the RX30 system. Tr. 228–29. The prescription is then scanned, and the pharmacy enters the doctor's information. Tr. 229. The pharmacy staff verifies that all of the prescriber's information (including COR and license numbers) is found in the system, and enters the medication, including the amount to be dispensed and the dosage instructions. *Id.* After obtaining and entering all this information, the pharmacy staff submits the information to the appropriate insurance carrier, which will determine whether it will reimburse based on the information submitted. *Id.* The pharmacy staff then counts out the medication, puts it in a basket, and presents it to a pharmacist for verification. *Id.* Upon successful verification, the prescription is placed in dispatch, and the pharmacy contacts the patient who signs for the prescription, collects the medication, receives instructions on use, and pays any applicable deductible. Tr. 229–30.

Moro-Perez stated that Best Pharma uses the same process of dispensing prescriptions as Farmacia Nueva. Tr. 245. He testified that Farmacia Nueva dispenses 500 prescriptions per day, with controlled substances accounting for approximately 10–15% of those sales. Tr. 244–45. Best Pharma dispenses 200–300 prescriptions per day, with approximately 10–15% of those sales derived from controlled substances. Tr. 245.

Moro-Perez testified that, for prescriber COR verification, his Respondent pharmacies have relied upon a system of entering information into their internal computers, submitting the information to medical insurance providers through pharmacy software, and basing the assumption of up-to-date doctor licensing on the receipt of insurance provider ''confirmation'' [41] of payment approval. Tr. 195–96, 230–32. Moro-Perez represented that both pharmacies purchased the RX30 system for their computers from a company named Ontime Soft, Inc. Tr. 196–97, 244. Pharmacy staff inputted a list of prescribing doctors and the doctors' information into the program. Tr. 199–200. Moro-Perez then explained that, when a patient visits one of the pharmacies with a prescription, the following information is entered into the system and then transmitted to the insurance providers: the patient, the patient's information, the doctor's information, the medication, the amount of medication, the directions for using the medication, and the amount of days that the medication will be supplied. Tr. 201. Moro-Perez eventually admitted that the pharmacies' method of ensuring the validity of the prescribing doctors' DEA licenses was to check, prior to dispensing, that the insurance company was willing to reimburse based on the electronically-transmitted claim. Tr. 200–01. He even conceded that although this was the method they employed to verify the prescribers' registration status,[42] the insurance companies never represented that reliance upon the benefits claim determination was an appropriate method to check COR status.[43] Tr. 202. Moro-Perez stated that he does not know why the insurance companies kept reimbursing based on Dr. Aguilar's controlled substance prescriptions when he no longer had a COR, and he even agreed that the Respondent pharmacies would likely never have stopped dispensing (unregistered) Dr. Aguilar's prescriptions if the DEA had not executed its search warrant on November 30, 2011. Tr. 202–03. Moro-Perez acknowledged that the Respondents made a mistake and that they erred in not calling the DEA to verify Dr. Aguilar's COR. Tr. 201–02.

When questioned regarding the Government's list of purportedly missing prescriptions from Farmacia Nueva,[44] Moro-Perez insisted that, when he was told that the DEA identified those scrips as missing, he queried the system by medication name and was able to locate and identify all but one of the missing scrips in the Farmacia Nueva Computer and found a hard copy of the single missing (apparently unscanned) scrip in the pharmacy.[45] Tr. 203–05. Copies of the imaged Dr. Aguilar scrips he purportedly printed from the pharmacy computer and supplemented with the single hard-copy scrip were received into the record (Moro-Perez FN Aguilar Scrips). Resp't Exs. 1, 2. Also received into evidence was a package of imaged prescription scrips that Moro-Perez testified he produced by querying the dispensing event numbers corresponding to the Dr. Aguilar controlled substance scrips that DEA alleged as missing (Moro-Perez FN Aguilar Found Scrips).[46] Resp't Ex. 4; Tr. 263. The Moro-Perez FN Aguilar Found Scrips document contains nine scrips that, according to Moro-Perez, he was able to create by querying the Farmacia Nueva RX30 system with the dispensing event numbers that DEA told him they were unable to match with Government FN Aguilar Scrips.[47]

Although, in a prehearing motion,[48] Farmacia Nueva averred that multiple dispensing events set forth in the Government FN Aguilar No-Scrip List document were the result of typographical errors, an analysis of the documents does not bear this out. Both of the purportedly mistyped dispensing events (00735388 & 00784686) were actually supplied by the Respondent in the Moro-Perez FN Aguilar Found Scrips document.[49]

A detailed analysis of the dispensing event exhibits from both sides presents a nuanced and initially confusing picture that would have benefitted greatly from explanation at the hearing. An examination of the Moro-Perez FN Aguilar Scrips [50] and the Moro-Perez FN Aguilar Found Scrips [51] documents reveals that they contain all but two of the dispensing events depicted in the Government FN Aguilar No-Scrip List [52] that was created by DI Antoine.[53] This testimony was offered by Farmacia Nueva in support of its contention that Moro-Perez, with some level of diligence, was able to retrieve all of the scrips that DEA identified to him as missing.

One of the two unaccounted-for dispensing events bears a dispensing event number preceded by an ''H'' (H00751567). Gov't Ex. 7. No witness who testified at the hearing explained the significance of an ''H'' affixed to a dispensing event number, but since a second ''H''-designated number (H00784094) was eventually paired with a scrip [54] by Moro-Perez, it seems unlikely that the ''H'' presents a reasonable explanation for the scrip's absence. DFE Herrmann testified that ''hold'' was a status setting available within the RX30 software structure, but she did not

[41] The witness never made clear what information was actually being transmitted or confirmed in the ''confirmation.''

[42] Moro-Perez also said that pharmacy staff checked prescriber licenses in the RX30 system. Tr. 230–31. However, since the pharmacies' internal systems were only updated by pharmacy staff, who relied exclusively on payment approvals from insurance companies, this step added little to the aggregate safeguards in place.

[43] Actually, the record contains no evidence that would objectively support a decision to rely on this approach or even support a conclusion that this method would be an effective manner to garner this information.

[44] Gov't Ex. 7.

[45] The supplemented scrip was identified by Moro-Perez as page 143 of Respondents Exhibit 2. According to Moro-Perez, the computer automatically affixes identifier information at the top of each prescription image it produces. Tr. 235. The scrip that Moro-Perez added to the package does not have the identifier heading on it. Resp't Ex. 2, at 143.

[46] The witness testified that the first five pages of the package contain Best Pharma scrips (identified by 5-digit dispensing event numbers) and the balance reflects Farmacia Nueva scrips (identified by 6-digit dispensing event numbers). Tr. 260–65.

[47] However, only two of the nine scrips (Resp't Ex. 4, at 191, 192) contained in the Moro-Perez FN Aguilar Found Scrips document correspond to Aguilar Farmacia Nueva dispensing events listed by the Government as missing scrips in its Government FN Aguilar No-Scrip List. Gov't Ex. 7. This is likely the result of a pre-hearing motion submitted by the Respondents (ALJ Ex. 10) wherein they pointed out that numerous scrips noticed by the Government (apparently including seven of the nine FN scrips contained in the Moro-Perez FN Aguilar Found Scrips document (Resp't Ex. 4, at 184–90)) refer to non-controlled substances. As a result of the Respondents' motion, the Government substituted the current version of Government Exhibit 7, which evidently omits reference to the non-controlled substances.

[48] ALJ Ex. 10, at 2. In their motion, the Respondents represented that when the typographical errors are factored into the equation, ''no prescription is missing.'' *Id.* at 3.

[49] Resp't Ex. 4, at 191, 192.

[50] Resp't Ex. 1–2.

[51] Resp't Ex. 4.

[52] Gov't Ex. 7.

[53] The following is a list of each entry found in the Government FN Aguilar No-Scrip List (Gov't Ex. 7), which listed the prescriptions missing from Farmacia Nueva. After each listed prescription event number entry, a corresponding citation to where that prescription can be found in the Respondents' exhibits (if at all) is provided: #00581227: Resp't Ex. 2, at 165; #00592053: Resp't Ex. 2, at 167; #00594763: Resp't Ex. 2, at 168; #00603582: Resp't Ex. 2, at 169; #00615341: Resp't Ex. 2, at 170; #00680204: Resp't Ex. 2, at 143–44; #00696609: Resp't Ex. 1, at 49; #00735388: Resp't Exs. 1, at 52, 4, at 191; #00739096: Resp't Ex. 1, at 28; #00740774: Resp't Ex. 1, at 29; #00748164: Resp't Ex. 1, at 31; #00750564: Resp't Ex. 1, at 92; #H00751567: no record; #00760079: Resp't Ex. 1, at 93; #00760079: Resp't Ex. 1, at 93; #00784105: Resp't Ex. 2, at 123; #00784686: Resp't Ex. 4, at 192; #00785359: Resp't Ex. 2, at 124; #00785837: Resp't Ex. 2, at 125; #00785837: Resp't Ex. 2, at 125; #00798150: Resp't Ex. 2, at 126; #00805523: no record; #00806899: Resp't Ex. 2, at 127; #H00784094: Resp't Ex. 4, at 190.

[54] Resp't Ex. 4, at 190.

know what it signified. Tr. 144–46. Moro-Perez likewise offered no explanations about the significance of an ''H'' before a dispensing event number, or ''hold'' status.[55] The second missing dispensing event (00805523) was never matched up with a corresponding scrip.

Moro-Perez testified that DEA personnel left the Respondent pharmacies in considerable disarray after the simultaneous execution of the search warrants, and that the agents left ''a lot of controlled [substance] prescriptions'' in drawers at ''both pharmacies.'' Tr. 243–44. At the hearing, when Moro-Perez was shown the Government's Administrative Request for Information to Farmacia Nueva [56] in which DEA requested the pharmacy to supply copies of all prescriptions issued by Dr. Aguilar during the period in question and dispensed by the pharmacy, he responded that he ''provided [DEA] everything that the system provided and all the prescriptions were submitted.'' Tr. 206–08.

Moro-Perez explained that RX30 creates a separate number for each dispensing event, and that once that number is created, it cannot be altered or manipulated manually.[57] Tr. 235. He offered his assurance that he has not nor would ever attempt to do so. *Id.* Moro-Perez indicated that Farmacia Nueva has had the same computer for about five years and that it has never left the pharmacy except for when the DEA took possession of it for about five days at the time the search warrant was executed. Tr. 232–33. Best Pharma's computers have also been in the business since it opened, and inasmuch as DEA extracted data from them on the date of the search warrant execution, these computers have never left the pharmacy. Tr. 242.

