asserted claims of the '932 patent are not invalid as obvious under 35 U.S.C. 103. The ALJ also found that the asserted claims of the '932 patent are not invalid for failure to satisfy the written description requirement under 35 U.S.C. 112, or for failure to satisfy the definiteness requirement under 35 U.S.C. 112. He further found that the asserted claims are not unenforceable due to inequitable conduct before the U.S. Patent and Trademark Office.

On March 13, 2013, ITRI filed a petition for review of the Remand ID's finding that U.S. Patent Application Publication No. 2003/0107892 to Yao (''Yao '892'') anticipates the asserted claims of the '932 patent. Also on March 13, 2013, LG filed a contingent petition for review of the Remand ID's finding that U.S. Patent No. 5,101,331 to Katoh (''Katoh '331'') does not anticipate asserted claims 6 and 10 of the '932 patent. LG also argues that the Remand ID errs in finding that Japanese Patent Publication 2000–338895 to Azuma (''Azuma '895'') does not anticipate claim 6 of the '932 patent. LG further argues that the Remand ID errs in not finding that the asserted claims of the '932 patent are obvious in light of various combinations of prior art references. On March 21, 2013, ITRI filed a response to LG's contingent petition for review. *See* ITRI's Remand Resp. Also on March 21, 2013, LG filed a response to ITRI's petition for review. *See* LG's Remand Resp. Further on March 21, 2013, the Commission investigative attorney filed a combined response to ITRI's and LG's petitions. *See* IA's Remand Resp.

Having examined the record of this investigation, including the ALJ's Final ID, the petitions for review, and the responses thereto, the Commission has determined to review the Remand ID in part. In particular, the Commission has determined to review the Remand ID's finding that Yao '892 anticipates claims 6, 9, and 10 of the '932 patent, and on review, finds that Yao '892 anticipates the asserted claims based on modified reasoning. The Commission has also determined to review the Remand ID's finding that LG has not shown by clear and convincing evidence that Katoh '331 does not anticipate claims 6 and 10 of the '932 patent, and on review, finds that Katoh '331 does not anticipate the asserted claims based on modified reasoning. The Commission has determined not to review the remaining issues decided in the Remand ID.

With respect to other issues the Commission determined to review in the Final ID, the Commission affirms the Final ID's construction of the limitation ''structured arc sheet'' of claim 6 of the '932 patent. The Commission also finds that the accused products do not infringe the asserted claims of the '932 patent based on slightly modified reasoning. The Commission further finds that ITRI has failed to satisfy the technical prong of the domestic industry requirement based on slightly modified reasoning. The Commission affirms the Final ID's finding that ITRI has satisfied the economic prong of the domestic industry requirement.

The investigation is terminated. A Commission opinion will issue shortly.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.42–46 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–46 and 210.50).

By order of the Commission.
Issued: April 29, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–10444 Filed 5–2–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–59]

Top RX Pharmacy; Decision and Order

On November 8, 2012, Chief Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached Recommended Decision. Neither party filed exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I have decided to adopt the ALJ's recommended rulings, findings of fact, and conclusions of law, except as discussed below.[1] I have also decided to adopt the ALJ's recommended order.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FT3034117, issued to Top RX Pharmacy, be, and it hereby is, revoked. I further order that any pending application of Top RX Pharmacy, to renew or modify the above registration, be, and it hereby is, denied. This Order is effective immediately.[2]

Dated: April 25, 2013.

Michele M. Leonhart,

Administrator.

Anthony Yim, Esq., and Frank Mann, Esq., for the Government
Jeffrey C. Grass, 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 August 1, 2012, the Administrator of the Drug Enforcement Administration (DEA), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) immediately suspending and proposing to revoke the DEA

[1] In his discussion of Factor Five—such other conduct which may threaten public health and safety—the ALJ cited the Agency's decision in *Paul Weir Battershell,* 76 FR 44359, 44368 n.27 (2011), for the proposition 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.'' Recommended Decision at 53 (slip op.) (emphasis added). However, as *Battershell* makes clear, it is not the case that such conduct is irrelevant under factor five, but simply, that such conduct, by itself, is not dispositive of whether a respondent's continued registration is consistent with the public interest. *See* 76 FR at 44368 n.27. Thus, evidence of non-compliance with provisions of the FDCA is relevant ''for the limited purpose of assessing the likelihood of [a] [r]espondent's future compliance with the CSA.'' *Id.* (citing *Wonderyears, Inc.,* 74 FR 457, 458 (2009)); *see also 4 OTC, Inc.,* 77 FR 35031, 35032–33 (2012).

Also, in his discussion of Respondent's failure to accept responsibility, the ALJ opined that ''[t]here is nothing in the record to rebut the persuasive record evidence that the conduct of the owner and PIC exceeded inaction and rose to the level of willing complicity in controlled substance diversion on a massive scale.'' Recommended Decision at 56. I agree that the evidence clearly shows that Respondent's principals knowingly diverted controlled substances. However, to the extent the ALJ's reasoning suggests that ''inaction'' on the part of a pharmacy's principals in dispensing prescriptions does not violate their duty under federal law to dispense only those prescriptions which have been ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,'' 21 CFR 1306.04(a), it is inconsistent with federal law. *See United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980) (upholding jury instruction that knowledge may be inferred from evidence that pharmacists ''deliberately closed their eyes to what would otherwise be obvious to them''); *Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44097 (2012) (quoting *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990) (''When prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescriptions.'')). As these cases make clear, inaction on the part of a pharmacist who fills a prescription can by, itself, support a finding of a violation of 21 CFR 1306.04(a) and the revocation of a registration.

As the ALJ noted earlier in his decision, when the circumstances surrounding a prescription present a red flag as to the prescription's legitimacy, that red flag must be resolved conclusively to show that the prescription is legitimate prior to dispensing it. Recommend Decision at 44. Indeed, the circumstances surrounding the prescription may be such that it cannot be dispensed. *See Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62317–22 (2012).

[2] Based on the egregious acts proven on this record, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

Certificate of Registration (COR), Number FT3034117, of the Respondent pursuant to 21 U.S.C. § 824(a), and to deny any pending applications for registration, renewal or modification pursuant to 21 U.S.C. §§ 823(f) and 824(a). On August 6, 2012, the Respondent, through counsel, timely requested a hearing, which was conducted in Dallas, Texas on October 2, 2012.

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 Respondent's COR should be revoked as inconsistent with the public interest, as that term is used in 21 U.S.C. §§ 823(f) and 824(a).

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.

The Allegations

In its OSC/ISO [3] and its Prehearing Statements,[4] the Government alleges that the Respondent, through its owner, agents, and employees: (1) failed to create an initial inventory of controlled substances, in violation of 21 U.S.C. § 827(a)(1) and 21 C.F.R. § 1304.11(b); (2) provided false information to controlled substance distributors; (3) failed to maintain accurate and complete records and failed to account for controlled substances in violation of 21 U.S.C. §§ 827(a)(3) and 842(a)(5) and 21 C.F.R. §§ 1304.03, 1304.04 and 1304.21; (4) diluted promethazine syrup before dispensing, in violation of 21 U.S.C. § 331; and (5) dispensed controlled substances under circumstances where it knew or should have known that the drugs were being diverted for illicit purposes and were not being dispensed for a legitimate medical purpose.

The Stipulations of Fact

The Government and the Respondent, through counsel, have entered into stipulations regarding the following matters:

1) Top RX Pharmacy is registered with DEA as a retail pharmacy in Schedules III–V under DEA Certificate of Registration FT3034117 at 2381 S. Collins Street, Arlington, Texas, 76014 with an expiration date of November 30, 2014.

2) Top RX is currently licensed as a pharmacy in the State of Texas pursuant to license number 27844, which is currently active and set to expire on January 31, 2014.

3) Top RX is owned by Mr. Jesse Sanders III. The pharmacist-in-charge of Top RX is Mr. Alonzo Grape, R.Ph.

The Evidence

The Government's Evidence

The Government called four witnesses in support of its case-in-chief. The Government's witnesses included Dale Newkirk, the lead (now retired) diversion investigator (DI) on the DEA case, Charles Pinkerton, an investigator from the Texas Department of Public Safety (DPS), Ronald White, an investigator from the Texas State Board of Pharmacy (Texas Pharmacy Board), and Heather Tippie, a pharmacy technician-in-training who was formerly employed at the Respondent Pharmacy.

DPS Investigator Pinkerton testified that he has been an investigator with the Regulatory Services Division of DPS for eleven years, and was a thirty-year veteran of the Fort Worth Police Department prior to joining DPS. Tr. 14. Investigator Pinkerton testified that as a DPS investigator he conducts regulatory investigations of pharmacies, which can include random inspections, pill counts, and pharmacy paperwork assessments. Tr. 15. Pinkerton stated that he has received training at DPS, and that in his eleven years on the job has conducted 75–80 pharmacy inspections. Tr. 15–16.

Investigator Pinkerton testified that he first visited the Respondent pharmacy on March 13, 2012, pursuant to a tasking from a DPS supervisor, based on a report that the Respondent had not been transmitting required data to the Texas prescription monitoring program (PMP).[5] Tr. 17–18. Upon his arrival at the Respondent pharmacy, Investigator Pinkerton and another DPS investigator, named Susan Furnas, spoke with the pharmacy owner, Jesse Sanders, III (Mr. Sanders). Tr. 18–19. The two DPS investigators informed Mr. Sanders that they were there to conduct an investigation/security audit (First DPS Audit) of the pharmacy.[6] Tr. 19–20. Pinkerton explained the DPS pharmacy audit protocol as follows:

What we do . . . is we pick a particular drug, okay, and then we look at the invoices showing where [the pharmacy has] bought what [it has] bought. We also look at the dispensing logs, what [the pharmacy has] sold, if [the pharmacy has] any credits where [it has] transferred drugs or have bought anything. We look at that. And then we have a formula that we go through and we add all this together and determine whether or not there's a shortage or an overage of the drug.

Tr. 26.

Investigator Pinkerton described the Respondent's invoices of controlled substances purchased and its ''storage of drugs'' as ''messy.'' [7] Tr. 20–21. According to Investigator Pinkerton, the invoices were not filed as they should have been, ''[t]hey were just laying on a desk . . . just kind of laying around haphazardly.'' Tr. 21

Additionally, Pinkerton testified that, as part of the First DPS Audit, he asked for an initial inventory. Tr. 23. Investigator Pinkerton explained the Texas initial inventory requirement as follows:

With the rules and regulations that we go by, an initial inventory is made by the pharmacy when they [sic] first start business. On the very first day of their [sic] business, they are to count all of their drugs, particularly the schedule drugs, to find out what they [sic] have on hand when they [sic] start their business.

Id. It was thus, Pinkerton's understanding that in Texas, the initial inventory requirement ripens on the first day a pharmacy opens.[8] Pinkerton testified that when he asked the Respondent's Pharmacist-in-Charge (PIC) Alonzo Grape, and its owner, Mr. Sanders, to produce an initial inventory, both men conceded that none existed and that they were unaware of any requirement to generate one. Tr. 23–24. According to Pinkerton, PIC Grape then stated that he did not think that he needed to have one until the pharmacy had been open six months. Tr. 24. Mr. Sanders, for his part, offered no explanation as to why the pharmacy had no initial inventory. Tr. 25. Further, the Respondent pharmacy staff was unable produce any dispensing logs. *Id.* Hard copies of prescriptions were the only dispensing records provided by the Respondent pharmacy. Tr. 25–26. On a positive note, Mr. Sanders did demonstrate to the DPS investigators that he had resolved his software issues sufficiently to transmit required weekly controlled substance reports

[3] ALJ Ex. 1.

[4] ALJ Exs. 7, 8.

[5] Investigator Pinkerton testified that Texas pharmacies are required to transmit a weekly accounting of all scheduled drugs filled in the previous seven days. Tr. 17.

[6] On cross-examination, Investigator Pinkerton acknowledged that when he first arrived at the Respondent pharmacy he was under the misimpression that it had been in business for over a year. Tr. 55. The evidence shows that the Respondent pharmacy opened its doors approximately two months prior to Investigator Pinkerton's March 13 visit.

[7] Investigator Pinkerton also described the ''general condition of the pharmacy'' as ''unclean.'' Tr. 20. When asked whether this cleanliness observation related to a regulatory standard, Pinkerton explained: ''I guess it's more of an observation. I noted dust, dirt, in and around the edges of the place, of the walls. We have no training as far as that goes. That was just an observation that I did make on my own.'' Tr. 22. Although Pinkerton was unable to identify the applicable state authority on point, 22 Tex. Admin. Code § 291.33(b) provides that ''[t]he pharmacy shall be arranged in an orderly fashion and kept clean.'' While maintaining an unclean or even unsanitary pharmacy is certainly unsavory, and may be a violation of state law, no clear nexus between Pinkerton's cleanliness observation and any law related to controlled substances is apparent in the record or proffered by the Government. *See Gregg & Son Distributors,* 74 Fed. Reg. 17517 n.1 ([I]t is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding.''). That Pinkerton felt the pharmacy was not sufficiently clean, at least as offered here, is not a relevant consideration in determining whether the Respondent can be entrusted with a DEA COR. *See Judulang v. Holder,* 132 S.Ct. 476, 556 U.S. ____ (2011) (actions of a regulatory agency must bear a rational relationship to the purposes of the statute it is charged with enforcing); *Tony T. Bui, M.D.,* 75 Fed. Reg. 49979, 49989 (2010) (holding that in order for a registrant's ''conduct to be actionable under factor five, there must be a substantial relationship between the conduct and the CSA's purposes of preventing drug abuse and diversion, and that the conduct may constitute a threat to public health and safety.''); *see also Paul Weir Battershell, N.P.,* 76 Fed. Reg. 44359 n.27 (2011) (to same effect).

[8] Although Investigator Pinkerton was unable to furnish a citation for any authority related to the Texas initial inventory requirement (Tr. 27), 22 Tex. Admin. Code § 291.17(b) requires that ''[a] new [community] pharmacy shall take an [initial] inventory on the opening day of business.''

to the Texas PMP, hence resolving the initial issue that spawned their visit. Tr. 19–20, 64.

The drug selected [9] by Investigators Pinkerton and Furnas for review at the Respondent pharmacy at the First DPS Audit was alprazolam.[10] Tr. 28. Pinkerton testified that, consistent with the DPS protocol, the audit was conducted on the pharmacy premises with pharmacy staff, and the audit counts recorded are the result of an agreement between the inspectors and the pharmacy personnel. Tr. 29. Heather Tippie, a pharmacy technician-in-training employed at the Respondent, counted the drugs with Investigator Pinkerton, with PIC Grape standing beside her.[11] Tr. 28–29, 59–60.

A copy of the audit results computation sheet prepared by the DPS investigators (DPS Computation Form 1) was received into evidence through Investigator Pinkerton's testimony. Gov't Ex. 3, at 1; Tr. 53. Based on Mr. Sanders' representation that there was no initial inventory, a zero was placed in the column of DPS Computation Form 1, denoting the initial inventory amount on board as of the January 16, 2012 date that Sanders told Pinkerton that the pharmacy opened (pharmacy opening date).[12] Gov't Ex. 3, at 1. A comparison of the total number of dosage units the Respondent pharmacy's paperwork reflects as having been purchased since the opening date, with the total amount of dosage units on hand (pursuant to the agreed-upon count), indicates that the pharmacy was 5,469 dosage units shy of alprazolam amounts that should have been there. Gov't Ex. 3, at 1; Tr. 35. This translated into a 43.06% difference between the amount of alprazolam justified by the paperwork and the amount the pharmacy could find in the store. Gov't Ex. 3, at 1; Tr. 37. Pinkerton stated that neither Sanders nor Grape could supply any reason for the shortage. Tr. 36. Pinkerton asked Sanders and Grape for additional information to explain the shortage (such as additional invoices or sale records) but none were supplied. *Id.* Pinkerton stated that he gave Sanders and Grape an additional seven days to find paperwork to account for the shortage. Tr. 37. About a week later, Pinkerton received a phone call from Mr. Sanders, who informed him that additional paperwork and drugs had been discovered in the pharmacy back room. Tr. 37–39. Mr. Sanders also telephonically communicated to Pinkerton that he was in possession of a computer printout showing that the number of prescriptions during the First DPS Audit should not have been 480 dosage units, but rather 690. Tr. 49.