Moro-Perez testified that Farmacia Nueva dispensed approximately two to three prescriptions authorized by Dr. Aguilar every two weeks and that there was sometimes a few months between prescriptions. Tr. 250. He also explained that Farmacia Nueva was about a three-to-four minute walk from Dr. Aguilar's office.[58] Tr. 250–51. Stunningly, Moro-Perez testified that personnel at Farmacia Nueva ''many times'' declined to fill controlled substance prescriptions authorized by Dr. Aguilar because they were deemed illegitimate. Tr. 252. Moro-Perez explained that, quite often, ''many'' patients brought controlled substance prescriptions issued by Dr. Aguilar where the Farmacia Nueva pharmacists ''knew that that patient didn't require the use of that medication [and] we told them that we were not going to dispense the prescription.'' *Id.* Notwithstanding the close proximity of Dr. Aguilar's practice to Farmacia Nueva (three to four minutes on foot), and the frequency with which the pharmacy declined to dispense controlled substances he prescribed, Moro-Perez provided the astonishing revelation that he never contacted Dr. Aguilar about any of his (bad) prescriptions. Tr. 252–54. When pressed as to why Dr. Aguilar's routine prescribing misconduct did not arouse any heightened scrutiny on the part of his pharmacies, Moro-Perez offered that ''if you analyze the amount of medications that were dispensed, the percentage is very low.'' Tr. 253. In other words, the Respondents knew Dr. Aguilar was regularly providing illegal controlled substance prescriptions to Respondents' customers, but no one on staff checked his registration in any serious way or even took the minimal step of reaching out to speak with him about his prescribing practices because ''the percentage [was] very low.'' *Id.* Moro-Perez stated that he never contacted Dr. Aguilar because ''I was aware that the doctor's license was up to date.'' Tr. 253–54. In addition to the fact that Dr. Aguilar was not, in fact, ''up to date'' on his DEA registration, Moro-Perez's answer is patently illogical and presents as intentional equivocation.

At the hearing, Moro-Perez identified a printed copy of the online registration application that he submitted on behalf of Farmacia Nueva. Tr. 210; Gov't Ex. 1; *see also* Stip. 5. He confirmed that he understood the application and Question 2 (asking whether the applicant had ever surrendered a COR for cause), agreed that he entered a ''no'' response, and explained that his reason for doing so was because he understood that, ''in relation to the criminal case, there was no cause against me.'' [59] Tr. 211. Moro-Perez conceded that no one from DEA told him that his former criminal case (which was actually dismissed three months prior to the surrender) was linked in any way to the surrender,[60] but he insisted that he believed that Farmacia Nueva's surrender was associated with his criminal case because ''all this is a consequence of the dispatch of the medications of Dr. Aguilar.'' Tr. 212–13. The witness persisted in this answer, even when pressed by the Government about how he could think that the nature of the Farmacia Nueva surrender could be affected by an event (the indictment dismissal) that preceded it. Tr. 212–13, 215. In response to a question asked by the Government, Moro-Perez responded that if Question 2 did not contain the words ''for cause,'' he would have answered ''yes'' to the question. Tr. 216–17, 219. Moro-Perez explained that he never wanted to lie to DEA because ''[t]hey are aware of the arrest that they executed.'' Tr. 216. Later in his testimony, Moro-Perez offered this:

> Really in relation to this particular case I'll repeat again. I answered no knowing and recognizing that you, the DEA office, are aware of, had knowledge and everything about me. Therefore, I have never had intentions [sic] to lie. I'm going to say the truth, and that's the truth.

Tr. 218–19. Moro-Perez clarified that the rationale he used for answering Question 2 in the negative on the Farmacia Nueva application was the same approach employed by him when answering the same question in the Best Pharma application. Tr. 222.

Although Moro-Perez acknowledged at the hearing that Question 2 was erroneously answered,[61] he expressed no remorse. In like manner, he stood by his ability to retrieve required records from the Respondent pharmacies' computers and questioned the thoroughness of DEA's search warrant execution, *see* Tr. 243–44. On the other hand, he readily accepted that the procedure previously employed for ensuring that controlled-substance prescribers had valid CORs was a ''mistake.'' Tr. 236. He offered that if the Respondent pharmacies are granted CORs, they would take several preventative steps to ensure that the doctors who wrote prescriptions for dispensing at the pharmacy had the requisite authority to do so.[62] *Id.* Moro-Perez represented that if the pharmacies were again registered, an employee would verify the registration status of prescribing physicians with the appropriate DEA Web site every month. Tr. 236–37. He also represented that he is ''establishing a new system of computers so the pharmacy will be able to study the patient file and the doctor's file'' and ''demand'' documentation that the patient is being treated by a specialist ''mostly on the narcotic medications, the pain medications and any other that we understand that is being used for alleged medical use [sic].'' Tr. 237–38. Moro-Perez also offered that the current PICs of both Farmacia Nueva and Best Pharma have spent a significant number of years practicing in the field. Tr. 241–42.

The testimony of Moro-Perez cannot be deemed entirely credible. There were times during his testimony where he offered answers that were intentionally equivocal and made no sense. For example, when asked why no increased scrutiny or contact resulted from ''many'' instances where Dr. Aguilar's patients attempted to fill bad prescriptions at the pharmacies and were refused, Moro-Perez responded that no action was taken because the percentages were very low and because he knew Aguilar's licenses were current.[63] These answers were inconsistent with his earlier recognition that the responsibility for accurate dispensing rests with the

[55] To the extent that the Respondents' closing brief avers that the ''H'' described in the record refers to a dispensing event being in a ''hold'' status (ALJ Ex. 24, at 8, 17), that assertion is simply not supported in the record. This record does not contain an explanation of the meaning of an ''H'' before a dispensing event transaction number.

[56] Gov't Ex. 4.

[57] Although the relevance of this testimony was likely linked to dispel any notion that Moro-Perez or other pharmacy personnel could have manually placed an ''H'' before certain dispensing event numbers, the lack of any witness to explain what an ''H'' signifies greatly diminishes the utility of this testimony. Stated differently, since the record never says what the ''H'' signifies, it does not much matter whether anyone could have manually added it to the transaction numbers or anywhere else.

[58] Moro-Perez testified that, of the dozen or so pharmacies in San Sebastian that dispensed controlled substances, Farmacia Nueva was the pharmacy located closest to Dr. Aguilar's office. Tr. 251.

[59] A copy of the March 28, 2012 federal criminal indictment dismissal where Moro-Perez was a defendant was received into the record (Resp't Ex. 3) and was also the subject of testimony (Tr. 212) and a stipulation between the parties (Stip. 8).

[60] Tr. 213, 218–19.

[61] Tr. 216.

[62] Although he directed his initial comments regarding remedial steps to Farmacia Nueva, Moro-Perez testified that the same measures would be taken at Best Pharma. Tr. 245–46.

[63] Tr. 250–54.

pharmacy,[64] bear little relation to the question, and are the obvious fruit of intentional equivocation. In like manner, Moro-Perez initially testified that when claims were submitted to insurance carriers, the pharmacies would receive a ''confirmation'' that the prescribers had valid licenses. Tr. 196. Later in his testimony, it became apparent that the ''confirmation'' from the insurance providers informed the pharmacy staff only that the reimbursement claim would be approved. Tr. 200–01. It was the same sort of equivocation employed when Moro-Perez testified that pharmacy staff would check prescriber licenses through RX30, a system that depended exclusively on input from staff who depended exclusively on the fact that claims were being approved.[65] When questioned as to why, at the hearing, he was able to produce scrips that were apparently not forwarded to DEA as part of his compliance with the Request for Information, Moro-Perez never explained why the new scrips were so late in coming or suggested that DEA did not have the complete set he forwarded, but merely continued to insist that he ''provided them everything that the [RX30] system provided, and all the prescriptions were submitted.'' Tr. 208. These answers presented inconsistencies, were less than complete, and were certainly less than candid. Similarly, when explaining his rationale for answering ''no'' to application Question 2, Moro-Perez adhered to the position that the nature of the June 2012 Farmacia Nueva surrender was somehow altered by the dismissal of a criminal indictment against him (not the pharmacies) that occurred three months earlier. It is inescapably illogical to insist that an event which occurred prior to the surrender would somehow alter its characterization from ''for cause'' to otherwise. Inasmuch as Moro-Perez is an educated and experienced pharmacist, to suggest that this *non sequitor* was the result of naiveté or inexperience is patently unreasonable. The answer was deceitful, intentionally so, and he well knew it. Similarly, when explaining his position on the negative response entered on Question 2, Moro-Perez qualified his testimony by twice adding that DEA knew about his arrest. Tr. 216, 218–19. Again, this is a non-answer, since the arrest, the indictment dismissal, and DEA's knowledge about those events do not bear any relation to the issue he was addressing, *to wit,* the ''no'' response to the question of whether the Respondents' registrations had been surrendered for cause. Thus, Moro-Perez tendered testimony that was at times implausible and inconsistent, and he substituted intentional equivocation for detail. His testimony, then, cannot be deemed fully credible in this recommended decision. That is not to say that all of his testimony is not worthy of belief, but in those places where his testimony conflicts with other record evidence, it must be considered with heightened vigilance.[66]

The Respondents' Evidence

In addition to the testimony from Moro-Perez that was elicited on cross examination, the Respondents' presented the testimony of Mr. Nelson Vale. Tr. 268. Mr. Vale testified that he has worked at Farmacia Nueva since February 2009 and has served as the chief pharmacist since August 2010. Tr. 272. Vale acknowledged that he was employed at the pharmacy during the time period when it was dispensing controlled substances on Dr. Aguilar's expired COR. Tr. 281. Before working at Farmacia Nueva, he worked as a pharmacist and chief pharmacist at two Walgreens pharmacies. Tr. 272–73. Vale testified that his role at Farmacia Nueva requires ensuring ''that the medication is dispensed properly'' and that the pharmacy maintains a correct inventory. Tr. 273. Consistent with other witnesses who have testified on the subject, Vale stated that the pharmacy uses the RX30 program, that the system automatically assigns dispensing event numbers to each prescription, and that the program cannot be manipulated to change the dispensing event numbers once they have been assigned. Tr. 273–74. Vale testified that a prescription dispensing event can be looked up on the RX30 program by its dispensing event number, by the type of medication, or by the doctor's name. Tr. 276. Further, Vale indicated that he could identify all prescriptions in the system that were authorized by Dr. Aguilar. Tr. 277. He also stated that, ''to the best of his knowledge,'' no one has ever tried to manipulate the numbers for Farmacia Nueva's RX30 program, that he has never tried to do so, and that he was never directed to do so. Tr. 276–77.

Vale described the dispensing process at Farmacia Nueva. Tr. 274. Vale's account of FN pharmacy operations was in substantial accord to the explanation provided by his boss, Moro-Perez. Tr. 274–75.

Vale also testified that he and Moro-Perez have discussed remedial improvements they intend to implement if Farmacia Nueva is granted its COR. Tr. 278. Among their plans is the future pursuit of a strict policy regarding dispensing controlled substances, a ''program'' [67] that will alert pharmacy personnel when a physician's license is expired in real time, and a plan to have staff access the DEA Web site at least once a month to ascertain prescriber COR status. Tr. 278–79.

Vale conceded that these safety measures could have been implemented before the execution of the search warrant on November 30, 2011. Tr. 280. He also admitted that, since November 30, 2011, he has not asked DEA whether they provide training against illegal distribution and he has not taken any training regarding anti-diversion efforts or anti-illegal distribution efforts. Tr. 281–82. Vale likewise acknowledged that the planned remedial measures stem from enforcement actions already taken by DEA as well as a desire to avoid the specter of future sanctions. Tr. 282.

Mr. Vale's testimony was sufficiently plausible, detailed, and internally consistent to be deemed credible in this recommended decision.

Additional facts required for a disposition of this case are set forth below.

The Analysis

The Government alleges two bases for denial of the Respondents' applications: (1) that Respondents' owner/president, Moro-Perez, materially falsified the Respondents' applications for CORs; and (2) that the granting of the Respondents' applications would be inconsistent with the public interest. These bases are addressed below, *in seriatim.*

Material Falsification

The Government has alleged that the Respondents' respective applications for CORs should be denied because each application contains a material falsification,[68] which, under the CSA, is a ground for a sanction against an existing COR. 21 U.S.C. 824(a)(1). The Agency may revoke or suspend a DEA COR upon a finding that the registrant has materially falsified any application filed to obtain it. *Id.* Under the theory that the law would not require issuance of a COR that should be revoked *ab initio,* a long line of Agency precedent has consistently held that the grounds for the revocation or suspension of an existing registration are also properly considered in adjudicating an application for a COR. *The Lawsons, Inc.,* 72 FR 74334, 74335 (2007); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23852 (2007); *Dan E. Hale, D.O.,* 69 FR 69402, 69405–06 (2004); *Anthony D. Funches,* 64 FR 14267, 14268 (1999); *Alan R. Schankman, M.D.,* 63 FR 45260, 45260 (1998); *Kuen H. Chen, M.D.,* 58 FR 65401, 65402 (1993). Thus, in the same way that materially falsifying an application provides an independent basis for revoking an existing registration without proof of any other misconduct, it also provides an independent and adequate ground for denying an application for a new COR. *The Lawsons,* 72 FR at 74338. It is settled Agency precedent that ''[s]ince DEA must rely on the truthfulness of information supplied by applicants in registering them to handle controlled substances, falsification cannot be tolerated,'' *Bobby Watts, M.D.,* 58 FR 46995, 46995 (1993), and that a ''cavalier attitude toward the importance of accurately executing [a registration] application suggests a lack of concern for the responsibilities inherent in a DEA registration.'' *Chen,* 58 FR at 65402.

To serve as a basis for an adverse application determination, it is incumbent upon the Government to establish that an applicant has provided false information in his or her application, and that the false

[64] Tr. 194.

[65] Tr. 229–31.

[66] The Government has argued in its closing brief that Moro-Perez ''frequently gave evidence that directly conflicted with the Government's evidence.'' ALJ Ex. 23, at 27. This misses the point. It is not that his testimony is lacking in credibility because it is incongruous with testimony elicited by the Government, but, rather, it is worthy of diminished credibility based on a dispassionate review of its own merits.

[67] No further explanation was offered as to what sort of a ''program'' is contemplated, how it would work, or how it would alert pharmacy staff when a prescriber's COR expires. This proposal was described by the witness in terms that seemed more ethereal than concrete.

[68] ALJ Ex. 4, at 3–5.

information provided is material. 21 U.S.C. 824(a)(1). The Government must prove that the false information is material by ''clear, unequivocal, and convincing'' evidence. *Hoi Y. Kam, M.D.,* 78 FR 62694, 62696 (2013) (quoting *Kungys* v. *United States,* 485 U.S. 759, 772 (1988)). A material falsification requires a showing that a statement tendered in a COR application is one that '' 'has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.' '' *The Lawsons,* 72 FR at 74338 (citing *Kungys,* 485 U.S. at 770); *see also Robles* v. *United States,* 279 F.2d 401, 404 (9th Cir. 1960), *cert. denied,* 365 U.S. 836 (1961). Proof that any Government decision, including the decision regarding the registration application, was actually influenced is not required. *The Lawsons,* 72 FR at 74339. The touchstone is whether the statement had the *capacity* to influence. *See United States* v. *Alemany Rivera,* 781 F.2d 229, 234 (1st Cir. 1985), *cert. denied,* 475 U.S. 1086 (1986); *Alvin Darby, M.D.,* 75 FR 26993, 26998 (2010). Since a materiality determination turns on an analysis of the relevant substantive law, *Kungys,* 485 U.S. at 772, the allegedly false statement must be analyzed in the context of the application requirements sought by DEA and provided by the applicant. The falsification must relate to a ground that could affect the decision, not merely a basis upon which an investigation could be initiated. *Darryl J. Mohr, M.D.,* 77 FR 34998, 34998 n.2 (2012); *Harold Edward Smith, M.D.,* 76 FR 53961, 53964 (2011); *Scott C. Bickman, M.D.,* 76 FR 17694, 17701 (2011). The entire application will be examined to determine whether there was an intention to deceive the agency. *See Jackson,* 72 FR at 23852–53.

Furthermore, the correct analysis hinges on whether the applicant knew or should have known that he or she submitted a false application. *Hale,* 69 FR at 69406; *The Drugstore,* 61 FR 5031, 5032 (1996); *Watts,* 58 FR at 46995. Although even an unintentional falsification can serve as a basis for adverse action regarding a registration, lack of intent to deceive and evidence that the falsification was not intentional or negligent are all relevant considerations. *Funches,* 64 FR at 14268.

The Government has alleged that each of the Respondent pharmacies surrendered a COR for cause and that, when Moro-Perez stated otherwise on their COR applications, he knew or should have known that his statement in this regard was untrue. In their closing brief, the Respondents assert that ''the Government did not submit any evidence to prove that Farmacia Nueva's registration was revoked or surrendered (for cause).'' ALJ Ex. 24, at 22. Although the record evidence tells a story somewhere between the parties' contentions, it is the Government's view that is better supported.

The DEA regulations related to COR termination provide, in pertinent part, that:

In the case of a surrender, termination shall occur upon receipt by any [DEA employee] of a duly executed DEA Form 104 or any signed writing indicating the desire to surrender a registration.

21 CFR 1301.52(a).

The evidence of record here clearly demonstrates that Best Pharma surrendered its registration through the execution of a DEA Form 104. Gov't Ex. 14, at 1. However, with respect to Farmacia Nueva, the Government has tendered neither a DEA Form 104 nor ''any *signed* writing indicating a desire to surrender a registration.'' 21 CFR 1301.52(a) (emphasis supplied). The Government tendered an unsigned email exchange and brought no witness with any personal knowledge about the circumstances underlying the exchange or even one able to identify the participants. However, the existence and validity of the Farmacia Nueva surrender was never challenged at the hearing. Additionally, the identification (through official notice regarding Government counsel and notice of appearance of FN's current counsel) of the names on the face of the email traffic, coupled with the fact that Farmacia Nueva filed an application for a new COR, provide a sufficiently reliable basis upon which to conclude that the COR was surrendered and that Farmacia Nueva accepts that as fact. In any event, the language employed in the surrender/termination provision [69] cited above appears more focused on fixing an effective date for when a surrender ripens into a termination than on circumscribing the exclusive means to surrender a COR.[70]

Whether the surrenders were ''for cause'' is yet even more nuanced. Neither the Best Pharma Surrender Form nor Farmacia Nueva's email exchange contain the words ''for cause.'' Gov't Ex. 14. In fact, the only mention of a surrender ''for cause'' is set forth in two regulatory sections devoted to security matters, each of which provides that:

For purposes of [the two security subsections], the term ''for cause'' means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of [a current or prospective employee's] handling of controlled substances. . . .

21 CFR 1301.76(a), 1309.72(a). There is no ''for cause'' definition set forth in the regulations related to COR surrender. 21 CFR 1301.52.

Agency precedent has looked into the circumstances surrounding a surrender to determine whether it was properly characterized as being ''for cause'' and whether a registrant is properly charged with understanding that characterization. *See, e.g., Shannon L. Gallentine, D.P.M.,* 76 FR 45864, 45866 (2011) (holding that the signing of a DEA Form 104 during a search warrant execution where the investigator was asking questions about prescribing practices and lack of documentation to justify prescriptions constituted circumstances sufficient to establish that COR applicant knew or should have known that his COR surrender, which occurred two years earlier, was ''for cause''); *see also Robert M. Brodkin, D.P.M.,* 77 FR 73678, 73679 (2012) (holding that an executed DEA Form 104 and subsequent federal and state disciplinary proceedings were circumstances sufficient to characterize a surrender as ''for cause''). The Best Pharma Surrender Form was executed by Moro-Perez while the investigators were executing a search warrant at the pharmacy, and they explained to him that the Form 104 ''dealt with the regulatory matter [and that i]f he chose not to sign the form then [DEA] would move for an order to show cause proceeding.'' Tr. 177. Thus, unrefuted testimony establishes that DI Taylor, through an interpreter, told Moro-Perez that the surrender related only to the administrative proceedings, and not any criminal case. There was no evidence as to why Moro-Perez would not take the DI at his word that the surrender related only to administrative issues, not a criminal case. The Farmacia Nueva surrender was effected by counsel via email while administrative revocation proceedings were apparently underway before the Agency. Gov't Ex. 14, at 2–4. The circumstances surrounding each surrender provided sufficient notice to Moro-Perez that DEA was intent upon seeking revocation based on what its agents perceived to be serious regulatory violations. While the record is not optimal in this regard, there is sufficient, unrefuted evidence [71] to establish that the BP and FN CORs were surrendered for cause and that Moro-Perez had reason to know this was the case.[72]

The COR surrenders for cause that were errantly denied in Question 2 of the Respondents' applications were founded in controlled substance recordkeeping and corresponding responsibility violations

[69] 21 CFR 1301.52(a).

[70] The Agency Final Rule promulgating the modification stated that the language is designed to ''clarify that a voluntary surrender of a registration signed by a registrant using any format has the legal effect of immediately terminating the registrant's registration without any further action by DEA.'' *Voluntary Surrender of Certificate of Registration,* 76 FR 61563, 61563 (Oct. 5, 2011). Thus, the primary focus appears to have been on providing clarity regarding the date upon which the surrender became effective, not the nature of the instruments required to make the surrender valid.

[71] In their closing brief, the Respondents argue that DI Antoine testified that he did not know what ''for cause'' meant. ALJ Ex. 24, at 13, 23. Even the record citation (Tr. 105–06) provided by the Respondents makes clear that Antoine testified that he did not know why the words ''for cause'' were in parentheses, not that he did not know what the phrase meant. In any event, highlighting this point does nothing to further the Respondents' position. If placement of the phrase ''for cause'' somehow renders it optional or diminishes its import, that would leave Question 2 as asking whether a COR had ever been surrendered (for any reason). A ''no'' answer tendered in response to a question interpreted thus would be false here irrespective of the Respondents' illogical association of the ''for cause'' clause to his indictment dismissal.