Based on the follow up call from Mr. Sanders, Pinkerton and Alicia Alexander, another DPS investigator, returned to the Respondent pharmacy on March 20, 2012 [13] and conducted another audit (Second DPS Audit). Tr. 39. The investigators re-counted, and the amount of alprazolam remained the same. Tr. 49–50. The results of the Second DPS Audit were memorialized by Pinkerton in another DPS computation form (DPS Computation Form 2). Gov't Ex. 3, at 2. In contrast to the First DPS Audit, which revealed a 5,469 dosage unit *shortage,* the Second DPS Audit, which was conducted ''from scratch,'' [14] reflected a 2,275 dosage unit *overage* (17.91%) of alprazolam 2 milligram (mg). Gov't Ex. 3, at 2; Tr. 41. Mr. Sanders and PIC Grape were present at the Second DPS Audit, but neither offered any explanation as to how the previous shortage had now morphed into an overage. Tr. 42. Mr. Sanders told the investigators that he assumed that the pills discovered in the back room of the pharmacy would remedy the audit anomalies identified in the First DPS Audit. *Id.*

On March 29, 2012, Sanders again telephoned Pinkerton and advised him that another invoice for 1,000 dosage units of alprazolam 2 mg had been discovered at the pharmacy. Tr. 45. Pinkerton did not return to the Respondent pharmacy, but based on Mr. Sanders' newest revelation, completed another drug computation form (DPS Computation Form 3), which incorporated the new information supplied by Mr. Sanders. Gov't Ex. 3, at 3; Tr. 45–46. Even assuming the accuracy of the purported newly-discovered invoice, DPS Computation Form 3 reflects a 1,275 dosage unit overage (9.3%) of alprazolam 2 mg. Gov't Ex. 3, at 3; Tr. 47. Investigator Pinkerton subsequently telephoned Mr. Sanders seeking further explanation of the overage, but the latter was unable to shed any light on the matter. Tr. 47.

Investigator Pinkerton testified that he returned to the Respondent pharmacy in May of 2012 at the request of Ronald White, an investigator with the Texas Pharmacy Board. Tr. 51. Investigator White invited Pinkerton to provide assistance during an audit to be conducted by DEA (DEA Audit). *Id.* Pinkerton testified that it was his recollection that the DEA Audit (discussed in greater detail, *infra*) focused on the following controlled substances: hydrocodone,[15] alprazolam, Soma,[16] and promethazine with codeine.[17] Tr. 52.

Investigator Pinkerton presented as an impartial investigator who tendered testimony that was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government also presented the testimony of retired DEA DI Dale Newkirk. Newkirk testified that he worked as a diversion investigator with DEA in Fort Worth, Texas for thirteen years, and retired in September of 2012. Tr. 68. DI Newkirk testified that he has undergone multiple training evolutions as a DEA DI, and that prior to his employment at DEA, he spent twenty-five years as a police officer in El Paso, Texas. Tr. 69–70.

Newkirk testified that he was aware of the Respondent pharmacy because he conducted its pre-COR investigation. Tr. 70. DI Newkirk recalled that the case came to him as a result of an application liability question, which alerted DEA that the Respondent's PIC, Alonzo Grape, had a history of discipline by the Texas Pharmacy Board. Tr. 70. Newkirk recalled that he approved the Respondent's application after he confirmed that the Pharmacy Board had resolved its issue with PIC Grape. Tr. 70–71. DI Newkirk testified that because of the issue encountered during the registration process, he periodically monitored ARCOS entries related to the Respondent, and observed that (at least in his opinion) the Respondent was ordering large amounts of hydrocodone. Tr. 71. According to DI Newkirk, because of his suspicions and the volume amounts reflected in the ARCOS data, he ''kept an eye on'' the Respondent.[18] *Id.*

Newkirk testified that on May 7, 2012, DPS Investigator Pinkerton telephonically advised him of the shortage/overage audit results obtained from his visits to the Respondent pharmacy. *Id.* Based on this information, Newkirk conducted an inspection of the Respondent the following day (First DEA Visit). *Id.* In addition to Investigator Pinkerton, DI Newkirk was accompanied on his inspection visit to the Respondent pharmacy by his partner, DI Christopher Hull, DPS Investigators Susan Furnas and Alicia Alexander, and Investigator Ronald White from the Texas Pharmacy Board. Tr. 71–72.

Newkirk testified that when the investigators arrived at the Respondent pharmacy, they were met by Heather Tippie (Ms. Tippie) at the window. Tr. 72. Newkirk recalled that Ms. Tippie ''represented herself as a pharmacy tech-in-training . . . told [the inspectors] that she had been through the required classes [to be a pharmacy technician], and [Newkirk observed that] her

[9] Investigator Pinkerton testified that the audit drug choice is selected at random. Tr. 18.

[10] Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1).

[11] There is simply no factual basis for the assertion made in the Respondent's post-hearing brief that the alprazolam counts were made exclusively by Ms. Tippie and that Investigator Pinkerton testified that ''this could be the reason why [Grape] and [Sanders] couldn't [sic] explain the variances that were resulting from Ms. Tippie's count.'' Resp't Brief at 4.

[12] During cross examination, Investigator Pinkerton acknowledged that although the Respondent's COR lists February 2, 2012 as the date of issuance, based on his discussions with Mr. Sanders, he fixed the initial inventory date as January 16, 2012 on DPS Computation Form 1. Gov't Ex. 1; Gov't Ex. 3, at 1; Tr. 56–57.

[13] There was some confusion at the hearing as to the date contained on the audit form. Investigator Pinkerton testified that although the form states the date as ''3–19–12,'' it was not an accurate date. Gov't Ex. 3, at 2; Tr. 43. According to Pinkerton, the Second Audit was actually conducted on March 20, 2012, but he ''[g]uess[ed he] just got the dates mixed up. . . .'' Tr. 43–44.

[14] Tr. 39.

[15] Hydrocodone is a Schedule III controlled substance pursuant to 21 C.F.R. § 1308.13(e)(1).

[16] Soma is the brand name of a drug containing carisoprodol. 5–S Attorneys' Dictionary of Medicine S–107381. Carisoprodol is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(5).

[17] Promethazine with codeine cough syrup is a Schedule V controlled substance pursuant to 21 C.F.R. § 1308.15(c)(1).

[18] No context was elicited regarding why DI Newkirk characterized the amounts of hydrocodone he reviewed as ''large.'' Tr. 71. Similarly, the record contains no elucidation of what Newkirk meant by ''ke[eping] an eye on'' the Respondent. *Id.*

[pharmacy technician-in-training] certificate was on the wall . . . to the left as you enter the pharmacy.'' Tr. 107–08. Ms. Tippie retrieved the Respondent's owner, Mr. Sanders, and upon the presentation of a DEA notice of inspection, Mr. Sanders executed the document and consented to the inspection. Tr. 72. Mr. Sanders inquired of Newkirk whether the inspectors had come to inquire about two recent burglaries at the Respondent pharmacy and was told that the break-ins would be discussed during the inspection. Tr. 73.

Newkirk described the inspection procedure undertaken by himself, DI Hull, the Texas DPS investigators, and Investigator White. Tr. 72–74. DI Hull and the three DPS investigators conducted a closing inventory of all controlled substances and interviewed Ms. Tippie and PIC Grape. *Id.* Investigator White periodically assisted DI Newkirk in his conversations with Mr. Sanders. Tr. 73–74. Newkirk stated that during the inspection several violations were observed. Tr. 74. According to DI Newkirk, although the Respondent pharmacy had been ordering controlled substances [19] since February 3, 2012,[20] it failed to take an initial inventory, did not maintain its records, and did not annotate inventories when product was received.[21] *Id.* Newkirk also testified that the Respondent was transferring controlled substances to a pharmacy in Houston with documentation that did not comply with DEA regulations. Tr. 75. Specifically, Newkirk testified that the transfer records were deficient in that ''[t]hey [did not] contain the bottle size, the full name of the product or the amount of tablets or amount of liquid in the product [and] the receipts did not annotate who received the product, the date it was received or the correct amount received.'' *Id.*

Newkirk also testified that he observed unmarked bottles containing promethazine with codeine, hydrocodone, and alprazolam.[22] Tr. 75–76. According to DI Newkirk, he was able to identify the contents of the bottles containing hydrocodone and alprazolam by examining the pills, and the promethazine syrup by smelling it. Tr. 76. Although Newkirk conceded that he was unable, through his smelling process, to discern the presence or concentration of codeine in the syrup, Ms. Tippie and PIC Grape acknowledged the correctness of his assumption, and (as discussed, *infra*) samples of the contents were subsequently tested by DPS. Tr. 76–78.

Newkirk testified about the results of the controlled substance audit conducted during the First DEA Visit. Tr. 87. Several controlled substances were audited, revealing both shortages and overages. *Id.* Following the audit, Newkirk conducted an exit interview with Mr. Sanders and PIC Grape. Tr. 89. Newkirk informed Sanders and Grape of the shortages and overages observed, along with the Respondent's lack of an initial inventory, and poor recordkeeping. Tr. 89–90. Newkirk informed them that in his view, poor recordkeeping was one of the reasons that the audit did not balance. Tr. 90. Newkirk also pointed out the lack of annotations on invoices, the fact that the pharmacy was dirty, and that there were bottles containing controlled substances that did not have labels as other issues he observed during his visit. *Id.* Mr. Sanders responded that he would correct those issues. *Id.* When Mr. Sanders explained to Newkirk that he was a new pharmacy owner, and that he did not understand DEA policies, Newkirk referred him to the DEA Web site for detailed information and suggested that he could even consult with his father, Jesse Sanders, II (Mr. Sanders, Sr.), who served as a PIC at another pharmacy, as well as an advisor to the Respondent pharmacy.[23] *Id.*

Newkirk returned to the Respondent pharmacy on May 22, 2012 (Second DEA Visit) with another Notice of Inspection, accompanied by DI Hull, and Investigators White and Adrian Bower from the Texas Pharmacy Board. Tr. 91. The Second DEA Visit was initiated so that Newkirk could obtain copies of prescription records and so that Investigator White could procure samples to confirm his suspicion that the bottles he encountered during the First DEA Visit actually did contain promethazine with codeine.[24] *Id.* Newkirk testified that he recollected that conditions there, in his estimation, had improved to the extent that the pharmacy appeared cleaner, and there was a new pharmacy technician, Danielle Colvin (Colvin). Tr. 100. During the Second DEA Visit, Mr. Sanders conceded that he still had not prepared an initial inventory. Tr. 92.

DI Newkirk testified that he returned to the Respondent pharmacy for a third time on July 31, 2012 (Third DEA Visit). Tr. 93. According to Newkirk, the Third DEA Visit was prompted by a request from the Houston DEA Office to investigate an intelligence lead that emerged from an investigation that was unrelated to Newkirk's prior two visits to the Respondent. *Id.* Upon his arrival at the Third DEA Visit to the pharmacy (which he observed to be in a cleaner condition, with no regulatory violations he could recall),[25] he encountered PIC Grape, and Pharmacy Technician Colvin. *Id.* Newkirk informed Grape and Colvin that he was there to reexamine prescription records, and that he ''wanted to verify [the pharmacy's] daily dispensing report to see the drugs that [it was] dispensing and [that he] also wanted to get a month's printout of [the pharmacy's] dispensing records so that [he] could see what doctors were prescribing and the patients that were getting the drugs filled at the pharmacy.'' Tr. 93–94. A subsequent review of the prescription records obtained that day revealed to DI Newkirk that the three controlled substances most frequently dispensed at the Respondent pharmacy were hydrocodone,[26] alprazolam, and promethazine with codeine cough syrup. Tr. 96. Although Newkirk referred to the combination of these medications as ''the trinity cocktail,'' he provided no explanation for that term. *Id.*

Newkirk's fourth and final visit to the Respondent pharmacy occurred on August 2, 2012 (Fourth DEA Visit), when he served the OSC/ISO that is the subject of the present proceedings and seized all controlled substances on board at that location into DEA custody.[27] Tr. 94.

Retired DI Newkirk presented as an impartial investigator whose testimony was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government also called Investigator Ronald White from the Texas Pharmacy Board. Investigator White testified that he has been an investigator with the Board for a little over two years. Tr. 111. Before becoming an investigator, White worked as an investigative analyst on a project with the federal government, a city marshal, and as a corrections officer. *Id.* In his current role, White testified that he investigates violations of the Texas Pharmacy Act, and that he has some diversion training and some college. Tr. 111–12.

---

[19] Although DI Newkirk testified that the Respondent had been ordering controlled substances from multiple sources in various locations around the country, and that this was ''one of [his] reasons for concern about the pharmacy'' (Tr. 105–06), there was no development or explanation of this observation that would render it relevant to any issue that must or should be decided in these proceedings. *See Alvin Darby, M.D.,* 75 Fed. Reg. 26993, 26999, n.31 (2010) (''[U]nder the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.' '') (citing *NLRB v. Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

[20] Tr. 104–05.

[21] Newkirk testified that when a pharmacy receives controlled substances on an invoice from a distributor, the person receiving the controlled substances must initial the inventory, date it, and verify the amount received. Tr. 74. Under 22 Tex. Admin. Code § 291.55(d)(4), pharmacists are required to ''verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances.''

[22] Photographs of the unlabeled bottles were received into the record without objection. Gov't Ex. 6, at 2–3; Tr. 85–86.

[23] Although the Respondent, in his post-hearing brief, provided some background information about Sanders, Sr.'s qualifications, no evidence on this subject (like many other factual elements set forth in the Respondent's brief) appears anywhere in the record. Resp't Brief at 3.

[24] Newkirk testified that the samples taken during this visit confirmed that the syrup was promethazine with codeine. Tr. 95. However, the testing detected no evidence of adulteration. *Id.*

[25] Tr. 94.

[26] DI Newkirk testified that the hydrocodone was dispensed at ''two different strengths, 10/650 and 10/325, which are both the strongest available.'' Tr. 96.

[27] Although DI Newkirk testified that on the Fourth DEA Visit he observed ''some unmarked bottles'' (Tr. 94), the record did not indicate what, if anything, was contained in those unmarked bottles. Similarly, although DI Newkirk testified to his understanding that on the day of the Fourth DEA Visit the Respondent pharmacy did not accept credit cards or Medicare or Medicaid Insurance plans, and was a cash-only business (Tr. 94–95, 102–03), the record did not contain competent expert testimony or sufficient contextual background information that would have rendered this information relevant to any issue that must be adjudicated in these proceedings. *See Alvin Darby, M.D.,* 75 Fed. Reg. 26993, 26999 n.31 (2010) (''[U]nder the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'''') (citing *NLRB v. Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939)).

The Government elicited testimony from Investigator White about his observations during the First DEA Visit. White testified that when he accompanied Newkirk to the Respondent pharmacy on May 8, 2012, it was his first time on the premises, and although he went there looking to evaluate the pharmacy for recordkeeping violations, he ''ended up conducting an actual audit.'' Tr. 113–14.