[72] In its brief, the Government points out that Moro-Perez ''never contacted [DI Antoine] to inquire as to what 'for cause' meant.'' ALJ Ex. 23, at 6. To be clear, there was no burden on Moro-Perez to contact DEA to ascertain the meaning of the language in the BP voluntary surrender form or the consequences of the surrender effected by counsel during the FN administrative proceedings. The language and circumstances of the voluntary surrender were sufficiently clear to find that the surrender here was ''for cause'' and that Moro-Perez knew it, whether he made inquiry or not. If the language and circumstances were not sufficiently clear, the absence of any efforts by Moro-Perez to contact DI Antoine would not advance the Government's case in any measure.

uncovered by DEA in the course of a criminal search warrant execution, and those violations would have supported the denial of the Respondents' applications. *See Kam,* 78 FR at 62697 & n.7 (holding that a material falsification, to be material, must be such that the truthful disclosure of the facts would have supported the denial of the Respondent's application). One of the CORs was surrendered during the course of DEA administrative hearing procedures. As discussed more fully, *infra,* allegations that the dispensing of controlled substance prescriptions authorized by an unregistered physician that resulted in their surrender for cause provided ''actionable grounds'' sufficient to merit a COR sanction. *Kam,* 78 FR at 62697. Hence, it is beyond argument that the alleged falsifications, if established, ''had the capacity to influence the Agency's decision to grant [the] application[s]'' and, thus, were material. *Id.*

Regarding Moro-Perez's position that he was confused about the whether the surrenders retained their ''for cause'' character based on his indictment dismissal, the timeline of events is key. Moro-Perez testified that he has owned Farmacia Nueva and Best Pharma since each establishment was opened. Tr. 192, 222, 238. A COR was issued to Farmacia Nueva in 2005 and to Best Pharma in 2010. Gov't Exs. 2, 9. The Best Pharma Surrender Form was executed by Moro-Perez [73] on November 30, 2011.[74] Gov't Ex. 14, at 1. The DEA COR applications that are the subject of these proceedings include four liability questions that require the applicant to choose a ''yes'' or ''no'' answer. The second liability question (Liability Question 2) contains the following language:

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?

Gov't Exs. 1, 8. Moro-Perez included a ''no'' response to Liability Question 2 on the online application he submitted for each Respondent. Gov't Exs. 1, 8. Notwithstanding the less-than-ideal sentence structure in Liability Question 2, since both CORs were surrendered for cause by Moro-Perez prior to the filing of the applications, the ''no'' response in each application is indisputably untrue. The principal issue remaining is whether the negative response entered by Moro-Perez on each application was objectively reasonable.

Moro-Perez testified that, while he now acknowledges that he should have answered the surrender for cause questions in the affirmative, he misunderstood the question at the time, and there was never an intention on his part to deceive DEA. Tr. 216–17. Specifically, Moro-Perez posits that the dismissal of an indictment against him led him to believe that the surrenders of the two CORs by the Respondents were not for cause. Tr. 211–13. When viewed against a backdrop of the timeline of events delineated in the evidence of record, Moro-Perez's explanation makes no sense.

As set forth in the table below, Moro-Perez surrendered the Best Pharma COR at the time of his arrest during the early morning hours of November 30, 2011. Tr. 72, 175, 181; Gov't Exs. 2, at 2, 14, at 2–4. The indictment referenced by Moro-Perez was dismissed on March 23, 2012, some four months later. Stip. 8; Resp't Ex. 3; Tr. 212. The Farmacia Nueva COR was surrendered for cause by counsel on June 28, 2012, three months after the indictment dismissal and seven months following the Best Pharma surrender for cause. Gov't Exs. 2, 14. The online COR applications that are the subject of these proceedings were submitted by Moro-Perez on October 10, 2012, eleven months after the for-cause surrender of Best Pharma's COR, four months following the Farmacia Nueva for-cause surrender, and (most significantly) seven months following the dismissal of the indictment against Moro-Perez. Gov't Exs. 1, 8; Stips. 5, 6.

Date	Event
November 30, 2011	Best Pharma COR Surrender Form Executed by Moro-Perez.
March 23, 2012	Indictment Against Moro-Perez Dismissed.
June 28, 2012	Farmacia Nueva COR Surrendered by Counsel via Email.
October 10, 2012	Respondents' COR Applications Submitted by Moro-Perez.

As is apparent in the table above, the indictment dismissal, the single event to which Moro-Perez ascribes the confusion that spawned his false answers on the COR applications, occurred between the for-cause surrenders of Best Pharma and Farmacia Nueva. The Farmacia Nueva surrender happened *after* the indictment dismissal [75] and was effected through counsel. In effect, Moro-Perez testified that he believed that the dismissal of the criminal charges (against himself) somehow washed away the sins of Best Pharma, resulting in what had previously been a surrender *for cause* being transformed into a surrender *not for cause.* Then, as if this gift was not good enough, he also asserted that not only did the dismissal of the indictment (against himself) forgive the sins of one of his pharmacies, but somehow it preemptively pardoned another pharmacy that surrendered for cause after the date of dismissal by characterizing that surrender as ''not for cause.'' But this cannot be. If the dismissal of indictment really cleaned up all issues surrounding Moro-Perez *and* his pharmacies, why would there even need to be a subsequent surrender of Farmacia Nueva's COR? And, in light of the subsequent surrender of Farmacia Nueva's COR, why would it be reasonable to believe that the dismissal of the criminal charges against Moro-Perez magically deemed a subsequent surrender *for cause* as a surrender *not for cause*?

There is simply no logical manner in which a rational person (much less an educated, experienced registrant holder) would or could reason that a surrender that was ''for cause'' when effected, could somehow morph into one that was not ''for cause'' by an action (the dismissal) that preceded it. Even if it were assumed, *arguendo,* that Moro-Perez's account that he subjectively believed the dismissal of an indictment against him (not the Respondents) could somehow change the character of the surrender for cause, no indictment dismissal or other operative fact occurred after the surrender of Farmacia Nueva's COR that could alter its character. Thus, even if credit were afforded to Moro-Perez's account that it was the dismissal of the indictment against him that led him to believe that the surrenders of the CORs were not for cause, this theory of ignorance, even in its best (most naïve) light, only covers the Best Pharma surrender that was signed before the indictment dismissal, not the Farmacia Nueva surrender, which occurred three months after the dismissal. Even putting aside the reality that, as a veteran registrant holder, Moro-Perez had the experience and bore the responsibility to understand the meaning of his answers to the applications he was filing, he failed to present a logical theory of subjective ignorance that corresponds with the facts. At the hearing, Moro-Perez acknowledged that he understood the question concerning the surrender for cause and his response to it. Tr. 210–11. The indictment dismissal occurred prior to the surrender for cause, and there is simply no rational view of the facts that could lead any reasonable person, much less an experienced COR holder, to believe that the surrender was suddenly no longer ''for cause'' due to a dismissal that came first. It is not insignificant that Moro-Perez (not the Respondents) was captioned in the indictment, and, given the timeline of events, the dismissal added no level of cognizable confusion here. Moro-Perez's assertions to the contrary are simply not credible. The ''provision of truthful information is absolutely essential to effectuating th[e] statutory purpose'' of determining whether the granting of an application is consistent with the public interest. *Darby,* 75 FR at 26998 (quoting *Peter A. Ahles, M.D.,* 71 FR

[73] Moro-Perez testified at the hearing with the benefit of a Spanish-language interpreter. Tr. 191. Uncontroverted record evidence establishes that the Best Pharma Surrender Form was read and explained to Moro-Perez in Spanish at the time it was executed. Tr. 175–78. At the hearing, the Respondents raised no issue regarding any impediment presented by language regarding Moro-Perez's execution of the Best Pharma Surrender Form or the COR applications he filed on their behalf. The Farmacia Nueva COR surrender was effected via email by its present counsel, who possessed sufficient command of the Spanish language to communicate with Moro-Perez throughout these proceedings and to offer numerous challenges during the hearing to translations supplied by the official hearing interpreter. *See, e.g.,* Tr. 195–96, 200, 206, 214–15, 220, 224. Thus, this record does not support any level of cognizable confusion on the part of Moro-Perez borne of a language barrier in understanding the COR surrenders or the filed applications.

[74] The Government also provided a certification by the Chief of the DEA Registration and Program Support Section (Farmacia Nueva Certification) that the same voluntary surrender took place on December 14, 2011. Gov't Ex. 9, at 2. Although no explanation was offered for the disparity, the date variance does not impact the outcome of the case.

[75] Gov't Ex. 14, at 2.

50097, 50098 (2006)); *see VI Pharmacy,* 69 FR 5584, 5585 (2004); *Terrence E. Murphy, M.D.,* 61 FR 2841, 2846 (1996). This finding, standing alone, is sufficient to recommend denial of both applications. *Cf. Gallentine,* 76 FR at 45866. It is clear that the Respondents, through their common owner, Moro-Perez, knew or should have known [76] that the answers provided to Question 2 were false, and that their COR applications contained material falsifications. The absence of any logical basis for confusion and the past experience of Moro-Perez as a registrant holder and pharmacist preponderantly support a finding that the misrepresentations were intentional, not negligent.[77] The Respondents are accountable for the actions of Moro-Perez as their owner/president,[78] and, even standing alone, the denial of the Respondents' COR applications is adequately supported on this record based on the material falsifications set forth in the filed applications.

Public Interest Determination: The Standard

The Government also seeks denial of the Respondents' respective COR applications based on a theory that each has committed acts inconsistent with the public interest. Pursuant to 21 U.S.C. 823(f), the Administrator [79] is permitted to deny an application for a COR if persuaded that an applicant ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' [80] The following factors have been provided by Congress in determining ''the public interest'':

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

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

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

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

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f) (2006 & Supp. III 2010).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *Id.; David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *see Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422, 16424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest. . . .'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009).

In the adjudication of an application for a DEA COR, the DEA has the burden of proving that the requirements for registration are not satisfied. 21 CFR 1301.44(d). Where the Government has sustained its burden and established that an applicant has committed acts inconsistent with the public interest, that applicant must present sufficient mitigating evidence to provide assurance that it can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Jackson,* 72 FR at 23853. Where the Government has met this burden, the registrant must show an acceptance of responsibility for its misconduct and a demonstration that corrective measures have been undertaken to prevent the re-occurrence of similar acts. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010). In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *David A. Ruben, M.D.,* 78 FR 38363, 38364, 38385 (2013).

Normal hardships to the practitioner, and even the surrounding community, which are attendant upon the denial of a registration, are not a relevant consideration. *Linda Sue Cheek, M.D.,* 76 FR 66972, 66972–73 (2011); *Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009). The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct, *Hoxie,* 419 F.3d at 483; *see also Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.,* 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981), the Agency's ultimate factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. While '''the possibility of drawing two inconsistent conclusions from the evidence''' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989) (quoting *Trawick,* 861 F.2d at 77), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered, *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *see Humphreys* v. *DEA,* 96 F.3d 658, 663 (3d Cir. 1996). The ultimate disposition of the case ''must be 'in accordance with' the weight of the evidence, not simply supported by enough evidence 'to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury.''' *Steadman,* 450 U.S. at 99 (quoting *Consolo* v. *Fed. Mar. Comm'n,* 383 U.S. 607, 620 (1966)).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)), *cert. denied,* 555 U.S. 1139 (2009). It is well settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Agency's final decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* § 8(a) (1947).

Factors 1, 3, and 5: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority; Any Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances; Such Other Conduct Which May Threaten the Public Health and Safety

Regarding Factor 1, the record contains no evidence of a recommendation by any state

[76] *See Hale,* 69 FR at 69406; *The Drugstore,* 61 FR 5031, 5032 (1996); *Watts,* 58 FR at 46995.

[77] *See Funches,* 64 FR at 14268.

[78] *See Top Rx Pharmacy,* 78 FR 26069, 26081–82 (2013); *EZRX, LLC,* 69 FR 63178, 63181 (2004); *Plaza Pharmacy,* 53 FR 36910, 36911 (1988); *Syncon Pharm., Inc.,* 53 FR 15155, 15156 (1988); *see also Neil Labs., Inc.* v. *Ashcroft,* 217 F. Supp. 2d 80, 87–88 (D.D.C. 2002).

[79] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

[80] 21 U.S.C. 824(a)(4).

licensing board, body, or authority related to the Respondent pharmacies. However, the fact that a state has not acted against a registrant's state authority is not dispositive in this administrative determination as to whether continuation of its registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that ''state [authority] is a necessary, but not sufficient condition for registration.'' *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006) (quoting *Leslie,* 68 FR at 15230). DEA bears an independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 8209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* 555 U.S. 1139 (2009). Congress vested authority to enforce the CSA in the Attorney General, not state officials. *Stodola,* 74 FR at 20735 n.31. Thus, on these facts, the absence of a recommendation by a state licensing board does not weigh for or against a determination as to whether granting the Respondents' applications would be consistent with the public interest. *See Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011) (''[T]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'').

Regarding the third factor (convictions relating to the manufacture, distribution, or dispensing of controlled substances), the record in this case does not contain evidence that the Respondents, their owner, or any pharmacist or key employee of either pharmacy has been convicted of (or charged with) a crime related to any of the controlled substance activities designated in the CSA.[81]

The standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest. Still, evidence that a registrant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA certificate. The probative value of an absence of any evidence of criminal prosecution is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities. *See Robert L. Dougherty, M.D.,* 76 FR 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.,* 75 FR 49956, 49973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.''), *aff'd, Mackay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.,* 74 FR 6056, 6057 n.2 (2009). Therefore, on the present record, the absence of criminal convictions (Factor 3), like the absence of a recommendation from any state licensing authorities (Factor 1), militates neither for nor against the COR denials sought by the Government.

The fifth statutory public interest factor directs consideration of ''[s]uch *other conduct* which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5) (emphasis added). Existing Agency precedent has long held that this factor encompasses ''conduct which creates a probable or possible threat (and not only an actual [threat]) . . . to public health and safety.'' *Dreszer,* 76 FR at 19434 n.3; *Michael J. Aruta, M.D.,* 76 FR 19420, 19420 n.3 (2011); *Beau Boshers, M.D.,* 76 FR 19401, 19402 n.4 (2011); *Jacobo Dreszer,* 76 FR 19386, 19386 n.3 (2011). Agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the CSA. *Terese, Inc.,* 76 FR 46843, 46848 (2011); *Tony T. Bui, M.D.,* 75 FR 49979, 49989 (2010) (stating that prescribing practices related to a non-controlled substance such as human growth hormone may not provide an independent basis for concluding that a registrant has engaged in conduct which may threaten public health and safety); *cf. Paul Weir Battershell, N.P.,* 76 FR 44359, 44368 n.27 (2011) (noting that although a registrant's non-compliance with the Food, Drug, and Cosmetic Act is not relevant under Factor Five, consideration of such conduct may properly be considered on the narrow issue of assessing a respondent's future compliance with the CSA).

Similar ''catch-all'' language is employed by Congress in the CSA related to the Agency's authorization to regulate controlled substance manufacturing and List I chemical distribution, but the language is by no means identical. 21 U.S.C. 823(d)(6), (h)(5). Under the language utilized by Congress in those provisions, the Agency may consider ''such *other factors* as are relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(h)(5) (emphasis added). In *Holloway Distributing,* the Agency held this catch-all language to be broader than the language directed at practitioners under ''other conduct which may threaten the public health and safety'' utilized in 21 U.S.C. 823(f)(5). 72 FR 42118, 42126 n.16 (2007). Regarding the List I catch-all language, the Administrator, in *Holloway,* stated:

> [T]he Government is not required to prove that the [r]espondent's conduct poses a threat to public health and safety to obtain an adverse finding under factor five. *See T. Young,* 71 [FR] at 60572 n.13. Rather, the statutory text directs the consideration of ''such other factors as are relevant to and consistent with the public health and safety.'' 21 U.S.C. 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. *See id.* § 823(f)(5) (directing consideration of ''[s]uch other conduct which may threaten the public health and safety'').

Id.[82] Thus, the Agency has recognized that, while the fifth factor applicable to List I chemical distributors—21 U.S.C. 823(h)(5)—encompasses all ''factors,'' the Factor Five applied to practitioners—21 U.S.C. 823(f)(5)—considers only ''conduct.'' However, because § 823(f)(5) only implicates ''such *other* conduct,'' it necessarily follows that conduct considered in Factors One through Four may not be considered in Factor Five.

The Government has not alleged any conduct against either Respondent in these proceedings that implicates Factor Five. Indeed, those portions of each party's closing briefs dedicated to Factor Five are exclusively (and mistakenly) devoted to a discussion of the burdens established under Agency precedent and the exercise of some of the appropriate discretionary considerations. Accordingly, consideration of the record evidence under Factors One, Three, and Five weigh neither for nor against the Governments' petition to deny the Respondents' COR applications.

Factors 2 and 4: The Respondents' Experience in Dispensing Controlled Substances, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government's public-interest-factors case seeking COR application denials for both Respondents is based exclusively on conduct properly considered under Factors Two and Four. The Government alleges and relies on recordkeeping and dispensing activity conducted by the Respondent pharmacies' pharmacists, staff, and management.

Regarding Factor Two, in requiring an examination of an applicant's experience in dispensing controlled substances, Congress manifested an acknowledgement that the qualitative manner and the quantitative volume in which an applicant has engaged in the dispensing of controlled substances may be significant factors to be evaluated in reaching a determination as to whether an applicant should be (or continue to be) entrusted with a DEA COR. In some (but not all) cases, viewing an applicant's actions

[81] The parties stipulated that Moro-Perez was indicted, but that the indictment was ultimately dismissed. Stip. 8; Resp't Ex. 3. The indictment itself was not offered into the record. The mere fact that Moro-Perez was the subject of a criminal indictment does not establish culpability for the acts charged by the indictment, and the dismissal in this matter has been considered only under the narrow *mens rea* theory upon which the Respondents offered it. *See Paul Weir Battershell, N.P.,* 76 FR 44359, 44364 n.17 (2011) (concluding that an indictment is an instrument containing accusations, not proof of a respondent's actions).

[82] In *Bui,* the Agency clarified that ''an adverse finding under [Factor Five did not require a] showing that the relevant conduct actually constituted a threat to public safety.'' 75 FR at 49988 n.12.

against a backdrop of how its regulated activities have been performed within the scope of its registration can provide a contextual lens to assist in a fair adjudication of whether registration is in the public interest. In this regard, however, the Agency has applied principles of reason, coupled with its own expertise, in the application of this factor. For example, the Agency has taken the reasonable position that this factor can be outweighed by acts held to be inconsistent with the public interest, and will be afforded scant weight in the face of proven allegations of intentional diversion. *Krishna-Iyer,* 74 FR at 463; *see also Hassman,* 75 FR at 8235 (acknowledging Agency precedential rejection of the concept that conduct inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities that occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 63 FR 51592, 51560 (1998) (''[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''). Similarly, in *Cynthia M. Cadet, M.D.,* the Agency determined that existing List I precedent [83] clarifying that experience related to conduct within the scope of the COR sheds light on a practitioner's knowledge of applicable rules and regulations would not be applied to cases where intentional diversion allegations were sustained. 76 FR 19450, 19450 n.3 (2011). The Agency's approach in this regard has been sustained on review. *Mackay,* 664 F.3d at 819.

Regarding Factor Four (compliance with laws related to controlled substances), to effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Under the regulations, ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a). Under this language, a pharmacist has a duty ''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.'' *Electronic Prescriptions for Controlled Substances,* 75 FR 16236, 16266 (Mar. 31, 2010). In short, a pharmacist has a ''corresponding responsibility under Federal law'' to dispense only lawful prescriptions. *Liddy's Pharmacy, L.L.C.,* 76 FR 48887, 48895 (2011). ''The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR 62316, 62341 (2012) (citing *Medicine Shoppe,* 73 FR at 384; *United Prescription Servs., Inc.,* 72 FR 50397, 50407–08 (2007); *EZRX, LLC,* 69 FR 63178, 63181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61613, 61617 (Oct. 16, 2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64921, 69424 (Nov. 19, 2007)). Settled Agency precedent has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist or pharmacy ''knows or has reason to know'' that the prescription is invalid. *E. Main St. Pharmacy,* 75 FR 66149, 66163 (2010); *Bob's Pharmacy & Diabetic Supplies,* 74 FR 19599, 19601 (2009) (citing *Medicine Shoppe,* 73 FR at 381); *see also United Prescription Servs.,* 72 FR at 50407–08 (finding a violation of corresponding responsibility where the pharmacy ''had ample reason to know'' that the practitioner was not acting in the usual course of professional practice). The pharmacy registrant's responsibility under the regulations is not coextensive or identical to the duties imposed upon a prescriber, but is, rather, a *corresponding* one. 21 CFR 1306.04(a). The Government has averred that for a period of over two years, the Respondents filled controlled substance prescriptions for Dr. Aguilar, a physician who did not possess a valid COR. These allegations impact both Factor 2 [84] and Factor 4.