Investigator White testified as to the physical appearance of the Respondent pharmacy, which is situated in what White characterized as a ''strip shopping center.'' Tr. 114. According to White, a customer entering the establishment traverses a short hallway which leads to a ''small [waiting] area with just a few chairs.'' *Id.* To the right of the windows looking out to the parking lot is a wall with two small openings [28] for prescription drop-off and pick-up, as well as a door opening into the back of the pharmacy. *Id.* Neither of the approximately 1.5 feet by 1.5 feet windows was adorned with a counter. Tr. 115. White said that bars on the outside door and windows of the pharmacy had been added to the structure after the First DEA Visit. Tr. 117. White testified that there were no other items available for sale as one might ordinarily see in a retail store. Tr. 116.

Upon arrival at the Respondent pharmacy for the First DEA Visit, White testified that he looked through one of the openings and observed that Pharmacy Technician-In-Training Tippie was filling prescriptions. Tr. 117–18, 189. White explained that ''[s]he appeared to be counting tablets into a bottle.'' *Id.* White stated that under ''our guidelines'' a pharmacy technician is not permitted to fill prescriptions without a pharmacist present. Tr. 118. He said it was also a violation of Texas Pharmacy Board regulations [29] for a pharmacy technician-in-training to fill prescriptions without a pharmacist present. Tr. 117–18, 121. White testified that PIC Grape was not present when White observed Ms. Tippie filling prescriptions. Tr. 118. White testified that he believed that Mr. Sanders was in his office at the time and that Ms. Tippie offered to go and retrieve him. Tr. 118–19. After agreeing to bring back Mr. Sanders, Tippie returned to the fill counter and resumed her activity filling prescriptions.[30] Tr. 119. White recalled that when he asked Tippie and Sanders about the current whereabouts of PIC Grape, they told him that he was likely on his way into the pharmacy. Tr. 190. White said PIC Grape did indeed appear later during this visit. *Id.*

White observed that the bottles Ms. Tippie filled during the visit were unlabeled, but that he could tell by the markings on the pills that Tippie was filling hydrocodone prescriptions. Tr. 120. White also saw Ms. Tippie fill some labeled bottles for specific patients' prescriptions and fill some prepackaged unlabeled bottles for customers visiting the pharmacy later in the day. *Id.* White explained that ''[p]harmacies are allowed to prepackage some drugs if they know a particular quantity of pills or a particular drug and quantity is what a doctor prefers and [the pharmacy] fill[s] a lot of scrip[]s for that doctor.'' Tr. 121. Although supplying no authority for the proposition, White testified that when a pharmacy prepackages bottles, the label must ''have the name of the drug, the strength of the drug, the expiration date, the National Drug Code (NDC) number, and the quantity of pills that are in the container.'' Tr. 122–23. However, according to Investigator White, there were no labels on the bottles Ms. Tippie prepackaged. Tr. 123.

White observed that Ms. Tippie was using the ''basket system for production,'' in which the wholesale bottle of the drug is placed in a small bread basket, along with the vial that they filled, the labels, and hard copies of the script. *Id.* Although, according to White, the ''basket'' system is not an uncommon procedure at pharmacies, the procedure being utilized at the Respondent pharmacy that day was infirm in that instead of keeping the hard copy prescriptions with the bottles, Mr. Tippie (who, at least in White's view, was not authorized to do this on her own) was filing the hard copy prescriptions away. Tr. 127–28. Ms. Tippie's explanation for this was that the prescriptions referred to in the hard copies had already been filled. Tr. 128. White testified the standard of practice for filling a prescription is to use a basket with hard copies of the prescriptions and the label on the wholesale manufacturer's bottle in order to identify the drug being filled. Tr. 127. When White pointed out to Ms. Tippie that it was a violation of Texas regulations for her to fill the prescriptions without any pharmacist present, she told him that Sanders had instructed her to fill the prescriptions, and explained that she was not familiar with all of the rules because she was just a technician-in-training. Tr. 126–27.

White then checked the shelves where the Respondent stored its controlled substances. *Id.* White observed that there were eight-ounce bottles of syrup on the shelf that did not have labels. *Id.* When White asked PIC Grape about the contents of the unlabeled bottles, the latter explained to the former that the bottles contained promethazine with codeine. Tr. 128–29. White testified (again, without supplying authority in support of his assertion) that it is a violation of Texas Board of Pharmacy regulations to store promethazine with codeine in an unlabeled bottle. Tr. 129.

White discussed several photographs that he took during his visit to the Respondent pharmacy. The photographs were offered by the Government and received into evidence as Government Exhibit 6. Among the photographs were several depicting the unlabeled bottles which PIC Grape had informed White contained promethazine with codeine. Gov't Ex. 6, at 2–4; Tr. 131. White also identified a picture showing an open, empty medication bottle lying on the ground with a ''white speck that's just a little ways forward from that bottle.'' Gov't Ex. 6, at 6; Tr. 133. The investigators determined that the white speck was a tablet of hydrocodone. Tr. 133.

White testified that he conducted an audit during the First DEA Visit.[31] Tr. 134. White began by asking Mr. Sanders for an initial inventory, which according to him, a pharmacy is required to prepare for controlled and non-controlled substances on the first day it is open for business. Tr. 135.[32] When White asked PIC Grape about the initial inventory, the latter replied that he was not sure that one had been prepared. *Id.* White then asked Sanders for Respondent's initial inventory. *Id.* Sanders told White that he also believed that an initial inventory had not been generated because he was not aware that one was required. *Id.* When White asked PIC Grape why an initial inventory had not been created, Grape referred White back to Mr. Sanders. *Id.* White also requested the Respondent's dispensing records for the drugs White planned to audit, along with any invoices, credits or returns, and any records of losses. Tr. 136.

White testified that in the course of conducting his audit, he consulted two DEA Report of Theft or Loss forms (DEA Form 106) documenting losses sustained during two break-ins to Respondent's pharmacy.[33]

[28] During his testimony, Mr. Sanders indicated that the windows were designed to limit the ability of customers to see into the pharmacy area. Tr. 267.

[29] White could not provide the citation for the relevant regulation, saying ''I believe it's under 219, and I can't tell you the exact section.'' Tr. 124. 22 Tex. Admin. Code § 291.32(d)(2) provides that the ''nonjudgmental and technical duties associated with the preparation and distribution of prescriptions drugs'' do not include duties enumerated under 22 Tex. Admin. Code § 291.32(c)(2) that must be performed by a pharmacist. Included among the enumerated pharmacist-only duties are ''interpreting drug orders,'' ''selection of drug products,'' and ''performing the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed.'' *Id.*

[30] During cross examination, White agreed although true that by filling prescriptions without a pharmacist present, Ms. Tippie was acting in violation of the regulations, no disciplinary actions have been lodged against her in this regard. Tr. 191.

[31] A copy of the written audit results completed by Investigator White was received into the record. Gov't Ex. 4; Tr. 158. A Combined Receipt Log was included in the audit results, and consists of a compilation of orders placed by the Respondent for controlled substances from distributors. Gov't Ex. 4, at 2–7. Also included in the audit results was a Combined Sales Log, representing a combination of the Respondent's dispensing, losses, and transfers out. Gov't Ex. 4, at 8–9. The Computation Chart documents the results of the audit of the following drugs: hydrocodone 10/650; hydrocodone 10/325; alprazolam 2 mg; carisoprodol 350 mg; and promethazine with codeine. Gov't Ex. 4, at 1. The audit results demonstrate a shortage of 17,119 dosage units of hydrocodone 10/650, an overage of 5,890 dosage units of hydrocodone 10/325, a shortage of 2,363 dosage units of alprazolam 2mg, a shortage of 2,800 dosage units of carisoprodol, and a shortage of 4,767 dosage units of promethazine with codeine syrup. *Id.*

[32] While 21 C.F.R. § 1304.11(b) requires that the initial inventory be taken on the date that the pharmacy ''first engages in the * * * dispensing of controlled substances,'' the initial inventory requirement under Texas regulations is slightly different. Under Texas regulations, the initial inventory must be taken ''on the opening day of business.'' 22 Tex. Admin. Code § 291.17(b)(1). However, regardless of the difference, the evidence establishes that the Respondent pharmacy did not take an initial inventory on either date, and thus was in violation of both federal and state regulations.

[33] Two DEA 106 Report of Theft or Loss of Controlled Substances Forms prepared on behalf of

Continued

Tr. 136–37. White said the forms ''were submitted by Top RX [to the DEA] in regards to the two nighttime burglaries.'' [34] Tr. 138. White witnessed a conversation between Newkirk and Sanders regarding the accuracy of these forms, wherein Newkirk asked Sanders ''how could these records be accurate if you didn't have a starting point and an ending point to figure the numbers.'' Tr. 138–39. White testified that Sanders admitted that the numbers he reported in the DEA Form 106s were ''really just guesses or an estimate.'' [35] Tr. 140; *see also* Tr. 210.

White stated that he consulted the DEA Forms 106 when completing his audit, along with invoices from wholesale distributors, transfer forms, and dispensing records. Tr. 146. With regards to the invoices, White said that he consulted the invoices available on the pharmacy premises and also requested wholesale records from the distributors supplying Respondent with controlled substances. *Id.* White testified that fifty (50) invoices were missing from the pharmacy, but copies of the missing invoices were made available by the distributors. Tr. 148. White added that under Texas law there is a requirement that pharmacies must keep all invoices regarding purchases of controlled substances. Tr. 149. Regarding the missing invoices, Mr. Sanders placed the blame on his pharmacy technician-in-training, explaining to Investigator White that Ms. Tippie ''had not taken care of the records properly.'' Tr. 150.

White described the records he created during the First DEA Visit to the Respondent pharmacy. White testified to creating a computation chart, combined receipt log for all of the drugs that came into the pharmacy, and a combined sales log of all of the drugs that were dispensed from the pharmacy. Tr. 150. White explained that he created these records from the invoices gathered from the wholesalers and the Respondent. Tr. 153. White said that these records are in a format traditionally used by the Texas Pharmacy Board, and were prepared using an Access-based software program. *Id.* White testified that his supervisor reviewed the file he prepared to check its accuracy. Tr. 153–54.

White testified that he physically counted the controlled substances on the premises. Tr. 154. A copy of the results from White's count was received into evidence. Gov't Ex. 4; Tr. 158. The counts were certified as being ''true and correct'' by PIC Grape. Tr. 154. White testified that he entered zero for the initial inventory of hydrocodone, with the concurrence of Mr. Sanders, and PIC Grape. Tr. 155. White stated that the audit revealed a shortage of hydrocodone 10/650, alprazolam 2 mg, carisoprodol 350 mg, and promethazine with codeine, and an overage of hydrocodone 10/325. Gov't Ex. 4, at 1; Tr. 157–59.

White testified that he also requested what he characterized as an annual inventory [36] from the Respondent during his first visit. Tr. 168. No annual inventory was produced and no one indicated to him what date they planned to conduct one. *Id.* White testified that the regulations require that an annual inventory be completed on May 1 of every year, but the regulations allow pharmacies the flexibility to choose their own date. *Id.* White testified that in practice, a majority of pharmacies take an annual inventory on May 1, but there are some exceptions. Tr. 170. Furthermore, like initial inventories, annual inventories require notarization within 72 hours of completion. Tr. 184. On cross-examination, White admitted that the pharmacy had only been open three or four months and that Respondent was not obligated to take the annual inventory on May 1. Tr. 196.

White discussed the audit results with Mr. Sanders and PIC Grape on July 31, 2012. Tr. 159. When White pointed out the discrepancies, Grape stated that he was surprised that the number was so high for hydrocodone 10/650. Tr. 160.

White then testified that he gave Mr. Sanders and PIC Grape two weeks to produce documents that could assist in accounting for the inconsistencies in the audit. Tr. 162. White advised that only authenticated documents, such as computer records from the pharmacy's software, would be helpful, and specifically informed Sanders and Grape that he could not accept an initial inventory at this point, in view of the fact that they had already told him that none had been prepared. Tr. 162, 197. White took all of the invoices obtained during the First DEA Visit with him at the conclusion of the audit. Tr. 197. Although White had afforded two weeks for the provision of additional documents, he waited for a total of four weeks before finalizing his audit, completing his case file and forwarding the file through his Texas Pharmacy Board channels. Tr. 163, 198, 202. No additional documents were provided by the Respondent. Tr. 198.

White returned to the Respondent pharmacy with DI Newkirk on May 22, 2012 (this event was previously described as the Second DEA Visit) to obtain samples of promethazine with codeine. Tr. 163. White's desire to take samples of promethazine with codeine was based on Ms. Tippie's representation that the pharmacy was diluting it. Tr. 164. White stated that during the Second DEA Visit, an inspector took approximately twelve samples and White helped the inspector send the samples to a laboratory for testing. Tr. 164–65. The results of the testing [37] indicated no dilution or adulteration. Tr. 192.[38] While the samples were collected, White testified that once again he observed unlabeled bottles of promethazine with codeine. Tr. 166. White pointed this fact out to PIC Grape, who insisted that, at least in his opinion, putting the manufacturer's bottle of promethazine with codeine in front of the other bottles on the shelf was sufficient identification of the contents of the unmarked bottles. *Id.* During the Second DEA Visit, White also noted ''[t]hey had done some cleaning, but still things were not that unchanged from the first visit.'' Tr. 170.

White testified that he met with Ms. Tippie on May 23, 2012 at a restaurant. Tr. 171. According to White, DIs Newkirk and Hull had already interviewed Ms. Tippie, but White arranged a meeting to obtain more information. *Id.* White confirmed that at the time this conversation took place, Ms. Tippie was no longer employed by the Respondent. Tr. 174. Tippie said that on numerous occasions she observed Mr. Sanders and his father (Mr. Sanders, Sr.) diluting bottles of promethazine with codeine by mixing seven ounces of promethazine with codeine with one ounce of regular promethazine; and that this dilution would typically be done in Mr. Sanders' office. Tr. 171–72. Ms. Tippie said that Mr. Sanders ''would do it full strength'' initially and then would start diluting it down to the point that customers started complaining. Tr. 172. Ms. Tippie told White that it got to the point that customers would ask to taste the promethazine with codeine before they bought it. *Id.* Eventually, employing a unique application of the *caveat emptor* principle, Mr. Sanders directed Ms. Tippie that she was not to allow customers to taste the promethazine with codeine before purchasing it. Tr. 173. White testified that Ms. Tippie told him there were times when the pharmacy would run out of promethazine syrup before the day was over. Tr. 173–74.

According to White, Ms. Tippie told him that the typical dilution routine involved diluting the mixture in Sanders' office as soon as it arrived at the Respondent pharmacy. Tr. 174. Ms. Tippie said that customers knew to come in the afternoon between 1:00 and 1:30 p.m. when the promethazine with codeine would be ready for dispensing. *Id.* White recalls Ms. Tippie saying that she confronted Sanders about the dilutions and that they ''got into some type of argument, which led to her leaving.'' Tr. 174–75.

White testified that Ms. Tippie told him there was also a ''suspicious . . . set of doctors'' that the Respondent pharmacy accepted prescriptions from. Tr. 176. Ms. Tippie said that it was her observation that these doctors would prescribe the same

the Respondent were received into evidence. Gov't Ex. 2; Tr. 211. The first form, dated April 25, 2012 (April 25, 2012 Form), identifies the Respondent as the registrant, and states the date of theft as April 24, 2012. Gov't Ex. 2, at 2. The Form identifies the filer as the owner of the pharmacy, Jesse Sanders. *Id.* It lists the following controlled substances as being stolen: (1) 10,000 tablets of hydrocodone/APAP 10–650; (2) 5,000 tablets of hydrocodone/APAP 10–500; (3) 5,000 tablets of carisoprodol 350 mg; (4) 10,000 tablets of hydrocodone/APAP 10–325; (5) 2,000 tablets of alprazolam 2 mg; and (6) 4,000 tablets of hydrocodone/APAP 10–325. *Id.* The second form, dated May 3, 2012 (May 3, 2012 Form), identifies the Respondent as the registrant, and states the date of theft as May 2, 2012. Gov't Ex. 2, at 3. The Form identifies the filer as the owner of the pharmacy, Jesse Sanders. *Id.* It lists the following controlled substances as being stolen: (1) 473 ml of promethazine-codeine syrup; (2) 1,000 tablets of hydrocodone/APAP 10–650; and (3) 500 tablets of hydrocodone/APAP 10–500. *Id.*

[34] Contrary to the assertion made in the Respondent's post-hearing brief, no video tapes regarding the purported burglary were offered or admitted into the record. Resp't Brief at 10.

[35] There is no portion of a DEA Form 106 that queries the preparer to note whether the numbers provided are estimates or the result of a particular metric or method of calculation.

[36] The Respondent pharmacy had not yet been open for a year.

[37] No lab reports were offered or admitted into the record.

[38] *See also* Tr. 95.

strength and quantity of pills to multiple patients. *Id.* White remembered Tippie saying that if an individual customer came in and did not agree with the strength or quantity of drug prescribed by one of these doctors, these doctors would easily approve an increase. *Id.* Tippie said that with some doctors, there was an understanding that it was acceptable for the Respondent to increase the dosage strength or quantity of the prescription, while other doctors required Tippie to contact them for approval. Tr. 177. On cross examination, White acknowledged that of the physicians referenced by Ms. Tippie, he was aware of only one, a Dr. Cruz, who had been the subject of professional discipline.[39] Tr. 193. White also testified that he discussed several customers with Ms. Tippie. Tr. 176–77. Tippie told White that a caller would phone the pharmacy and inquire about whether a multitude of prescriptions for multiple patients were ready for pick up. *Id.* Then, the controlled substances dispensed in the names of the multiple patients would be provided to a single individual who would arrive to retrieve them. Tr. 177.

White recalled a discussion with Ms. Tippie regarding the prices charged for promethazine at the Respondent pharmacy. Tr. 177–78. Ms. Tippie advised White that the Respondent was charging $400.00 for a pint of promethazine,[40] which, in White's experience, is many times higher than the price charged at a typical chain pharmacy, and is consistent, in White's experience, with the ''black market'' prices charged ''on the street,'' in Texas. Tr. 182–83. On cross examination, White testified that ''as far as [he is] aware,'' Respondent has continued to conduct business involving non-controlled substances after DEA suspended Respondent's controlled substances registration. Tr. 194.

Investigator White presented as an impartial investigator who tendered testimony that was sufficiently detailed, plausible, and internally consistent to be fully credited in this recommended decision.

The Government also presented the testimony of the Respondent's former Pharmacy Technician-in-Training, Heather Tippie. Tr. 213. Ms. Tippie testified that she graduated from Remington College, and that her major was in the pharmacy technician field.[41] Tr. 214–15. Tippie testified that she became registered as a pharmacy technician-in-training while enrolled at Remington. Tr. 215. She explained that ''[t]hey registered me right then about three months into the program as a tech-in-training.'' *Id.* Tippie clarified that this registration was with the State of Texas. *Id.*

Tippie testified that she worked at the Respondent pharmacy for ''three or four months'' as a pharmacy technician-in-training. *Id.* Ms. Tippie was unequivocal in her assertion that she never told Mr. Sanders that she was licensed. Tr. 233. Rather, Tippie stated that she told Mr. Sanders that she had taken her licensure test, but had not paid the $80 to have the ''tech[nician]-in-training'' title removed from her name. *Id.*

Tippie related that she initially learned of this position from her mother, who was working at a restaurant when she encountered Mr. Sanders and his father (Mr. Sanders, Sr.) as patrons. *Id.* Tippie's mother, upon overhearing the two Sanders discussing their business, seized upon the opportunity to solicit employment for her daughter, who had training in the pharmacy technician field. *Id.* For her efforts, Tippie's mother received a business card from Mr. Sanders, and following separate interviews with Mr. Sanders and his father, Ms. Tippie was ultimately rewarded with a position at the Respondent pharmacy. Tr. 213–14. Ms. Tippie acknowledged that personal health issues had resulted in roughly a year of unemployment prior to obtaining work at the Respondent pharmacy. Tr. 213–14, 233.

Ms. Tippie testified that while she was working at the Respondent pharmacy, she routinely dealt with several men she characterized as ''runners.'' Tr. 215. According to Tippie, these runners would ''come in several times throughout the week,'' and ''drop off multiple prescriptions, 5, 10, sometimes 20 prescriptions all at the same time.'' *Id.* Tippie said that the prescriptions were not for the runners themselves, but for other people. Tr. 216. Along with the prescriptions, the runners brought the drivers' licenses of the individuals whose names appeared on the scrips. *Id.* Tippie testified that these runners came into the pharmacy ''once or twice a week, on the upwards of five times a week.'' *Id.*

Tippie described her encounters with some of the runners in greater detail. One such runner, who called himself ''Mike,'' would frequently visit the pharmacy. Tr. 216–17. Tippie testified that on several occasions ''while I was outside smoking he would—we would talk, or in the pharmacy we would talk.'' Tr. 217. Tippie learned Mike's real name when Mike ''came into the pharmacy one day'' and confided to her ''that he had to actually see the doctor to get prescriptions for himself.'' *Id.* Mike told Tippie that his real name was ''Alfonso Jones,'' and presented his driver's license. *Id.* Tippie clarified that Mike told her that he ''had to see the doctor [himself] because [he] didn't have anybody else.'' Tr. 218. It was Ms. Tippie's opinion that Alfonso Jones, a/k/a ''Mike,'' is a drug dealer. *Id.* Her opinion was principally founded in a conversation between the two outside the pharmacy during a smoking break where he admitted as much. Tr. 219. During their conversation, Mike offered to Ms. Tippie ''that if I—if you ever need anything, you just let me know.'' *Id.* Mike also asked Ms. Tippie if she could ''slip him a couple extra'' pills when dispensing the drugs. *Id.* Ms. Tippie stated that she spoke several times with Mr. Sanders about her conversations with drug-dealer Mike. *Id.* Ms. Tippie testified that she told Mr. Sanders, ''that's what they're doing with the pills.'' *Id.* Ms. Tippie testified that Mr. Sanders responded, ''what they do outside once they leave the pharmacy, I can't do anything about it. It's none of my business.'' *Id.* Ms. Tippie said that PIC Grape was present ''[m]ost of the time'' when Mr. Sanders made these statements regarding the runners. *Id.* Ms. Tippie testified that she raised these concerns with Mr. Sanders every time the runners came in to the Respondent pharmacy, which was ''[f]ive times a week, just about every day that [Tippie] was there for three months.'' Tr. 220. Tippie testified that Mr. Sanders provided her with the same response each time she raised her concerns. *Id.*

Tippie also testified that she overheard a remarkable conversation between Mike and Mr. Sanders. The interaction, as described by Ms. Tippie, proceeded this way:

> Mike had come in one day, and I was making photocopies of the driver's licenses, and he had said, I don't need the non-controls, if you want to just keep them, and I'll pay for them, that's okay with me because I just end up throwing them away anyway. And I kind of looked at [Mr. Sanders] and [PIC Grape], and he was told by [Mr. Sanders] that he had to take them because it would mess up our inventory.

Tr. 220–21. Ms. Tippie testified that after Sanders explained to Mike that he would have to take the non-controlled substances so that there would be no inventory anomaly, none of the participants to the conversation had anything further to add on the matter. Tr. 222.

Ms. Tippie testified that she also encountered a two-man runner team who employed the monikers ''Jay'' and ''Uncle Bo.'' *Id.* Jay and Uncle Bo worked in tandem, with Uncle Bo dropping off the prescriptions and Jay picking up the filled prescriptions. *Id.* During her testimony, Ms. Tippie recounted how the enterprise, based in a Dallas homeless shelter, was explained to her by Uncle Bo and Jay:

> Uncle Bo said they were running a homeless shelter. Jay told me what they did is they take these people at this homeless shelter to the doctors, and they pay them to get their prescriptions, and then they bring their prescriptions to a pharmacy. . . . Jay and Uncle Bo pay for the prescriptions, and they keep them. They don't give them to the people that are actually going to the doctor.

Tr. 222–23.

Ms. Tippie testified that she approached Mr. Sanders and told him, ''you know, you know what they're doing with these. They're distributing them themselves out on the street.'' *Id.* Ms. Tippie recalled that Mr. Sanders replied, ''what they do is none of my business.'' *Id.* Ms. Tippie stated that PIC Grape overheard these conversations with Mr. Sanders. Tr. 223–24.

Ms. Tippie stated that Jay and Uncle Bo were not the only runners who used the address of the Dallas homeless shelter to fill prescriptions. Tr. 224, 231. Sometimes Mike would use the address, as would another runner, who referred to himself as ''Wendell.'' Tr. 224. Ms. Tippie said that Wendell came in to the Respondent pharmacy, and ''explained that he was running this homeless shelter along with

[39] During his testimony, Mr. Sanders stated that the Respondent pharmacy did not fill prescriptions for Dr. Cruz ''because more or less even if we hear of any bad reputations of medical doctors, we decide not to fill those prescriptions.'' Tr. 281.

[40] Tr. 178.

[41] Tippie testified that a college degree is not required to become a certified pharmacy technician-in-training in Texas. Tr. 214.

Uncle Bo.'' *Id.* Ms. Tippie testified Wendell would not deal with her, but ''would always ask for [Mr. Sanders or Mr. Sanders, Sr.]'' Tr. 224–25. Ms. Tippie estimated that ''a couple hundred [prescriptions] I guess'' came from the homeless shelter, and testified that she specifically raised her concerns about the common address of so many prescriptions with Mr. Sanders. Tr. 231.

Ms. Tippie also testified that she also dealt with a runner who referred to himself as ''Polo.'' Tr. 225. Ms. Tippie said that Polo would bring in several prescriptions for other people and carried large quantities of cash. *Id.* Ms. Tippie stated that Polo ''made it very well-known that he had 2—, 3—, $4,000 on him at a time,'' and usually sought Xanax, hydrocodone, and promethazine with codeine. Tr. 225–26.

Ms. Tippie testified that while working at the Respondent pharmacy she also grew suspicious of some prescribing physicians. For example, the pharmacy frequently filled prescriptions from a physician named Dr. Vandervoot.[42] Tr. 234. Ms. Tippie testified Dr. Vandervoot was prescribing to Mike, as well as to other runners. *Id.* In addition, Tippie said she filled prescriptions from a practitioner named Dr. Okechku [43] and also the U.S. Physicians Group. Tr. 235. Ms. Tippie testified that the runners dropped off prescriptions written by these physicians and the prescriptions were written for Xanax,[44] hydrocodone, and promethazine with codeine. Tr. 226, 239. According to Ms. Tippie, the runners paid for these prescriptions in cash; never by credit card. Tr. 226.

In response to a question on cross-examination, Ms. Tippie testified that it was her understanding that as a licensed pharmacy technician-in-training, she bore a legal responsibility similar to a pharmacist to dispense only prescriptions written for a legitimate medical purpose. Tr. 236.[45] Ms. Tippie testified that she ''called Dr. Vandervoot's office at the beginning to make sure that the prescriptions were a legitimate prescription.'' *Id.* Ms. Tippie said PIC Grape was present for this call because she was challenging a prescription written for Xanax and hydrocodone. Tr. 237. Ms. Tippie testified that she went through a similar process with prescriptions for Dr. Okechku, since his prescriptions were also for large amounts of controlled substances. *Id.*

Ms. Tippie also testified that she witnessed the dilution of promethazine with codeine at the Respondent pharmacy. *Id.;* Gov't Ex. 5.[46] Ms. Tippie testified that she observed Mr. Sanders and/or his father funneling pure promethazine into a promethazine with codeine mixture, and that this took place in Sanders' office or in the back room of the pharmacy. Gov't Ex. 5; Tr. 226. Ms. Tippie testified that when she asked the pair why the syrup was being diluted, ''[t]hey said that it was cost effective because the promethazine with codeine was so expensive for a pint bottle.'' Tr. 227.

According to Ms. Tippie, the dilutions she observed occurred before the First DEA Visit on May 8, 2012, but not after that date. Tr. 226. Ms. Tippie testified that things changed because Mr. Sanders ''seemed a little bit worried, nervous about it.'' Tr. 226. Interestingly, although Mr. Sanders appeared concerned, his father, Sanders, Sr., according to Ms. Tippie, ''acted like it was no big deal. He said that they're just trying to scare us, that they don't have anything against us.'' Tr. 227.

Ms. Tippie testified that on the Friday following the First DEA Visit, after working for Top RX for three months, she quit. Tr. 228, 237. Ms. Tippie recalled telling PIC Grape before she left, ''what they're doing is wrong, and you know it as well as I do.'' *Id.* Ms. Tippie testified that PIC Grape answered ''best of luck, and you know, you got to do what you got to do.'' *Id.* Ms. Tippie then informed Mr. Sanders that she was leaving because ''ethically'' she could not stay at the pharmacy. *Id.* Ms. Tippie testified that Mr. Sanders asked her why she was quitting and why she felt she could no longer work at his pharmacy. *Id.* Ms. Tippie also testified that she talked with Mr. Sanders, Sr. that day as well. Tr. 229. Before Ms. Tippie left the pharmacy that day, Mr. Sanders (who had listened to her explain her reasons for leaving) paid her in cash for the hours she had worked. *Id.* On cross examination, Ms. Tippie stated that on the day she left the Respondent's employ, she was neither disgruntled, nor complaining, and had not been fired. Tr. 237. Ms. Tippie unequivocally declared that she had not been fired from the pharmacy, and denied ever receiving any documentation to the contrary. Tr. 228–29.

Ms. Tippie met with a DEA investigator on May 23, 2012. *Id.* Ms. Tippie admitted that initially she was concerned about having a disciplinary action initiated against her license, but explained that she is no longer concerned since she now understands that she ''didn't do anything wrong'' and that she ''was working under the supervision of a pharmacist as a tech[nician]-in-training.'' Tr. 238. Ms. Tippie testified that she has never been promised anything in exchange for her cooperation with the Texas Pharmacy Board. *Id.* Ms. Tippie no longer works as a pharmacy technician-in-training and instead, is employed as a live-in caregiver. Tr. 233.