To show a violation of a pharmacy registrant's corresponding responsibility, ''the Government must establish three elements: (1) the registrant dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance.'' *Holiday CVS,* 77 FR at 62341. ''The steps necessary to resolve the red flag conclusively will *perforce* be influenced by the nature of the circumstances giving rise to the red flag.'' *Id.* (emphasis added). When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the *entity,* not the pharmacist, can be charged with the requisite knowledge. *See United Prescription Servs.,* 72 FR at 50407 (finding that the Respondent pharmacy violated its corresponding responsibility because ''an *entity* which voluntarily engages in commerce [to] other States is properly charged with knowledge of the laws regarding the practice of medicine in those States'' (emphasis added)); *see also Pharmboy Ventures Unlimited, Inc.,* 77 FR 33770, 33771 n.2 (2012) (''DEA has long held that it can look behind a pharmacy's ownership structure 'to determine who makes decisions concerning the controlled substance business of a pharmacy.''' (quoting *Carriage Apothecary,* 52 FR 27599, 27599 (1987))); *S & S Pharmacy, Inc.,* 46 FR 13051, 13052 (1981) (holding that the corporate pharmacy acts through the agency of its PIC). Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself. *See United States* v. *7326 Highway 45 N.,* 965 F.2d 311, 316 (7th Cir. 1992) (''Only knowledge obtained by corporate employees acting within the scope of their employment is imputed to the corporation.''). Agency precedent has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employees. *Holiday CVS,* 77 FR at 62340; *EZRX,* 69 FR at 63181; *Plaza Pharmacy,* 53 FR 36910, 36911 (1988). Thus, it is necessary and appropriate to analyze the relevant conduct of each pharmacy's personnel, including Moro-Perez, who serves as the owner/president of each.[85]

The DEA regulations provide that a controlled substance prescription may only be issued by a practitioner with state and federal authority to do so. 21 CFR 1306.03(a). For a controlled substance prescription to be effective, it must be issued by a practitioner. 21 CFR 1306.04(a). To be a ''practitioner'' under the CSA in this context, an individual must possess authority to prescribe controlled substances. 21 U.S.C. 802(21). Thus, a controlled substance prescription issued by one who lacks authority to prescribe is issued by a non-practitioner and is ineffective. A pharmacy registrant who dispenses a controlled substance based on an ineffective prescription, in the face of a red flag that was recognized or should have been recognized, has violated its regulatory corresponding responsibility. 21 CFR 1306.14; *Holiday CVS,* 77 FR at 62341. The question then devolves to whether Dr. Aguilar's lack of a COR is a red flag that should have been recognized. As discussed, *infra,* this question must be answered in the affirmative.

On the present record, it is beyond argument that controlled substances were dispensed by the Respondent pharmacies on scrips issued by (unregistered) Dr. Aguilar (Element 1). The remaining issues concern whether this was done in the face of an unresolved red flag that should have been recognized [86] before the prescriptions were filled (Elements 2 & 3).

The unrefuted evidence of record establishes that, for over two years, the Respondent pharmacies filled controlled substance prescriptions without checking COR status beyond insurance payment confirmation. From Antoine's testimony, it appears that, from the period of January 31, 2009 to November 30, 2011, Dr. Aguilar's lack of a DEA COR had no perceptible impact on either the enthusiasm with which he issued controlled substance prescriptions,

[83] *See, e.g., Volusia Wholesale,* 69 FR 69409, 69410 (2004).

[84] This case contained no allegation (or evidence) of intentional diversion, but the Respondents offered no evidence or argument regarding the length and character of their experience in dispensing controlled substances. ALJ Ex. 24, at 24–25. Thus, it is unnecessary to determine whether such evidence would have been relevant to a disposition of the case. *See Cadet,* 76 FR at 19450 n.3; *Krishna-Iyer,* 74 FR at 463.

[85] Tr. 192, 219, 222, 223, 226, 238.

[86] The Government has not alleged or proved actual knowledge on the part of Moro-Perez or the staff at the Respondent pharmacies that Dr. Aguilar lacked a valid COR at the time the dispensing events in issue occurred.

nor the Respondents' willingness to fill them. Tr. 17. As acknowledged by Moro-Perez during his testimony, during that thirty-four month period, Farmacia Nueva and Best Pharma made no attempt (that was reasonably calculated for success) to ascertain whether Dr. Aguilar (or apparently any other physician for whom they were filling controlled substance prescriptions) had a valid COR. Tr. 194. Moro-Perez testified that his pharmacy staff assumed the validity of all prescriber CORs if insurance carriers provided notification that the patients were covered and the claims related to the prescription would be paid. Tr. 196. He indicated that the pharmacies would only have had reason to know that a doctor's COR had expired if, regarding a particular scrip, the insurance company signaled its intent to decline payment. Tr. 201. At no point during the hearing did Moro-Perez give any basis to establish that insurance providers would know whether medical practitioners were authorized to prescribe controlled substances, much less why insurance companies would have a legal or contractual duty (or even an inclination) to pass on COR information to dispensing pharmacies. Moro-Perez testified that his pharmacies relied on the approvals they received from insurance providers, but he did not even attempt to describe why such a practice was rational or supported by any level of common sense, much less why such a practice could be a responsible discharge of the authority of a registrant. The only notification apparently provided by the insurance companies' notifications is that the claim would be paid—and that is apparently the point at which these registrants' interest in the subject waned.

The responsibility for ensuring the authority of the practitioner writing the controlled substance prescription is abjectly integral to the pharmacy registrant's corresponding responsibility. The uncontroverted evidence of record establishes that, as DEA pharmacy registrants, the Respondents could have checked the COR status of Dr. Aguilar (and all prescribing doctors) by accessing a link on the DEA Diversion Web site, by consulting a list of current registrants that is regularly updated by the Department of Commerce, by contacting the local DEA office, or by contracting with a private company to perform due diligence in this regard. Tr. 20–21. The Respondents' irresponsible practice of ending their COR inquiry at the moment an insurance company agrees to remit payment speaks volumes on the subject of whether these Respondents should be entrusted with the responsibility of a controlled substance registrant. That the Respondents chose a patently ineffective and illogical manner to check COR statuses cannot absolve them of their responsibility to ensure this most basic of requirements. The Agency has never been, and cannot be, persuaded by a policy of ''see no evil, hear no evil.'' *Cf. Gonzalez,* 76 FR at 63142. Even in a criminal context regarding prescriptions illegitimately issued, the courts have held that a factfinder ''may consider willful blindness as a basis for knowledge.'' *United States* v. *Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006). The absence of Dr. Aguilar's COR is the most glaring of red flags that could and should have been recognized by the Respondents upon the exercise of even the most minimal due diligence. Conclusively resolving such a fundamental red flag was a mandatory condition precedent to the legal dispensing of a controlled substance, and the Respondents' failure to do so (on multiple occasions) was a clear breach of their corresponding responsibility under the regulations. 21 CFR 1306.04(a). ''It would be difficult to imagine a duty of a pharmacy registrant that is more fundamental to the law and spirit of the CSA than the obligation to ensure that controlled substance prescriptions are issued only on the authority of those empowered to prescribe by the DEA.'' *Holiday CVS,* 77 FR at 62341; *see also Liddy's Pharmacy,* 76 FR at 48895. Absent confirmation of a COR, a prescription written by one without COR authority would authorize the routine distribution of dangerous narcotics on the approval of anyone from the uninformed to the malevolent. The DEA's *Pharmacist's Manual* specifically provides that controlled substance prescriptions may only be issued by a practitioner who is, *inter alia,* ''[r]egistered with DEA or exempted from registration.'' DEA, *Pharmacist's Manual* § IX (2010).

It is hardly insignificant that more than serving merely as the owner/president of both pharmacies, Moro-Perez has been a trained pharmacist since 1999. He acknowledged at the hearing that he had received training regarding the lawful procedures for handling controlled substances. Tr. 194. In addition to the readily available means for checking COR statuses outlined by DI Antoine, it is worthy of note that, with minimal effort, Aguilar's office could have been contacted or even (in light of its close proximity to FN) visited.[87] The Respondent pharmacies knowingly pursued a course of deliberate ignorance, satisfying themselves in a sort of collective shrug that if there was ever a problem with a physician's COR, the insurance company would deny the claim. Tr. 201. Passively waiting to receive an insurance carrier claim rejection is not a responsible manner to discharge the duties of a registrant, and it certainly does not satisfy a registrant's obligation to ensure the authority of the issuer of the prescription. It is merely an effective manner to ensure payment.

The practice of relying on insurance carrier claim rejections as the principal means of due diligence is particularly egregious here. Moro-Perez testified that both pharmacies denied ''many'' of the controlled substance prescriptions written by Dr. Aguilar based on a review of the scrips submitted by his patients. Tr. 252–53. The pharmacies declined to fill these prescriptions based on the (repeated) professional judgment of the pharmacists that the scrips were invalid. Tr. 252. Yet, even armed with the knowledge that Dr. Aguilar was engaged in writing ''many'' illegitimate controlled substance prescriptions that could not legally be filled, Moro-Perez testified that his pharmacies never looked into Dr. Aguilar's practice or COR status in any way. Tr. 252–54. Instead, the Respondents blithely continued to fill Dr. Aguilar's prescriptions—and presumably, the pharmacies continued to receive payments. Tr. 250–52. Thus, it is clear on the present record that even though Dr. Aguilar had repeatedly given the professional staff working at both Respondent pharmacies reason to suspect his *bona fides* as a legitimate controlled substance prescriber, none of the Respondents' personnel was inspired to employ even the minimal effort that would have been required to check the status of his registration. Over and over again, the Respondents' pharmacists rendered their professional judgment that Dr. Aguilar was writing unsupported controlled substance prescriptions that were so sufficiently irregular that they were refused, yet they did not check into his authority beyond ensuring insurance carrier approvals for payments. It is a testament to the Respondents' irresponsibility (and exclusive focus on remuneration) that Moro-Perez acknowledged that if the DEA had not executed its search warrant on November 30, 2011, Farmacia Nueva would still be filling Dr. Aguilar's (unauthorized) controlled substance prescriptions. Tr. 202–03.

The Government's evidence established that, for thirty-four months, Farmacia Nueva filled over 140 prescriptions for controlled substances written by Dr. Aguilar on his expired COR. Gov't Ex. 5. Similarly, the Government's evidence demonstrated that during the same period, Best Pharma filled 32 controlled substance prescriptions written by Dr. Aguilar. Gov't Ex. 10. Respondents clearly violated their ''fundamental'' duties under the CSA by failing to ensure that Dr. Aguilar's COR was valid. *Holiday CVS,* 77 FR at 62341. In so doing, they breached their corresponding responsibilities as pharmacy registrants under Federal law to dispense only lawful prescriptions. *Liddy's Pharmacy,* 76 FR at 48895.

Thus, in addition to Element 1, the Government's evidence preponderantly established that the absence of a valid COR is a ''red flag'' that should have been known prior to dispensing (Element 2), and that (inasmuch as the deficiency revolved around Dr. Aguilar's lack of a valid registration) it was not and could not have been adequately resolved prior to dispensing controlled substances (Element 3). Having established all three elements, there is no question that each Respondent violated its corresponding responsibility under the regulations.