The testimony presented by Pharmacy Technician-in-Training, Heather Tippie, was not without some causes for caution. Even by her own account, Ms. Tippie was well aware of ongoing activity that made her sufficiently alarmed that she raised her concerns with her PIC and her employer. Yet she continued to perform her part in the dance. She knew Mike was a drug dealer because he told her so, and had actual knowledge that the dangerous drugs she was doling out to drug-dealer-runners were never destined to reach the patients named in the scrips and the labels on the bottles. It is not unreasonable to extrapolate that had the Respondent not been visited by the authorities on the First DEA Visit, that Ms. Tippie would, even now, be blithely shelling out copious amounts of dangerous narcotics into the hands of those who brazenly sold them for profit. Ms. Tippie cannot fairly be described as an innocent bystander who fled to the authorities at the first sign of impropriety. The credible evidence of record supports the proposition that she cooperated with DEA because she felt she got caught. That said, the record contains scant bases for her to embellish her testimony. Although Investigator White testified that the Texas Pharmacy Board investigation concerning the Respondent pharmacy is still an open matter,[47] he also acknowledged that there is currently no case currently pending against Ms. Tippie.[48] Furthermore, the Texas Code that circumscribes the duties and responsibilities of a pharmacy technician-in-training virtually insulates her from judgment calls related to the dispensing of prescriptions. 22 Tex. Admin. Code § 291.32(d). Ms. Tippie's testimony that she has been offered no

[42] Ms. Tippie testified that while Mike brought prescriptions exclusively from Dr. Vandervoot's office, other runners, such as Polo, Jay, and Uncle Bo, also presented prescriptions from Dr. Vandervoot and other physicians to the pharmacy. Tr. 233–35.

[43] Ms. Tippie testified that Jay and Uncle Bo brought prescriptions from the offices of Dr. Okechku and Dr. Vandervoot. Tr. 234–35.

[44] Xanax is the brand name of a drug containing alprazolam. 6–X Attorneys' Dictionary of Medicine X–125138. Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1).

[45] *But see* 22 Tex. Admin. Code § 291.32(d) (2012). This Texas Administrative Code section on ''Personnel'' indicates that ''[p]harmacy technicians and pharmacy technician trainees may perform only *nonjudgmental* technical duties associated with the preparation and distribution of prescription drugs.'' *Id.* § 291.32(d)(2)(C) (emphasis added). They ''may not perform any of the duties listed'' under the duties of a pharmacist, which most notably includes ''interpreting prescription drug orders.'' *Id.* § 291.32(d)(2)(A), (c)(2)(B). Thus, Texas law insulates pharmacy technicians in training from the sort of judgment calls Ms. Tippie referenced in her testimony, which would have required her to determine whether a prescription had been written for a legitimate medical purpose.

[46] The handwritten statement by Heather Tippie, dated May 23, 2012, was later received into the record as Government Exhibit 5. Tr. 301. In it, she stated that Mr. Sanders and Mr. Sanders, Sr. ''has [sic] mixed promethazine w/codine [sic] with regular promethazine many times.'' Gov't Ex. 5, at 1. She said that Sanders and Sanders, Sr. mixed ''one (1) ounce of promethazine with no codine [sic] . . . with seven (7) ounces of promethazine with codine [sic].'' *Id.* Tippie's statement also asserts that she had been working at the Respondent pharmacy since February, and she ''quickly learned that there is a relationship between [Sanders and Sanders, Sr.] and the staff at [D]r[. C]apastrano['s] office.'' *Id.* Tippie also testified that the controlled substance prescriptions from each of these three practitioners fell into its own definable pattern. *Id.* at 1–2. If the patients came from ''Dr Vanderoots office they usually wrote for (120) one hundred and twenty of the pain meds and sixty (60) of the two (2) milligram Xanax. If the script came from Capistranos office (80) eighty Soma eighty (80) or ninety (90) pain meds and thirty (30) Xanax.'' *Id.* at 1. If the patient came from ''Okechuku, the prescription is usually wrote [sic] for one hundred and fourty [sic] (140) or one hundred and fifty (150) pain pills and 30 (thirty) flexerel.'' *Id.* at 2. Although the Government introduced this evidence, it presented no argument relative to the significance to be attached to these numbers.

[47] The representation in the Respondent's post-hearing brief that ''[Investigator] White confirmed . . . that there was no pending or planned disciplinary action against the Respondent by the [Texas Pharmacy Board]'' is not accurate. Resp't Brief at 8. Investigator White stated that the ''case is still open . . . '' Tr. 191.

[48] Tr. 191.

consideration for her cooperation [49] stands unchallenged and unrefuted. When pressed on the issue, Tippie stated that while she was initially fearful of the status of her state license, she is no longer concerned ''[b]ecause I know that I didn't do anything wrong. I was working under the supervision of a pharmacist as a tech[nician]-in-training.'' Tr. 238. Ms. Tippie is not a DEA registrant, and in view of the State of Texas law regarding her responsibilities and obligations as a pharmacy technician-in-training, her potential exposure to discipline at the hands of the Texas Board, at least on this record, appears minimal to nonexistent.[50] Based on her subjective understanding of her potential disciplinary exposure, which is consistent with the state of the law, it would be difficult to conjure up a persuasive motive for her to fabricate testimony against the Respondent, its owner, and its PIC. Accordingly, notwithstanding its shortcomings, Ms. Tippie's hearing testimony was sufficiently detailed, consistent, and plausible to be deemed credible in this recommended decision.

The Respondent's Evidence

In support of its case on the merits, the Respondent presented the testimony of PIC Grape and Mr. Sanders. PIC Grape testified that he earned his Bachelor of Science degree in pharmacy from the Texas Southern School of Pharmacy, located in Houston, Texas, in 1963. Tr. 242–43. He testified that he has been registered as a licensed pharmacist since 1963. Tr. 243. Although he was either unwilling or unable to provide much detail on the early phases of his pharmacist career,[51] PIC Grape testified that he was the owner of a ''medicine shop'' in Fort Worth, Texas from 1992 to 2000, and that he retired from a Walgreens pharmacy after ten years of employment there. Tr. 254. Grape testified that following his retirement in 2010, he has filled in ''as needed'' as a pharmacist at Sam Healthcare Pharmacy in Arlington for two years. Tr. 252.

Grape admitted that during his career he had sustained a single disciplinary action against his license to practice pharmacy in 2008. Tr. 244–45. The action arose when he simultaneously dispensed medications that, if taken together, would have caused an ''adverse reaction.'' *Id.* Grape testified ''[i]t was prescription that had anti-gout with an anti-fungus medication.'' Tr. 245. According to PIC Grape, the patient never ingested the medications and the Texas Pharmacy Board resolved the action by assessing a $1,000.00 fine against his license. *Id.* PIC Grape testified that his state pharmacy license is presently active and unrestricted, and that he has never been arrested, charged, or convicted of any crime. Tr. 245–46.

When Respondent's counsel expanded questioning of the direct testimony to topics of continuing education and regulations, PIC Grape became increasingly difficult to understand. Although, at the outset of his testimony, Grape indicated that he is difficult to understand due to a diagnosis of sleep apnea,[52] his demeanor presented less as sleepy than it did as profoundly confused, and his testimony was punctuated with long pauses. While some testimony was elicited from the witness regarding some continuing education classes he participated in, this was done with the highest degree of leading questions. Tr. 246, 249–50. Other than answering in the affirmative when asked if he took courses that were named in various documents he did not prepare and which were never offered into evidence, PIC Grape gave no indication that he possessed the capacity to explain any content from any of the classes he was asked about. Tr. 246–47, 249–50. The most Grape could contribute through his testimony was a simple ''yes'' in response to a series of leading questions, which included ''[i]s this a certification that you took a class called ''Update on Federal Controlled Substances,'' ''[d]id you take that class,'' ''[d]id you complete it,'' ''did you get credit for it,'' ''[i]s this a certificate that shows that you've complied and got credit for that?'' Tr. 250. However, as this line of questioning progressed, PIC Grape agreed with the suggestions of the Respondent's counsel that he participated in courses entitled ''Pharmacist's Special Knowledge,'' ''Update on Federal Controlled Substances,'' and ''Prescription Errors and Their Legal Consequences.'' Tr. 249–50.

Notwithstanding the length of his experience as a pharmacist, the force of PIC Grape's testimony was significantly undermined when he struggled to testify about the requirements for issuing a valid prescription. PIC Grape seemed abjectly unable to focus. The following colloquy between PIC Grape and the Respondent's counsel is illustrative:

Q As being a pharmacist licensed by the state of Texas, are you familiar with what's required in order to have a valid prescription?

A Yes.

Q What is that?

A You file the written prescription in one blank—I mean one folder, and your control in another folder, and at that time the class two folder you file that one in that, so you had three different folders to file the prescription.

Tr. 255. PIC Grape, a pharmacist with decades of experience in the field, in an ultimately fruitless effort to clarify his answer on the subject, then offered the following:

Oh, issuing a valid prescription? I apologize. A valid prescription would have the patient name, address, the name of the medication with a strength. You have the—whether a tablet or capsule, the quantity, and if it was a regular prescription—will, in a controlled prescription you have the DE number, the doctor's DE number with some type of—you can qualify some relation with the doctor to this patient, you know. That's what I did.

Id. Suffice it to say, that in all of this, there was no reference made to any requirement set forth in federal or state regulations. *See* 21 C.F.R. § 1306.04.

Since PIC Grape's unintelligible answer did contain the words ''doctor,'' ''relation,'' and ''patient,'' he was invited to clarify that part of his response. This effort was similarly unrewarding. In response to this entreaty, PIC Grape testified ''[t]he patient or the—I mean the doctor know[s] his patient, and then he prescribe[s] medication according to his diagnosis or what he want[s] to give it for, that particular ailment.'' Tr. 255–56. To add additional discomfiture to an already disquieting dynamic, when asked to repeat his answer, PIC Grape responded as follows:

The doctor relation with the patient is—he will prescribe medication that dictate[s] what he want[s] to give to the patient because the relationship is not just the patient, and either element he's think he will prescribe the medication for.

Tr. 256. Grape then added:

Well, the patient and the doctor—the doctor is familiar with his patient. I'm trying to think of a term they use. But the two, the doctor know[s] his patient, and the patient know[s] the doctor, but the doctor know[s] the patient because he is prescribing medication for him.

Tr. 257. These statements indicate no understanding of any of the elements of what a pharmacist might be looking for in evaluating whether a particular controlled substance prescription reflects a valid physician-patient relationship, apart from a generalized feeling that PIC Grape appears generally to be in favor of such a relationship.

In response to a direct question from the Respondent's counsel, Grape agreed that he has declined to fill a prescription in the past when he was ''unsure about—I was uneasy about the client or especially if I can't get in touch with the doctor to verify the prescription.'' *Id.* Grape explained his recollection of the prescription he turned down this way:

It's something about the signature, mainly the signature, and the patient, the way I feel about the patient, whether I feel something is illegal or something, the reason why they have the prescription.

Id.

Grape further testified in barely audible phrases that he would contact a doctor before making a decision about whether a prescription is valid, saying he would check ''if that's what he [the doctor] want[s], or did he write the prescription, or thing of that nature [sic].'' Tr. 258. When asked whether he would confirm that the patient is actually a patient of the doctor, Grape said incoherently:

It depend[s]. I talked with them about it, but mainly if you think it's the wrong prescription, maybe you go to the phone and check the patient who knew, get out of the store place, you know, going to give you a chance. But if you have no chance, and you can't get in touch with the doctor, I just tell the patients I need to contact the doctor so I can verify the—I'll say, I'll give any answer

[49] Tr. 238.

[50] The multiple representations in the Respondent's post-hearing brief that Investigator White ''confirmed that a disciplinary action was pending against Heather Tippie's Pharmacy Tech license [sic]'' is simply contrary to the evidence of record. Resp't Brief at 9–10.

[51] Tr. 253–54.

[52] Tr. 240.

like I want to check something with the doctor before I can fill it.

Id.

When asked ''how [he] might identify evidence of diversion,'' a truly bedrock competence inquiry at this level, and presumably a topic that would have been covered in at least one of the recent continuing education courses supposedly completed, he offered the following:

Sometime[s] you can tell by the way the prescription is written, if it's written a certain way, the direction is written a certain way. And that way I normally pick them up. Then I'll sit with the patient, you know, observe the patient. And then that's the way I know to check it, the prescription, especially if it's out of, say the metro area while I'm working in Fort Worth, if out of town or something like that, or another state, that way I would recognize it.

Tr. 258–59.

Since the witness was generally unable to clearly articulate the key elements of specific federal or state regulations that apply to pharmacies or pharmacists, the Respondent's counsel attempted to demonstrate that Grape at least knew where to look up the information that he was unable produce from memory. Tr. 259. However, even this attempted line of questioning proved futile. When asked by Respondent's counsel where he could find rules and regulations concerning the practice of pharmacy, Grape responded, ''the Texas law book.'' *Id.* This ended the witness's direct testimony and the Government declined the opportunity to cross-examine him. Tr. 259–60. PIC Grape concluded his testimony by saying, ''Okay. And I apologize for not understanding.'' Tr. 261.

PIC Grape's testimony, to the extent it was not undermined by excessive leading on the part of the Respondent's counsel, was largely incoherent. To the extent that PIC Grape did understand the rudimentary questions he was asked, he was unable or unwilling to convey answers in a way that provided any level of confidence in his competence as a pharmacist. While there is no way from the record to discern the extent to which Grape's communication issues were genuine or contrived, it is worthy of note that none of the witnesses who testified about prior conversations with PIC Grape, indicated that communication with him was as problematic as it was when he took the stand. *See, e.g.,* Tr. 18, 24, 36, 60 (Investigator Pinkerton), 70, 72, 86, 100 (DI Newkirk), 128–29, 131, 135, 155, 159–60, 162–63, 166, 197 (Investigator White), 219, 228, (Ms. Tippie), 271–72, 282–83, 288–89, (Mr. Sanders). After PIC Grape's testimony, Sanders noted a respiratory ailment that required hospitalization about a month prior to the hearing,[53] described Grape as ''a little nervous'' and offered the modest observation that ''sometimes his speech is kind of hard to understand.'' Tr. 264. Irrespective of the origins of deficits in communication and understanding, it is undisputed that this witness was unable to articulate virtually anything helpful about the scrutiny he applies to executing his duties as a pharmacist on behalf of a DEA registrant. Either PIC Grape was feigning impairment, a behavior which would eviscerate his credibility, or he was genuinely bereft of any ability to relate his obligations as a pharmacist. In either event, his testimony did little, if anything to advance the Respondent's position, and if anything, was supportive of the revocation sought by the Government.

The Respondent also presented the testimony of its owner, Mr. Sanders. Mr. Sanders testified that he is not a pharmacist, but rather a licensed insurance broker with a bachelor's degree in finance and marketing and a master's degree in finance from the University of North Texas. Tr. 262. After his graduation in 2003, he worked as a mortgage broker at AmeriQuest Mortgage and a senior account executive at Century Payments. *Id.* Sanders emphasized on several occasions throughout his testimony that he has never been trained in the practice of pharmacy and that he is not a licensed pharmacist. Tr. 263, 268, 270, 273. When asked about his ''role as the owner of the [Respondent] pharmacy,'' Mr. Sanders explained ''I do the marketing, trying to find—you know, get business in, hiring and firing'' and that he had no ''intent to manage'' the ''day-to-day operations.'' Tr. 265. In response to a question, Mr. Sanders testified that his ''business plan,'' was to hire experienced staff to run the business, such as PIC Grape. Tr. 265–66.

Mr. Sanders testified that the Respondent pharmacy was issued a DEA COR on February 2, 2012. Tr. 267.[54] According to Sanders, when the pharmacy first opened it had no controlled substances on hand. Tr. 267–68. Mr. Sanders's recollections regarding the status of the initial inventory issue is at some variance with the accounts of all the investigators who testified. As discussed, *supra,* Investigator Pinkerton testified that he asked Mr. Sanders and PIC Grape about an initial inventory and was told by the two men that they were unaware of the need to create such a document. Tr. 23–34. Investigator White recalled asking Mr. Sanders about an initial inventory during the First DEA Visit and being told by Mr. Sanders that one had never been generated. Tr. 134–35. DI Newkirk testified that, although he explained the requirement of preparing an initial inventory to Sanders and PIC Grape during DEA Visit 1, during DEA Visit 2, Sanders conceded that he had not yet prepared one. Tr. 92. Mr. Sanders, however, testified that an initial inventory had indeed been prepared, that the number on board had been recorded as zero, and that the document had been stored in the pharmacy's safe. Tr. 268, 271–72, 293–94. When asked ''Did you tell either Mr. White or Mr. Pinkerton or Mr. Newkirk that you had [the initial inventory] in the safe?'' Mr. Sanders replied:

More or less . . . I wasn't exactly, you know, sure about [the] beginning inventory. I wasn't a licensed pharmacist. I know one was done, but in regards to the day-to-day operations, where all the—everything was held, I wasn't 100 percent aware.

Tr. 268. When asked why a document reflecting an initial inventory was not provided to inspectors, Mr. Sanders attributed the misstep to ''organizational issues'' and Ms. Tippie, explaining that ''anything regarding to [sic] inventories and invoices Heather Tippie mostly took care of that.'' Tr. 270. Sanders also testified that the investigators asked him questions, but he could not help them since he is ''not a pharmacist'' and only ''do[es] the marketing.'' *Id.* Mr. Sanders also allowed that he ''might have actually misunderstood, the investigator, where they are wanting [sic] to see some documentation of controls when we first opened, when we had indeed one.'' Tr. 272. Mr. Sanders explained that to the extent that Ms. Tippie was not responsible, the fault lied with PIC Grape:

In regards to like the beginning inventory and what is required, see, I wasn't exactly sure. Learning the fact that it was done after the fact—like I said, I didn't do it. I'm not the licensed pharmacist—that it was actually done. But initially, I wasn't—like I said, I was—I didn't do the beginning inventory, so I wasn't 100 percent aware of all of the logistical paperwork where it all—that's why I hired [Grape] as well as Heather Tippie, where they can maintain that.

Tr. 272–73.

Although Mr. Sanders testified that he spoke with his pharmacist-father, Mr. Sanders, Sr., who served as a consultant for the Respondent pharmacy,[55] about the matters raised during the visits and investigations, and he knew that multiple authorities were looking for an initial inventory, he stated that he never asked his father for advice on this point. Tr. 274.

Even setting aside issues as to whether an initial inventory of controlled substances that complied with DEA regulations was ever prepared, Mr. Sanders testified that it is his understanding that an initial inventory (such as the one purportedly in the Top RX safe and never presented to the investigators) should be prepared before controlled substances are brought into a pharmacy, and should reflect zero substances. Tr. 268–69. This (incorrect) belief about the nature of the initial inventory required by DEA regulations persisted even to near the close of the hearing. Tr. 294–96. Sanders explained that the reason for this supposition is founded in his assessment that his pharmacy is ''not like a large wholesaler like—large pharmacy like Walgreens or these larger places where they have a wholesaler.'' Tr. 269. According to Sanders:

Being a smaller wholesaler, we had to call a lot of different wholesalers to either—we didn't meet their criteria. A lot of them wanted us to do a [$]50– to $60,000 opening order. So we didn't have any beginning inventory, so we sent the form in. We did a beginning inventory of zero, and we notated that, where it took us a week to two weeks to start actually getting [controlled substances] in.

Id. During his testimony, Mr. Sanders never explained where he ''sent the form in''

[53] Tr. 287.

[54] Sanders initially said that he obtained the DEA COR on the same day that the pharmacy opened for business, which he indicated was February 6, 2012, but corrected to February 2, 2012, when prompted by the Respondent's counsel. Tr. 267.

[55] Tr. 90.

to, why he and PIC Grape repeatedly told the investigators seeking the document that no initial inventory had been generated, why he was unable to produce the form (whatever it was) to the investigators, or why the initial inventory requirements under federal or state law were somehow dependent on the size of a pharmacy. *Id.*

Mr. Sanders, who testified that he attended a single day of a two-day conference about diversion in Houston, Texas with Grape approximately three weeks prior to the hearing,[56] provided some testimony regarding his knowledge of some controlled substance dispensing prerequisites. He stated that in order to dispense a controlled substance, there must be a ''doctor-patient relationship'' and a ''legitimate medical purpose.'' Tr. 275. After some level of prompting, he explained that ''[i]f you have any question [sic], you would need to call a doctor or a staff to verify the prescription. You also need to verify DEA, DPS. Also, we also on all of our issuings [sic], if we have a new doctor that sends us prescriptions, we do a site visit . . . .'' Tr. 275–76. When asked about record-keeping regulations, Sanders said a pharmacy is ''[r]equired to keep [its] inventory separated with controls and non-controls for the course of two years.'' Tr. 276.

When asked to detail some signs of potential diversion, Mr. Sanders provided the following:

If a prescription is coming from a city 2- or 300 miles away, I believe that's a sign of diversion. If the prescription doesn't have the same signature—I guess the doctor doesn't have the same signature, it's not consistent, or the DEA isn't matching up, or I don't know.

Tr. 279–80. Focusing in on signature anomalies, Sanders explained that ''there's been situations . . . where doctors have got their scrip[] pads stolen, where if it's not a consistent signature, if a doctor usually signed his name on a scrip[], and someone actually writes it in English or regular letters, that's a sign of diversion.'' Tr. 281. When asked to describe additional signs of diversion, Sanders restated the geographic considerations he previously explained, and added ''[i]f you feel like you know, more or less it's not for a legitimate purpose, that could be a sign of diversion.'' *Id.* In explaining how he would determine that a prescription was not for a legitimate purpose, Mr. Sanders stated:

I don't know. I wouldn't make that decision, honestly. You know, if something was ever brought to my attention, I would ask [PIC Grape] regarding it. But I wouldn't, you know, for a legitimate purpose—like I know for a fact that when I looked at the prescriptions that I know [PIC Grape] would look at it where if it didn't have a PRN pain or PRN, you know, muscle spasms, if it didn't have a diagnosis on most of the prescriptions, he didn't feel comfortable filling that prescription.

Tr. 282. When invited to supplement his answer with any additional reasons he could think of that should result in refusing to fill a prescription, Mr. Sanders added:

And the patient doesn't have a legitimate doctor-patient relationship, and it's not for—let me see. If you suspect—I don't know any other reasons.

Id.

Mr. Sanders disavowed any knowledge of the runners described by Ms. Tippie. Tr. 280, 296. Further, Sanders did not even include drug dealer-runners presenting multiple prescriptions among the factors which would justify a refusal to dispense controlled substances. *Id.* According to Sanders, Ms. Tippie is a disgruntled employee and her testimony about the runners she dealt with at the pharmacy was merely a fabrication. Tr. 296. Although Mr. Sanders testified that he terminated Ms. Tippie for ''[i]ncompetence [and] laziness,'' ''talking to customers outside on a regular basis,'' and because ''she misrepresented herself as being a licensed pharmacy tech[nician],'' [57] no paperwork to corroborate any of these claims was received (or even offered) into evidence. When asked if such paperwork exists, Mr. Sanders said that there ''[p]ossibly'' was such paperwork ''at the pharmacy.'' Tr. 297. Mr. Sanders's contention that Ms. Tippie misrepresented her status as a pharmacy technician-in-training is belied by the credible testimony of DI Newkirk, who observed Ms. Tippie's pharmacy technician-*in-training* certificate on the wall of the Respondent pharmacy. Tr. 107.

In similar fashion, Ms. Tippie's testimony regarding the diluting of promethazine with codeine was met by Mr. Sanders with a flat, unembellished denial. Tr. 264. When asked about various doctors whose prescriptions were filled at Top RX, Sanders responded that he had heard of and filled prescriptions for Dr. Vandervoot, but was confident that that the Respondent pharmacy had not filled prescriptions for Dr. Cruz because the pharmacy did not fill prescriptions written by doctors with ''bad reputations.'' Tr. 280, 281.

Regarding the shortages and overages described by the investigators who testified, Sanders offered that ''[w]e were a fairly new pharmacy, and we had overstock of alprazolam and some boxes close to the back.'' Tr. 285; Gov't Ex. 3. When asked to explain how it happened that the pharmacy came upon more alprazolam ''in a box in the back with overstock'' that Sanders was unaware of until after the First DPS Audit with Investigator Pinkerton, Sanders again placed the blame on the Pharmacy Technician-in-Training Tippie. Mr. Sanders explained that ''[m]ore of the questions that Pinkerton—he was doing a lot of the questions towards Heather Tippie and regarding, you know, getting stock, counting drugs, and so she must have missed that.'' Tr. 286, 290.

Mr. Sanders also testified that the Respondent pharmacy was victimized by two burglaries, and that he completed and submitted DEA Forms 106 documenting the events. Tr. 288. According to the information on the forms, the Respondent pharmacy reported burglaries occurring on April 24 and May 2, 2012. Gov't Ex. 2. The burglaries were thus reported to have occurred after the two DPS Audits, but before the First DEA Visit. Mr. Sanders acknowledged that he was unsure of the amounts of controlled substances reported as missing in the two DEA Forms 106, and conceded that he did not indicate that the amounts reported were estimates.[58] Tr. 289–90. Mr. Sanders explained that he and PIC Grape analyzed surveillance videos and the amount of drugs they felt were on board at the time the break-in occurred when making these estimates. Tr. 288–89. To explain how these amounts were distilled into the forms, Mr. Sanders placed the responsibility on the shoulders of PIC Grape. According to Mr. Sanders, Grape was his only source of advice on the matter of completing the DEA Forms 106. Tr. 289.

Suffice to say that during his testimony, Mr. Sanders did not excel in the area of accepting responsibility for the actions of his pharmacy. In addition to exhibiting a consistent pattern of blaming his then-pharmacy technician-in-training and his PIC at the hearing, when asked what, if any part of the pharmacy's shortcomings are his responsibility, Sanders had this to say: ''I'm responsible to the fact [sic] where if I see some issues, I should *probably* take action, maybe get new people.'' Tr. 273 (emphasis supplied).

On the issue of whether remedial steps have been taken to guard against reoccurrence of any established deficiencies, Mr. Sanders testified that the Respondent pharmacy has now purchased new inventory management software, which ''is a system where we will track any incoming inventory we have coming in verifying the lot number, NDC.'' [59] Tr. 277. Sanders indicated that there has been a marked improvement ''regarding where paperwork is stored, the cleanliness, [and] documentation.'' Tr. 273. Sanders also expressed a future intention to conduct site visits on the physicians who write controlled substance prescriptions handled by the pharmacy. Tr. 299. Furthermore, Sanders testified that the Respondent pharmacy will be more compliant in the future because he has replaced his pharmacy technician-in-training with a new, superior employee. Tr. 293. Inasmuch as Mr. Sanders has provided his testimonial assurance that PIC Grape ''has been a great pharmacist,'' [60] it is difficult to deem his representation that the Respondent pharmacy is in the process of recruiting a new pharmacist in charge, as a plan of remedial action. Tr. 287, 298. Stated differently, if his PIC has been a ''great pharmacist,'' then no cognizable remedial benefit to past regulatory deficiencies would be accrued by replacing him.

The testimony of Mr. Sanders cannot be considered entirely credible. It makes little sense for Sanders to at once vouch for the skill and ability of PIC Grape while presenting his poor advice and incompetence as excuses for violations of the duties

[56] Tr. 283.

[57] Tr. 266.

[58] As discussed, *supra,* the Form 106 does not contain a query related to whether the loss amounts are estimates, or any place to designate the manner in which the losses are calculated.

[59] Since the DEA imposed the OSC/ISO that is the subject of these proceedings, the system remains in use for non-controlled substances. Tr. 278.

[60] Tr. 298.

required by the DEA registration and simultaneously offering up the recruitment of a new PIC a remedial step. Likewise, Sanders' testimony that Ms. Tippie was terminated without offering a shred of documentation to corroborate that action, profoundly undermines its reliability, and lends support to her version—that she walked out of her own volition from fear of the misconduct that permeated the establishment. Further, it was ludicrous and incredible for Mr. Sanders to maintain that he had been somehow duped by Ms. Tippie into believing that she was a licensed pharmacy technician (not a pharmacy technician-in-training) when her certificate reflecting her status was hanging on the wall of the Respondent pharmacy on the day that DI Newkirk conducted the First DEA Visit. Tr. 107. Similarly, Sanders' statements that he was not aware that an initial inventory was required (because he is not a trained pharmacist), stands in sharp contrast with his more recent insistence that such an inventory (reflecting zero controlled substances) was timely generated and lies undisturbed in his safe. Additionally, when asked to furnish details about important issues, Sanders offered marginally responsive testimony. In short, even apart from the reality that Mr. Sanders, as the owner of the Respondent pharmacy, had the most at stake in these proceedings, his testimony was not sufficiently consistent, detailed, or plausible to be afforded full credit in this recommended decision. Accordingly to the extent that Mr. Sanders' testimony conflicts with other credible evidence of record, it will not be afforded controlling weight.

The Analysis

Pursuant to 21 U.S.C. § 824(a)(4) (2006), the Administrator[61] is permitted to revoke a COR if persuaded that the registrant ''has committed such acts as would render . . . registration under section 823 . . . inconsistent with the public interest. . . .'' 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 [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

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

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

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

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

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 Fed. Reg. 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 a registration should be revoked. *Morall v. DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs,* 53 Fed. Reg. 43945, 43947 (1988); *David E. Trawick, D.D.S.,* 53 Fed. Reg. 5326, 5327 (1988); *see also Joy's Ideas,* 70 Fed. Reg. 33195, 33197 (2005); *David H. Gillis, M.D.,* 58 Fed. Reg. 37507, 37508 (1993); *Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16422, 16424 (1989). Moreover, the Administrator is ''not required to make findings as to all of the factors . . . .'' *Hoxie v. DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173–74. The Administrator 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) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and 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, M.D.,* 74 Fed. Reg. 459, 462 (2009).

In an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 C.F.R. § 1301.44(e). The Government may sustain its burden by showing that the Respondent has committed acts inconsistent with the public interest. *Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8235–36 (2010). Once DEA has made its *prima facie* case for revocation of the registrant's COR, the burden of production then shifts to the respondent to present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23848, 23853 (2007); *Morall,* 412 F.3d at 174; *Humphreys v. DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 Fed. Reg. 72311, 72312 (1980). ''[T]o rebut the Government's *prima facie* case, [the respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. at 8236. Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Linda Sue Cheek, M.D.,* 76 Fed. Reg. 66972, 66973 (2011); *Abbadessa,* 74 Fed. Reg. at 10078; *see also Gregory D. Owens, D.D.S.,* 74 Fed. Reg. 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. 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.[62] *Mackay v. DEA,* 664 F.3d 808, 822 (10th Cir. 2011); *Hoxie,* 419 F.3d at 483.

While the burden of proof at this administrative level is a preponderance-of-the-evidence standard, *see Steadman v. SEC,* 450 U.S. 91, 100–01 (1981), the Administrator's factual findings will be sustained on review so long as they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. Thus, ''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,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77. However, in rendering a decision, the Administrator must consider all ''important aspect[s] of the problem,'' such as a Respondent's defense or explanation that runs counter to the Government's evidence. *Wedgewood Vill. Pharmacy v. DEA,* 509 F.3d 541, 549 (DC Cir. 2007); *Humphreys,* 96 F.3d at 663. 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 (internal quotation marks omitted).

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. Mere unevenness in application standing alone does not, however, render a particular discretionary action unwarranted. *Chein v. DEA,* 533 F.3d 828, 835 (DC Cir. 2008) (citing *Butz v. Glover Livestock Comm. 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 a recommended decision are entitled to significant deference. *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 496 (1951). Thus, a recommended decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are not 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 (1947).