The record of both pharmacies indicates a clear disregard for following proper legal procedures designed to protect the public from the dangers of the unregulated dispensing of controlled substances. Furthermore, both pharmacies displayed a lack of motivation to follow through even the most basic of procedures, such as verifying a prescribing physician's COR. The Government's evidence that the Respondent pharmacies continued, for thirty-four months, to recklessly fill Dr. Aguilar's controlled substance prescriptions when he was unregistered and when they had actual knowledge that he was writing ''many'' illegitimate prescriptions negatively impacts

[87] Tr. 250–51.

both Factor 2 (experience in dispensing) and Factor 4 (compliance with federal controlled substance laws) and militates strongly in favor of the application denial sought by the Government.[88]

The Government's allegations regarding missing records/poor recordkeeping also relate to considerations under Factor Four. It is beyond argument that accurate and reliable records are an obvious bedrock safeguard that is essential to ensure the integrity of the closed regulatory system designed by Congress. *See Gonzales* v. *Raich,* 545 U.S. at 13. ''Recordkeeping is one of the central features of the CSA's closed system of distribution. . . . 'A registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.' '' *Satinder Dang, M.D.,* 76 FR 51424, 51429 (2011) (internal punctuation and citations omitted) (quoting *Paul H. Volkman,* 73 FR 30630, 30644 (2008)). There is no question that the maintenance of accurate records by registrants is key to DEA's ability to fulfill its obligations to regulate controlled substances. *See Volkman,* 73 FR at 30644, *aff'd, Volkman* v. *U.S. DEA,* 567 F.3d 215, 224 (6th Cir. 2009) (specifically upholding the DEA Administrator's reliance on recordkeeping violations in denying a COR application). Thus, where established by reliable evidence, recordkeeping deficiencies may provide a reason—''which is sufficient by itself''—to find that the granting of a registration would be inconsistent with the public interest. *Id.* DEA has also held that non-compliance with recordkeeping obligations can lend ''substantial credence'' to allegations that a registrant is engaged in ''massive diversion.'' *Grider Drug #1 & Grider Drug #2,* 77 FR 44069, 44101 (2012). However, the Agency has also held that where non-egregious recordkeeping errors are acknowledged and remedied promptly, revocation may not always be required. *Terese,* 76 FR at 46848.

In *Terese,* substantial evidence established that the registrant had failed to conduct an initial inventory as required under 21 CFR 1304.11(b), failed to execute a power of attorney form as required by 21 CFR 1305.05(a), and failed to include dates on DEA Forms 222 as required by 21 CFR 1305.13(e). *Id.* In declining to revoke Terese's registration, the Agency, emphasizing that the registrant had accepted responsibility for its violations and had instituted corrective actions, determined that, under the circumstances, the three recordkeeping violations did not render its continued registration inconsistent with the public interest. *Id.* at 46848. In *Ideal Pharmacy Care, Inc.,* an audit of the registrant's records showed a shortage of 150,000 dosage units of hydrocodone, 83,000 dosage units of alprazolam, and 1.6 million milliliters of promethazine with codeine. 76 FR 51415, 51416 (2011). However, in contrast to *Terese,* the Agency found[89] that Ideal Pharmacy's failure to maintain accurate records constituted an act that rendered its continued registration inconsistent with the public interest. *Id.* at 51416. Taken together, *Ideal* and *Terese* indicate that, when considering recordkeeping violations, the Agency has coupled consideration of the degree of severity of the non-compliance with an analysis of whether the registrant has both acknowledged culpability and demonstrated credible efforts aimed at correction. The current state of the Agency's precedent, thus, provides a logical framework upon which the current evidence can be evaluated.

DEA regulations provide that ''[e]very registrant required to keep records pursuant to § 1304.03[90] shall maintain on a current basis a complete and accurate record of each substance . . . imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.'' 21 CFR 1304.21(a). The regulations also mandate that ''every . . . record[] required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such . . . records, for inspection and copying by authorized employees of the [DEA].'' *Id.* § 1304.04(a). Pharmacy registrants, such as the Respondents used to be, are required to maintain separate records of Schedule II controlled substances, and to maintain records of controlled substances listed in Schedules III–V ''either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from the ordinary business records of the pharmacy.'' *Id.* § 1304.04(h). Readily retrievable is defined in the regulations as records kept ''in such a manner that they can be separated out from all other records in a reasonable time . . . .'' 21 CFR 1300.01(b).

On this record, the Government's allegations regarding alleged infirmities in the Respondents' recordkeeping are simply not supported by the presentation it made at the hearing. It is uncontroverted that both pharmacies used a computer program called ''RX30'' to manage and record prescriptions and corresponding dispenses. Tr. 234, 244. While DI Antoine testified that, consistent with the Government's allegations, there were missing records from the computer systems of both pharmacies,[91] the Government only offered exhibits relating to the missing records at Farmacia Nueva. Gov't Exs. 5–7.

Exhibits supplied by both the Government and Farmacia Nueva purport to constitute copies of all controlled substance prescription scrips filled for Dr. Aguilar's patients between January 31, 2009 to November 30, 2011. Gov't Ex. 5; Resp't Exs. 1, 2. It is uncontroverted that the RX30 system employed at Farmacia Nueva automatically affixes an informational heading at the top of each copy of a scrip that has been scanned into the system. Tr. 263. Both the Government's version and Farmacia Nueva's version contain scrip copies that display the informational heading and copies that do not.[92] DI Antoine testified that he assembled the Government's version of Dr. Aguilar's Farmacia Nueva scrips from material seized at the search warrant execution and from material forwarded by Moro-Perez in response to DEA's Supplemental Information Request. Tr. 23–25.

Moro-Perez, for his part, testified that he was able to generate a copy of all but one of every Aguilar controlled substance prescription scrip through a query of the Farmacia Nueva RX30 program. Tr. 203–04, 248; Resp't Exs. 1, 2. While it strains credulity that Moro-Perez would intentionally hold back material that could have conceivably cleared up the issue of missing scrips until the hearing process commenced, the Government (who bears the burden on this issue) presented no testimony or other evidence that would explain why its version should be deemed the more complete one. The Government presented no testimony from anyone who was present at the search warrant execution at Farmacia Nueva. Likewise, instead of calling DFE Gladieux, who extracted the digital information, the Government presented a terse, barebones declaration.[93] Gov't Ex. 15.

On the state of the present record, there is no way to determine which party has presented the more persuasive set of the Aguilar prescription scrips maintained at Farmacia Nueva. DFE Herrmann, the DEA digital forensic examiner who analyzed the data pulled from FN's RX30 program, acknowledged the possibility of a ''margin for error,'' [94] but testified that she was able to create a duplicate of the Farmacia Nueva computer as it existed on the day the data was extracted from it. Tr. 141–42. The Government initially alleged that Best Pharma and Farmacia Nueva did not maintain controlled substance scrips authorized by Dr. Aguilar, but withdrew and/or did not proceed on all of the Best Pharma scrips[95] and many of the Farmacia Nueva scrips when the Respondents pointed out in a prehearing motion[96] that the noticed scrips included non-controlled substances. Farmacia Nueva was able to produce purported copies of scrips for all but two (H00751567 & 00805523) of the (reduced number of) Aguilar scrips that the Government alleged as missing.[97] Resp't Exs.

[88] In view of the lengthy (34-month) period of time during which the scrips of (unregistered) Dr. Aguilar were filled, it is not necessary to discern exactly when the duty to re-check COR credentials emerges. A more precise divination of that issue may require resolution on different facts in another case.

[89] The registrant in *Ideal* waived its right to a hearing and presented no evidence to the Agency on its behalf. *Ideal,* 76 FR at 51415.

[90] Section 1304.03(a) provides that ''[e]ach registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section.'' 21 CFR 1304.03(a). The record contains no contention that any of the § 1304.03 exemptions apply in this case.

[91] Tr. 23–25, 96.

[92] Resp't Ex. 2, at 143–44; Gov't Ex. 5, at 1–6.

[93] At the hearing, Government counsel represented that Gladieux was local and available, but not called as a witness because he felt that the declaration was sufficient. Tr. 135–37.

[94] Tr. 155.

[95] In its closing brief, the Government made no mention of the Best Pharma recordkeeping allegations. ALJ Ex. 24, at 25.

[96] ALJ Ex. 10.

[97] So much of the Government's evidence in this regard was withdrawn or readily contradicted by

Continued

1–2, 4. While admittedly true that Farmacia Nueva did little to explain the origin, structure, or reliability of its own scrip-related exhibits, the Government produced no credible challenge to Farmacia Nueva's purported scrip copies and declined to challenge their admission into evidence. Tr. 249, 257, 264–65. Even though he was not unavailable, DFE Gladieux, the technician who imaged the Farmacia Nueva computer, was not called as a witness to explain the data extraction process or defend its integrity and completeness. It is also worth noting here that Moro-Perez never explained why, if the FN scrips in question did exist and were available from the outset, they were not forwarded to the Government with his Response to Government Administrative Request for Information,[98] wherein he provided the assurance that ''all of the requested prescriptions'' were included—a position he re-affirmed during his testimony. Tr. 206–08. Still, the Government presented no evidence whatsoever in support of its BP recordkeeping allegations, and, with respect to Farmacia Nueva, its evidence was confusing and wholly unpersuasive. It would be virtually impossible on the present record to assign one party's batch of copied, purported prescriptions more credibility than the other party's batch in any manner that could be logically defended on appeal. In this mutually confusing contest of admitted evidence, it was the Government that bore the burden to establish the violations of the laws it had alleged. Regarding the recordkeeping allegations, its burden was simply not carried.

Accordingly, to the extent the Government alleged that the Respondents violated 21 U.S.C. 827(b)(1) and 21 CFR 1304.04 by failing to maintain controlled substance scrips authorized by Dr. Aguilar, those allegations are not sustained.

That said, the Respondents' actions in filling Dr. Aguilar's controlled substance prescriptions over the course of over two and a half years without checking his (expired) COR status in any logical manner, even though pharmacy personnel had rejected ''many'' of his prescriptions as illegitimate, balance powerfully in favor of denying both COR applications under Factors Two and Four.

Recommendation

Based on the foregoing, the Government has established that the Respondents have submitted COR applications that bear material falsifications [99] and have committed acts that are inconsistent with the public interest. 21 U.S.C. 823(f). Accordingly, the Government has sustained its *prima facie* burden to establish that the Respondents' COR applications should be denied. Hence, under established Agency precedent, the burden is shifted to the Respondents to demonstrate that each can be entrusted with a DEA registration.

''[T]o rebut the Government's *prima facie* case, [the Respondents are] required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts.'' *Hassman,* 75 FR at 8236; *see Hoxie,* 419 F.3d at 483; *Lynch,* 75 FR at 78754 (holding that a respondent's attempts to minimize misconduct undermined acceptance of responsibility); *Mathew,* 75 FR at 66140, 66145, 66148; *Aycock,* 74 FR at 17543; *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387. The acceptance of responsibility is a condition precedent for the Respondents to prevail once the Government has established its *prima facie* case. *Mathew,* 75 FR at 66148. This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *Mackay,* 664 F.3d at 822. In determining whether and to what extent a sanction, such as denial of an application, is appropriate, consideration must be given to both the egregiousness of the offenses established by the Government's evidence and the Agency's interest in both specific and general deterrence. *Ruben,* 78 FR at 38364, 38385.