[61] This authority has been delegated pursuant to 28 C.F.R. §§ 0.100(b) and 0.104.

[62] *See, e.g., Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (2010) (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *East Main Street Pharmacy,* 75 Fed. Reg. 66149, 66165 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Abbadessa,* 74 Fed. Reg. at 10078; *Krishna-Iyer,* 74 Fed. Reg. at 463; *Medicine Shoppe,* 73 Fed. Reg. at 387.

Factors 1 and 3: 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

Regarding Factor 1, it is undisputed that the Respondent pharmacy holds a valid license in the State of Texas. Stip. of Fact 2. It is likewise undisputed that, although the Texas Pharmacy Board has been intimately involved in multiple visits and audits conducted in connection with these proceedings, there is no recommendation from any state licensing board in this matter. However, the fact that a state has not acted against a registrant's medical license 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 Fed. Reg. 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 Fed. Reg. at 461. It is well-established Agency precedent that a ''state license is a necessary, but not a sufficient condition for registration.'' *Leslie,* 68 Fed. Reg. at 15230; *John H. Kennedy, M.D.,* 71 Fed. Reg. 35705, 35708 (2006). DEA bears an independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 Fed. Reg. 9209, 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 Fed. Reg. 6580, 6590 (2007), *aff'd, Chein v. DEA,* 533 F.3d 828 (DC 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 Fed. Reg. at 20375. 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 continuation of the Respondent's DEA certification is consistent with the public interest. *See Roni Dreszer, M.D.,* 76 Fed. Reg. 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 Respondent, its owner, or any pharmacist or key employee of the pharmacy has been convicted of (or charged with) a crime related to the manufacture, distribution, or dispensing of controlled substances. DEA administrative proceedings are non-punitive and ''a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA COR, and who have not presented sufficient mitigating evidence to assure the [Administrator] that they can be trusted with the responsibility carried by such a registration.'' *Jackson,* 72 Fed. Reg. at 23853; *Leo R. Miller, M.D.,* 53 Fed. Reg. 21931, 21932 (1988). Where evidence in a particular case reflects that the Respondent has acquired convictions relating to the manufacture, distribution, or dispensing of controlled substances, those convictions must be carefully examined and weighed in the adjudication of whether the issuance of a registration is in the public interest. 21 U.S.C. § 823(f).

Although 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, 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 Fed. Reg. 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.,* 75 Fed. Reg. 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 Fed. Reg. 6056, 6057 n.2 (2009). Therefore, 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 revocation sought by the Government.

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

Regarding Factor Two, in requiring an examination of a registrant's experience in dispensing controlled substances, Congress acknowledged that the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances may be significant factors to be evaluated in reaching a determination as to whether a registrant should be (or continue to be) entrusted with a DEA COR. In some cases, viewing a pharmacy registrant's actions against a backdrop of how it has performed activity within the scope of its certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest. In this regard, however, the Agency has held that this factor can be outweighed by acts held to be inconsistent with the public interest. *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463; *see also Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8235 (2010) (acknowledging Agency precedential rejection of the concept that conduct which is inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities which occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 63 Fed. Reg. 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.''). Moreover, in *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. 19450, 19450 n.1 (2011), the Agency determined that existing List I precedent [63] holding 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. The Agency's approach in this regard has been sustained on review. *Mackay,* 664 F.3d at 819.

On the present record, that portion of Factor Two relating to the Respondent's knowledge of his obligations as DEA registrant presents a troubling picture. Under Texas law, a non-pharmacist owner of a community pharmacy [64] may receive advice from a PIC, but the ''responsibility for all administrative and operational functions of the pharmacy'' rests with him alone. 22 Tex. Admin. Code § 291.32(b). The Respondent's owner, Mr. Sanders, holds a degree in finance and marketing and is licensed, not as a pharmacist, but as an insurance broker. Tr. 262. Mr. Sanders has repeatedly averred that he is not a pharmacist. Tr. 262–63, 268–71, 273; Resp't Brief at 11. Indeed, apart from attendance for one day of a two-day seminar, the record has no evidence that Sanders has training in any aspect of drug diversion. Tr. 283. When asked by the Respondent's counsel to detail his understanding of diversion and signs of diversion, Mr. Sanders' testimony was disjointed and confusing. Tr. 275–76, 279–82. Yet, when compared to the testimony of PIC Grape, Sanders' answers were a model of clarity. *See e.g.,* Tr. 258–61. To the extent these two men have the knowledge and/or skill set to protect the closed regulatory system against diversion, it is not supported at all in this record.

The manner in which controlled substances were dispensed at the Respondent pharmacy impacts both Factor Two (experience in dispensing) and 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). Agency precedent has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the

[63] *See, e.g., Volusia Wholesale,* 69 Fed. Reg. 69409, 69410 (2004).

[64] *See* 22 Tex. Admin. Code § 291.17(b).

pharmacy's owners, majority shareholders, officers, managing pharmacist or other key employee. *EZRX, LLC,* 69 Fed. Reg. 63178, 63181 (1988); *Plaza Pharmacy,* 53 Fed. Reg. 36910 (1988).

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 C.F.R. § 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 Fed. Reg. 16236, 16266 (2010). In short, a pharmacist has a ''corresponding responsibility under Federal law to dispense only lawful prescriptions.'' *Liddy's Pharmacy, L.L.C.,* 76 Fed. Reg. 48887, 48895 (2011).

The corresponding responsibility to ensure the dispensing [65] of valid prescriptions extends to the pharmacy itself. *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 384 (2008) (finding that a respondent pharmacy was properly charged with violating corresponding responsibility); *see also United Prescription Services, Inc.,* 72 Fed. Reg. 50397, 50407–08 (2007) (same); *see* Drug Enforcement Administration, *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 Fed. Reg. 64921, 69424 (2007) (referring to a *pharmacy's* corresponding responsibility); *see also* Drug Enforcement Administration, *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 Fed. Reg. 61613, 61617 (2010) (referring to a pharmacy's ''corresponding responsibility regarding the dispensing of controlled substances.''); *EZRX, LLC,* 69 Fed. Reg. at 63181 (''DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill *their* corresponding responsibility in Internet prescribing operations.'') (emphasis added). 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. *Bob's Pharmacy & Diabetic Supplies,* 74 Fed. Reg. 19599, 19601 (2009) (citing *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. at 381 (quoting *Medic-Aid Pharmacy,* 55 Fed. Reg. 30043, 30044 (1990))); *see also United Prescription Services, Inc.,* 72 Fed. Reg. 50397, 50407–08 (2007) (finding violation of corresponding responsibility where pharmacy ''had ample reason to know'' that the practitioner was not acting in the usual course of professional practice).

DEA has interpreted the ''legitimate medical purpose'' feature of the corresponding responsibility duty ''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,'' and has been equally consistent in its admonishment that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Sun & Lake Pharmacy, Inc.,* 76 Fed. Reg. 24523, 24530 (2011); *Liddy's Pharmacy, L.L.C.,* 76 Fed. Reg. at 48895; *East Main Street Pharmacy,* 75 Fed. Reg. 66149, 66163 (2010); *Lincoln Pharmacy,* 75 Fed. Reg. 65667, 65668 (2010); *Bob's Pharmacy,* 74 Fed. Reg. at 19601.

The Agency does not require omniscience. *Carlos Gonzalez,* 76 Fed. Reg. 63118, 63142 (2011) (citing *Holloway Distrib.,* 72 Fed. Reg. 42118, 42124 (2007)). However, when the circumstances surrounding the presentation of a prescription would give rise to suspicion in a ''reasonable professional,'' there is a duty to ''question the prescription[].'' *Bertolino,* 55 Fed. Reg. at 4730. Though initially framed as a ''reasonable professional'' standard, the Agency has considered the duty to discharge the corresponding responsibility by evaluating the circumstances in light of what would be considered suspicious by a ''reasonable pharmacist.'' *East Main Street Pharmacy,* 75 Fed. Reg. at 66165; *see also Winn's Pharmacy,* 56 Fed. Reg. 52559, 52561 (1991). Accordingly, a pharmacist or pharmacy may not dispense a prescription in the face of a red flag (i.e., a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he or it takes steps to resolve the red flag and ensure that the prescription is valid. *Id.* Because Agency precedent limits the corresponding responsibility to circumstances which are known or should have been known, *Sun & Lake Pharmacy, Inc.,* 76 Fed. Reg. at 24530, it follows that, to show a violation of a corresponding responsibility, the Government must establish that: (1) the Respondent 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. *See Sun & Lake Pharmacy,* 76 Fed. Reg. at 24532 (finding that pharmacy violated corresponding responsibility where it took no steps to resolve red flags prior to dispensing controlled substances). Necessarily, the conclusiveness of the resolution will be judged in light of a reasonable pharmacist standard. *East Main Street Pharmacy,* 75 Fed. Reg. at 66165. 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.

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 Services,* 72 Fed. Reg. 50397, 50407 (Respondent pharmacy violated 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.''). *See also Pharmboy Ventures Unlimited, Inc.,* 77 Fed. Reg. 33770, 33772 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.' ''); *S&S Pharmacy, Inc.,* 46 Fed. Reg. 13051, 13052 (1981) (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 U.S.* v. *One Parcel of Land,* 965 F.2d 311, 316 (7th Cir.1992) (''Only knowledge obtained by corporate employees acting with the scope of their employment is imputed to the corporation.'').

The Texas state standard is in substantial accord with the DEA regulations. The Texas Pharmacy Board has been authorized to regulate the practice of pharmacy within the state, including the regulation of issues related to conduct and competence. Tex. Occ. Code § 551.02. Under applicable state regulations, a pharmacist is required to ''exercise sound professional judgment with respect to the accuracy and authenticity of any prescription drug order dispensed.'' 22 Tex. Admin. Code § 291.29(a). The regulation echoes the federal standard, requiring that a pharmacist ''make every reasonable effort to ensure that any prescription drug order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a practitioner in the course of medical practice. . . .'' *Id.* § 291.29 (b). The regulations further indicate that, ''a pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued without a valid pre-existing patient-practitioner relationship.'' *Id.* Reasons for a pharmacist suspecting that a prescription was written in the absence of a valid patient-practitioner relationship include ''the manner in which the prescriptions are . . . received by the pharmacy,'' ''the number of prescriptions authorized on a daily basis by the practitioner,'' and whether ''a disproportionate number of patients of the practitioner receive controlled substances.'' *Id.* § 291.29 (c).

The preponderant evidence of record establishes that, on a regular basis, the Respondent pharmacy filled controlled substance prescriptions presented by ''runners.'' The Respondent's owner and PIC both had actual knowledge, through their pharmacy technician-in-training, Heather Tippie, that individuals bearing made-up names such as ''Uncle Bo,'' ''Jay,'' and ''Wendell,'' were providing bundles of fraudulent scrips with photocopies of driver's licenses meant to give the appearance that the patients themselves had been at the pharmacy, and receiving dangerous controlled substances for distribution and profit. These ''runners'' would ''drop off multiple prescriptions, 5, 10, sometimes 20 prescriptions all at the same time.'' Tr. 215. Tippie explained that these visits occurred ''once or twice a week, on the upwards of five times a week.'' Tr.

[65] Under the CSA, ''[t]he term 'dispense' means to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of, a practitioner . . . .'' 21 U.S.C. § 802(10). The Respondent's registration as a retail pharmacy authorizes the dispensing of controlled substances to ultimate users. 21 C.F.R. 1301.13(e).

216. Ms. Tippie credibly testified that she repeatedly informed Mr. Sanders and his PIC that the Respondent pharmacy was essentially serving as a drug supplier to unapologetic street dealers, and that Sanders turned a blind eye. In fact, when directly told about the criminal enterprise his business was facilitating, and the admissions made to his own employee by one of the perpetrators, Mr. Sanders dismissed Ms. Tippie's concerns, stating ''what they do outside once they leave the pharmacy, I can't do anything about it. It's none of my business.'' Tr. 219. The owner and PIC at the Respondent pharmacy received actual knowledge that controlled substances were being provided to drug dealers and acted neither to stop it, nor to even investigate the report by its employee. At a minimum, to the extent that Ms. Tippie's statements to Sanders and Grape constituted a red flag, it should have stopped all controlled substance dispensing until resolved. To the more likely extent that Sanders and Grape knew well that the runners (one of whom offered to forgo collection of non-controlled substances) were drug traders, their conduct (and so the conduct of the Respondent pharmacy) amounted to intentional diversion. It would be difficult to conjure up a more egregious example of a registrant pharmacy violating its legal responsibility to ensure that the controlled substances being dispensed were pursuant to legitimate prescriptions. Facilitating a steady stream of dangerous controlled substances into the hands of willing drug traffickers reflects negatively on the Respondent's experience in dispensing controlled substances (Factor Two) and the Respondent's lack of compliance with applicable federal and state laws relating to controlled substances (Factor Four). This willing complicity with obvious drug dealing is sufficient, even standing alone, to meet the Government's burden to demonstrate acts as would render the Respondent's continued registration inconsistent with the public interest. 21 U.S.C. § 824(a)(4).

Record evidence related to the Respondent's recordkeeping also impacts upon Factor Four. ''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 Fed. Reg. 51424, 51429 (2011) (internal punctuation and citations omitted). There is no question that the maintenance of accurate records by registrants is critical to DEA's ability to fulfill its obligations to regulate controlled substances. As previously held by the Agency, ''[r]ecordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Paul H. Volkman,* 73 Fed. Reg. 30630, 30644 (2008), *aff'd, Volkman,* 567 F.3d at 224 (DEA Administrator's reliance on recordkeeping violations in denying COR application specifically upheld). Accurate and reliable records are an obvious bedrock safeguard that is essential to ensure the integrity of the closed regulatory system. A truly closed system requires that certain records and inventories be kept by all those registrants who either generate or take custody of controlled substances in any phase of the distribution chain until they reach the ultimate user. Stated differently, where a registrant is unable to produce the documentation required by the regulations to establish the integrity of his function in the closed system, the Agency cannot determine whether diversion has occurred. The Agency has held that a registrant's ''failure to maintain accurate records'' is in and of itself sufficient to support revocation. *Id.* That said, the Agency has also declined to revoke a registration where non-egregious recordkeeping errors were acknowledged by the pharmacy PIC and remedied promptly. *Terese, Inc., d/b/a/Peach Orchard Drugs,* 76 Fed. Reg. 46843, 46848 (2011).

DEA regulations require a registrant pharmacy to ''take an inventory of all stocks of controlled substances on hand on the date [it] first engages in the . . . dispensing of controlled substances.'' 21 C.F.R. § 1304.11(b). The initial inventory provides a vital baseline by which the controlled substances handled by the registrant can be accounted for. The DEA regulations require that this inventory take place on the day when controlled substance dispensing commences. *Id.* Texas regulations require that new community pharmacies ''take an inventory on the *opening day of business''* of ''all controlled substances.'' 22 Tex. Admin. Code § 291.12(b)(1)(A) (emphasis supplied); *see also* Tr. 23, 134–35; *but see* 183–84 (Investigator White mistakenly indicated that the initial inventory is required under Texas regulations on the first day a pharmacy begins dispensing). The Texas regulations further provide that ''[i]n the event the . . . pharmacy commences business with [no controlled substances] on hand, the pharmacy shall record this fact as the initial inventory.'' *Id.* at § 291.12(b)(2).