The issue of acceptance of responsibility presents something of a mixed bag for the Respondents. Moro-Perez, the owner/president of both Respondent pharmacies, spoke on their behalf and, through counsel, represented their interests. As discussed in more detail, *supra,* the pharmacies are responsible for his actions. *See EZRX,* 69 FR at 63181; *Plaza Pharmacy,* 53 FR at 36911. Moro-Perez acknowledged that he and his staff substituted what was essentially affirmative payment notification by insurance carriers in place of their responsibility to ensure that prescribing physicians, such as Dr. Aguilar, have valid CORs. The representations rendered by Moro-Perez and echoed by Farmacia Nueva PIC Nelson Vale regarding their intent to be more careful and purchase computer screens in the future were too amorphous to provide evidence sufficient to engender enough confidence that the pharmacies should be entrusted with CORs in the future. The Farmacia Nueva and Best Pharma PICs told DI Antoine that, as recently as two weeks prior to this hearing, no written controlled substance handling procedures had been promulgated by either pharmacy.[100] Tr. 107. Even if the tacit admissions of wrongdoing by Moro-Perez were embraced as sufficient acceptance of responsibility to carry the pharmacies' burden (a dubious proposition), the showing of remedial measures is too weak to carry the day. In like manner, the intentional decision by an experienced registrant to have his staff substitute insurance approvals for COR checks over the course of over two years is bad enough, but when coupled with the actual knowledge by the Respondent pharmacies that Dr. Aguilar had written ''many'' bad controlled substance prescriptions, it elevates the level of egregiousness to a point where it militates powerfully in favor of denial of the CORs. While true that the Government's failure to sustain its recordkeeping allegations substantially diminishes the gravity to be attached to the 2008 Letter of Admonition,[101] it is still relevant that Moro-Perez had been counseled once by the Agency to exercise an appropriate level of care, and that the Agency's warning did not inspire sufficient vigilance to check the COR status of a prescribing physician who was engaged in writing ''many'' bad controlled substance prescriptions. To grant registrations in the face of such conduct would be a statement to the regulated community of pharmacy registrants that employing a patently infirm system of COR checks for prescribing physicians can serve as an effective shield to the consequences of failure to exercise due care. Thus, the Agency's interests in deterrence also weigh in favor of denial of the requested registrations.

In their closing brief, the Respondents argue that mitigation is found in: (1) what they posit as a relatively modest number of dispensed prescriptions issued by (unregistered) Dr. Aguilar; (2) ''minimal'' pecuniary gain to the registrants that resulted in filling Dr. Aguilar's scrips; (3) their continuing representation that the Respondents' pharmacists actually turned down ''many'' of Dr. Aguilar's controlled substance prescription that were illegitimate; (4) the fact that forty employees working at the Respondent pharmacies stand to lose their jobs upon an unfavorable decision by the Agency on the applications; and (5) that the Government offered no evidence that any of the scrips in question were for other than a legitimate medical purpose. ALJ Ex. 24, at 20–21, 26. None of these arguments, all but one of which are offered under an apparent theory that ''it could have been worse,'' are persuasive on the present record.

While the Respondents characterize the number of the Dr. Aguilar scrips during the relevant period as modest in comparison to the pharmacies' other business, their numbers (even if assumed as accurate) do not further their cause. These dispensing events were executed during a time when the pharmacies had no rational system for checking the COR status of any of the prescribers whose scrips they were filling. To compare the Dr. Aguilar scrips with the scrips of other physicians while the pharmacy was not checking anyone's COR

evidence offered by the Respondent that it would be difficult to assign persuasive weight to even the two instances where the Respondent did not produce corresponding scrips. Stated differently, the Government's evidentiary presentation in this regard was simply too shaky and shifting to merit sufficient confidence to sustain the allegations. But even if the Government's evidence was deemed sufficiently reliable to believe that two Aguilar scrips were not maintained in accordance with the regulations, Agency precedent provides support for the proposition that, standing alone, these two missing scrips would not have been a sufficient violation to merit the application denial the Government seeks. *See Terese,* 76 FR at 46848 (determining that three recordkeeping violations that were acknowledged and timely corrected were insufficient to warrant COR revocation).

[98] Gov't Ex. 4, at 2–3.

[99] 21 U.S.C. 824(a)(1).

[100] While Moro-Perez made a fleeting reference to a ''continuing education'' that he participated in after the execution of the search warrant (Tr. 203), there was no evidence as to what the class covered or whether it was in any way related to controlled substance diversion issues.

[101] Gov't Ex. 3. Indeed, none of the deficiencies cited in the Letter of Admonition are the basis of any allegation in these proceedings.

status confounds logic. Stated differently, the level of care exercised on Dr. Aguilar's scrips was the same as every other controlled substance scrip issued during the relevant period. The Agency has revoked based on as few as two acts of intentional diversion, and it held that one such act can be sufficient. *MacKay,* 75 FR at 4997; *Krishna-Iyer,* 74 FR at 463. While the dispensing acts proven on this record may not have been intentional, there were certainly well more than one or two.

Similarly, that the Respondents argue (without specific figures) that they have made ''minimal'' pecuniary gain due to their lack of care helps their respective causes not at all. A reduced profit margin is no more persuasive evidence in the context of a registrant pharmacy as it would be in the case of a street dealer in illicit drugs. The focus is on maintaining a closed regulatory system that protects the public from the unlawful distribution of controlled substances. *Gonzales,* 545 U.S. at 13. A registrant's voluntary decision to abandon the most basic of its registrant obligations should not result in any profit. Further, as is true with the Respondents' argument regarding the relative percentage of scrips that can be attributed to Dr. Aguilar, in an environment where no serious COR checking was employed, there is no basis in reason for evaluating the money Moro-Perez's pharmacies made from prescriptions authorized by Dr. Aguilar as compared to those by other practitioners. Who knows which of the issuing prescribers were actually registered? Hence, that the ''pecuniary benefits gained'' from dispensing controlled substances on Dr. Aguilar's scrips ''is minimal'' [102] means nothing and mitigates nothing.

As discussed in detail, *supra,* the Respondents argument that they turned down ''many'' of Dr. Aguilar's prescriptions they thought to be illegitimate actually exacerbates the pharmacies' positions. Turning down ''many'' prescriptions from Dr. Aguilar that pharmacists determined to be illegitimate should have caused increased circumspection about dispensing on Aguilar's scrips. Instead, even by their own account, the pharmacies identified Dr. Aguilar as a problematic prescriber, never checked his COR status, and kept dispensing many of the prescriptions he authorized.

In their closing brief, the Respondents ask that, in making its decision on the COR applications, the Agency consider that ''[t]here are . . . more than 40 employees among two pharmacies whose welfare depend on their jobs at the pharmacies [and that in] small towns like San Sebastian and Moca in Puerto Rico, this means a lot.'' ALJ Ex. 24, at 21 (internal transcript citations omitted). Even setting aside for a moment Moro-Perez's testimony that controlled substances account for only 10–15% of the prescription medications dispensed at each of the Respondent pharmacies,[103] any blame for the lost jobs must properly be laid at the feet of the Respondents themselves, and Moro-Perez in particular. It is settled Agency precedent that normal hardships to the practitioner, and even the surrounding community, which are attendant upon the denial of a registration, are not a relevant consideration in determining whether status as a COR registrant is in the public interest within the meaning of the CSA. *Cheek,* 76 FR at 66972–73; *Owens,* 74 FR at 36757; *Abbadessa,* 74 FR at 10078.

Finally, insofar as the Respondents point to the fact that the Government's theory of the case and its evidence have never relied on the absence of a legitimate medical purpose (LMP) for any of the scrips in question, it is certainly true that the Agency has looked at the LMP issue where prescriptions were issued by a prescriber who lacked proper authorization. *Kam,* 78 FR at 62698. However, that the Government has advanced no LMP evidence does not mitigate the evidence that was received regarding the Respondents' breach in their respective duties of due care in ensuring that controlled substance prescriptions were authorized by a practitioner with a valid COR.

Regarding the material false misrepresentations intentionally placed into the COR applications, Moro-Perez doggedly adhered to his illogical position that he was reasonable in representing on the COR applications that neither pharmacy had ever surrendered a registration for cause. By Moro-Perez's intractable logic, the dismissal of an indictment against him (not either pharmacy) that occurred after the for-cause surrender of Best Pharma's COR, but before the for-cause surrender of Farmacia Nueva's COR, rendered both surrenders no longer ''for cause.'' Moro-Perez is an experienced COR holder and an educated, veteran pharmacist. His insistence that his false response to an application query regarding whether each pharmacy had ever surrendered a COR for cause was some sort of reasonable misunderstanding is simply not credible and defeats the Respondents' efforts to meet the Government's case. The false misrepresentation regarding the errant denial of the Respondents' prior surrenders for cause are sufficiently egregious on their face to warrant sanction, and the denial of the Respondents' applications here serve the Agency's interest in deterring false statements on the applications that it depends upon in its decisionmaking.

The Respondents have, thus, failed to rebut the Government's *prima facie* case regarding either material falsification of their applications or a balancing of the public interest factors. Further, consideration of the egregiousness of the offenses, coupled with the Agency's interest in both specific deterrence regarding these pharmacies, and general deterrence among the regulated community, supports the denial of both COR applications. Accordingly, the Respondents' respective applications for DEA Certificates of Registration should be DENIED.

Dated: October 24, 2013.

s/JOHN J. MULROONEY, II,

Chief Administrative Law Judge.

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[102] ALJ Ex. 24, at 21.

[103] Tr. 244–45.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14–27]

Maryanne Phillips-Elias, M.D.; Decision and Order

On October 23, 2014, Administrative Law Judge (ALJ) Christopher McNeil issued the attached Recommended Decision. Therein, the ALJ found that it was undisputed that Respondent's Nevada Controlled Substance Registration had been revoked and that she does not possess authority to dispense controlled substances in Nevada, the State in which she holds her DEA registration. R.D. at 6; *see also id.* at 2. The ALJ thus concluded that Respondent is no longer a practitioner within the meaning of the Controlled Substances Act and is therefore not entitled to be registered. He therefore recommended that I ''deny Respondent's application for a DEA Certificate of Registration.'' R.D. at 9.

There is, however, no evidence that an application is currently pending before the Agency. Rather, the Government seeks the revocation of Respondent's registration, which does not expire until March 31, 2017, and authorizes her to dispense controlled substances in schedules II through V, at registered premises located in Henderson, Nevada. Order to Show Cause, at 1.

Pursuant to 21 U.S.C. 824(a)(3), ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has had [her] State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' This Agency has further held that notwithstanding that this provision grants the Agency authority to suspend or revoke a registration, other provisions of the Controlled Substances Act ''make plain that a practitioner can neither obtain nor maintain a DEA registration unless the practitioner currently has authority under state law to handle controlled substances.'' *James L. Hooper,* 76 FR 71371, 71372 (2011), *pet. for rev. denied, Hooper* v. *Holder,* 481 F. App'x 826 (4th Cir. 2012).

These provisions include section 102(21), which defines the term ''practitioner'' to ''mean[ ] a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which [s]he practices . . . to distribute, dispense, [or] administer . . . a