The evidence of record establishes that the Respondent did not conduct an initial inventory of its controlled substances on either the first day the pharmacy began dispensing (federal requirement) controlled substances or on its first day of business (state requirement). Investigator Pinkerton (DPS) and Investigator White (Texas Pharmacy Board) both testified that each sought an initial inventory from the Respondent and that none was provided. Tr. 23–24, 134–35. Pinkerton credibly testified that PIC Grape told him he believed (incorrectly) that no such inventory was required until a pharmacy had been open for six months, and Mr. Sanders indicated that he did not have one because he did not realize that one was required. Tr. 24. Investigator White credibly testified that Mr. Sanders told him that no such inventory was prepared. Tr. 135.

DI Newkirk likewise testified that he requested an initial inventory from Mr. Sanders and PIC Grape ''on multiple occasions'' during both the First and Second DEA Visits. Tr. 86–87, 92. Newkirk recounted that Sanders and Grape indicated that they did not have an initial inventory during the course of the First DEA Visit, and at the Second DEA Visit, Mr. Sanders told Newkirk that ''he had still not made one.'' Tr. 86, 92.

In view of the multiple, credible accounts from multiple investigators from multiple agencies which consistently relate that Mr. Sanders and PIC Grape unwaveringly maintained that no initial inventory was created or available, Mr. Sanders' assertion (first heard during his testimony at the hearing) that he had in fact prepared an initial inventory and that it resided (inexplicably) in the Respondent's safe,[66] is simply unpersuasive.

In addition to requiring an initial inventory, DEA regulations provide that ''[e]very registrant required to keep records pursuant to § 1304.03[67] shall maintain on a current basis a complete and accurate record of each substance * * * imported, received, sold, delivered, exported, or otherwise disposed of by [it], except that no registrant shall be required to maintain a perpetual inventory.'' 21 C.F.R. § 1304.21(a). Additionally, 21 C.F.R. § 1304.22 requires dispensers of controlled substances to maintain records of: ''the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.'' Likewise, the regulations require that the date on which controlled substances are actually received serve as the receipt date for purposes of records and accountability. *Id.* § 1304.21(d).

The evidence presented at the hearing demonstrates serious recordkeeping deficiencies on the part of the Respondent pharmacy. When DPS Investigator Pinkerton first went to the Respondent pharmacy on March 13, 2012, the only records of the pharmacy's dispensing were hard copies of prescriptions written; no dispensing logs were provided. Tr. 25–26. Further, Investigator White testified that when he requested invoices from the Respondent's distributors, he discovered that the Respondent pharmacy was missing fifty invoices[68] in violation of Texas Pharmacy Board regulations requiring pharmacies to keep a record of ''suppliers' invoices of controlled substances.'' 22 Tex. Admin. Code § 291.55(d)(4). This regulation was further violated by the lack of annotations on the Respondent's invoice records, as observed by DEA DI Newkirk. Tr. 74. Under Texas regulations, pharmacies are required to maintain

> suppliers' invoices of . . . controlled substances; a pharmacist shall verify that the controlled drugs listed on the invoices were actually received by clearly recording his/her initials and the actual date of receipt of the controlled substances.

22 Tex. Admin. Code § 291.34(h)(4).

The Respondent's violations of recordkeeping regulations are further

[66] Tr. 268, 271–72; Respt's Brief at 4–5.

[67] Section 1304.03 provides that ''[e]each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section.'' Respondent does not contend that any of the § 1304.03 exemptions apply in this case.

[68] Tr. 148.

demonstrated by the inconsistent results of numerous audits conducted by state and federal investigators. Three audits conducted over a period of two months revealed multiple shortages and overages of controlled substances. Tr. 35, 41, 87, 157–59. These findings demonstrate that, at best, the Respondent's recordkeeping was so deplorably insufficient that there was no accurate means of ascertaining the precise quantity of controlled substances that the Respondent pharmacy was handling. *See Bill Lloyd Drug,* 64 Fed. Reg. 1823, 1824 (1999) (''The shortages and overages revealed by the accountability audit show that Respondent does not keep complete and accurate records of its controlled substance handling as required by 21 U.S.C. 827 and 21 CFR 1304.21.''); *see also Alexander Drug Company, Inc.,* 66 Fed. Reg. 18299, 18303 (2001) (shortages or overages constitute violations of 21 C.F.R. § 1304.21 and 21 U.S.C. § 827); *Ellis Turk, M.D.,* 62 Fed. Reg. 19603, 19605 (1997) (same). Where, as here, a pharmacy registrant is abjectly unable to account for ''extraordinary quantities'' of controlled substances, the Agency has held that ''it has committed acts which render its registration 'inconsistent with the public interest' [within the meaning of] 21 U.S.C. § 824(a)(4).'' *Ideal Pharmacy Care, Inc. d/b/a/Esplande Pharmacy,* 76 Fed. Reg. 51415, 51416 (2011).

As the owner of the Respondent pharmacy, Mr. Sanders is responsible for ''establish[ing] policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.'' *Id.* § 291.32(b)(5). His consistent insistence that the true fault lies with the pharmacy technician-in-training he hired is simply unavailing. Likewise, even acknowledging that the PIC has defined state-law responsibilities in the pharmacy,[69] as discussed, *supra,* a registrant pharmacy bears the responsibility for the actions of its managing pharmacist or other key employees. *EZRX,* 69 Fed. Reg. at 63181; *Plaza Pharmacy,* 53 Fed. Reg. 36910 (1988); *see Neil Labs, Inc. v. Ashcroft,* 217 F.Supp.2d 80, 87–88 (D.D.C 2002).

As a result of its abysmal recordkeeping practices, the Respondent violated both federal and Texas laws relating to controlled substances to a degree that consideration of the evidence under Factor Four gravely and negatively impacts in favor of the COR revocation sought by the Government.

DI Newkirk credibly testified that during the First DEA Visit he came across evidence that the Respondent pharmacy was ''transferring controlled substances to a pharmacy in Houston by the name of RX Max Pharmacy'' with inadequate documentation. Tr. 75. Specifically, Newkirk testified that the transfer records fell short of the regulatory requirements in that:

They didn't contain the bottle size, the full name of the product or the amount of tablets or amount of liquid in the product [and] the receipts did not annotate who received the product, the date it was received or the correct amount received.

Id.

The CSA provides that ''every registrant . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each . . . substance . . . received, sold, delivered, or otherwise disposed of by [it]. . . .'' 21 U.S.C. § 827(a)(1). The DEA regulations likewise require the registrant to ''maintain on a current basis a complete and accurate record of each such substance . . . received, sold, delivered . . . or otherwise disposed of by [it]. . . .'' 21 C.F.R. § 1304.21(a). When recording the date of distribution or transfer, the regulations require the registrant to use ''the date on which the substances are actually . . . distributed . . . or otherwise transferred . . . as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).'' *Id.* § 1304.21(d).

In Texas, the Administrative Code mandates pharmacies authorized to distribute controlled substances to other pharmacies [70] to maintain records of the transfer of controlled substances contained in Schedules III–V.[71] 22 Tex. Admin. Code § 291.34(g)(3). These records must document: (1) ''the actual date of distribution;'' (2) ''the name, strength, and quantity of controlled substances distributed;'' (3) ''the name, address, and DEA registration number of the distributing pharmacy;'' and (4) ''the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.''

Id.

In neglecting its responsibilities in correctly completing the required transfer documents, the Respondent was in violation of both federal and Texas laws relating to controlled substances and, under Factor Four, provides additional support to the COR revocation sought by the Government.

The Government also presented testimony at the hearing regarding alleged violations of labeling regulations. DI Newkirk credibly testified that he observed unmarked bottles containing promethazine with codeine, hydrocodone, and alprazolam. Tr. 75–76. Photographs depicting unlabeled bottles of promethazine with codeine were received into the record. Gov't Ex. 6, at 2–4; Tr. 131. The record evidence clearly establishes that the investigators who entered the Respondent pharmacy encountered controlled substances in unlabeled containers. Under 21 C.F.R. § 1302.03(a), ''[e]ach commercial container of a controlled substance . . . shall have printed on the label the symbol designating the schedule in which such controlled substance is listed.'' However, the scope of this section is defined by 21 U.S.C. § 825,[72] which, by its terms, applies to distribution.

But see Paul Weir Battershell, N.P., 76 Fed. Reg. 44359, 44367 (2011) (finding practitioner dispensing controlled substances to patients to be in violation of 21 C.F.R. § 1302.03(a) by storing ''controlled substances in unlabeled prescription bottles''). However, inasmuch as the Government has not sought reliance upon 21 C.F.R. § 1302.03(a), and in light of the other violations of federal and state controlled substance regulations that were established on the record, there is no need to determine whether the discovery of controlled substances in unmarked containers at the Respondent pharmacy constituted a violation of DEA regulations.

The regulations cited by the Government [73] provide that:

> The pharmacist *filling a prescription* for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

21 C.F.R. § 1306.24(a) (emphasis supplied); *see also* 22 Tex. Admin. Code § 291.33 (itemizes the information required on a label at the ''time of delivery of the drug''). However unwise the practice of maintaining controlled substances languishing in bottles unencumbered by correct labels, the plain language of the DEA regulation mandates specified label requirements that ripen when the pharmacist is ''filling a prescription.'' 21 C.F.R. § 1306.24(a). Inasmuch as there is no record evidence that any controlled substances were dispensed by the Respondent pharmacy without appropriate labels, this allegation stands as unsustainable.

The evidence convincingly establishes that the Respondent pharmacy, through its owner, PIC, and its (then) directed employee, provided large amounts of controlled substances to runners (i.e., drug dealers) who supplied obviously illegitimate prescriptions. The poor recordkeeping and lack of knowledge regarding federal and state regulatory requirements predictably yielded staggering overages and shortages. The Respondent's owner and PIC did not know the amount of controlled substances on board, and had no way to ascertain how much should have been on board, for multiple audits and when completing reports of theft or loss. Even if the Respondent's dubious version of the facts were given some credence, it would only demonstrate that no one at the Respondent pharmacy knew what was going on, or what was required by federal and state regulations. This is hardly a scenario that engenders confidence. Clearly, application of Factors Two and Four militate powerfully and persuasively in favor of the COR Revocation the Government seeks.

[69] 22 Tex. Admin. Code §§ 291.29(a)(2)(E), (G), 291.32(c)(2)(E).

[70] 22 Tex. Admin. Code § 291.34(g).

[71] The Respondent's DEA COR is limited to controlled substances contained in Schedules III–V. Stip. Of Fact 1.

[72] *See* 21 C.F.R. § 1302.01 (''Requirements governing the labeling and packaging of controlled substances pursuant to sections 1305 and 1008(d) of the Act (21 U.S.C. 825 and 958(d)) are set forth generally by those sections and specifically by the sections of this part.'')

[73] Gov't Brief at 15.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

The fifth statutory public interest factor directs consideration of ''[s]uch *other conduct* which may threaten the public health and safety.'' [74] 21 U.S.C. § 823(f)(5) (emphasis supplied). 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 Fed. Reg. at 19434 n.3; *Aruta,* 76 Fed. Reg. at 19420 n.3; *Boshers,* 76 Fed. Reg. 19403 n.4; *Dreszer,* 76 Fed. Reg. at 19386–87 n.3. 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,* 76 Fed. Reg. at 46848; *Tony T. Bui, M.D.,* 75 Fed. Reg. 49979, 49989 (2010) (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 Fed. Reg. 44359, 44368 n.27 (2011) (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.'' *Id.* (emphasis supplied). In *Holloway Distributors,* 72 Fed. Reg. 42118, 42126 (2007), 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). In *Holloway,* the Agency stated that regarding the List I catch all:

[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 [Fed. Reg.] 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'').

72 Fed. Reg. at 42126.[75] 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.'' Because section 823(f)(5) only implicates ''such *other* conduct,'' it necessarily follows that conduct considered in Factors One through Four may not be considered at Factor Five.

The Government alleged that the Respondent ''diluted the Actavis brand of promethazine [codeine] syrup before dispensing, in violation of 21 U.S.C. § 331.'' ALJ Ex. 1 at 2. 21 U.S.C. § 331(b) prohibits the ''adulteration . . . of any . . . drug . . . in interstate commerce.'' 21 U.S.C. § 351(c) provides, in turn, that ''[a] drug shall be deemed to be adulterated . . . if . . . any substance has been . . . mixed or packed therewith so as to reduce its quality or strength.'' Agency precedent has considered this conduct under Factor Five. *Dan E. Hale, D.O.,* 69 Fed. Reg. 69402, 69406 (2004) (finding evidence that ''some injectable medications were diluted below their therapeutic dosages'' to be a relevant consideration under Factor Five). The admitted evidence of record here renders it unnecessary to decide whether diluting promethazine with codeine raises diversion issues properly within the purview of these DEA enforcement proceedings. *See Judulang v. Holder,* 132 S.Ct. 476, 556 U.S. ____ (2011) (actions of a regulatory agency must bear a rational relationship to the purposes of the statute it is charged with enforcing).

To be sure, the credible testimony of Ms. Tippie supports her observations that she witnessed Mr. Sanders and Mr. Sanders, Sr. pouring promethazine into bottles that she believed to contain promethazine with codeine. Tr. 171–75, 192, 226–27. Similarly supported is Tippie's account of her conversation with Mr. Sanders wherein the latter explained that such diluting ''was cost effective because the promethazine with codeine was so expensive for a pint bottle.'' Tr. 227. Likewise credible is Ms. Tippie's testimony that she heard complaints from numerous customers who were unhappy about the strength of the promethazine dispensed to the point that customers began insisting on tasting the medicine before paying, and that this phenomenon was sufficiently prevalent that Mr. Sanders issued a policy prohibiting the practice. Tr. 172–73, 226–27. Although Mr. Sanders' unembellished, one-line denial that ''[t]here was no dilution of promethazine with codeine,'' could arguably have been enhanced by the tender of some explanation of any details that could supply a benign explanation to Ms. Tippie's credible observations, no such details were presented, and her account was the more believable one. Tr. 264. That subsequent testing of a limited subset of the promethazine with codeine on board at the Respondent pharmacy revealed no anomalies [76] does not detract from the strength of Ms. Tippie's testimony.

However, the present record does not have the benefit of expert testimony regarding the safe or appropriate strength of promethazine with codeine. Likewise, the anonymous, unsatisfied consumers of the dispensed syrup hardly can be perceived as sufficiently expert to supply relevant evidence. There is simply no record evidence from which it is possible to discern the safety implications of varying concentrations of codeine in promethazine, what concentrations (if any) were dispensed, and to the extent any promethazine with codeine was dispensed after dilution, what the label on the bottle(s) may have indicated relative to the strength of the mixture. In short, there is insufficient evidence of record to gauge the significance of Ms. Tippie's observations on the issue of whether it constituted a threat to public health and safety under Factor Five. 21 U.S.C. § 823(f)(5). Accordingly, consideration of the record evidence under Factor Five weighs neither for nor against the revocation of Respondent's DEA COR sought by the Government.

Recommendation

Based on the foregoing, the Government has established that the Respondent has committed acts that are inconsistent with the public interest.

Because the Government has sustained its burden of showing that the Respondent committed acts inconsistent with the public interest, the burden shifts to the Respondent to show that it can be entrusted with a DEA registration. 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 employee. *EZRX,* 69 Fed. Reg. at 63181; *Plaza Pharmacy,* 53 Fed. Reg. 36910 (1988); *see Neil Labs, Inc. v. Ashcroft,* 217 F.Supp.2d 80, 87–88 (D.D.C 2002). A long line of consistent Agency precedent has established that ''to rebut the Government's *prima facie* case, [the Respondent is] required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. at 8236; *Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 463 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008). The acceptance of responsibility is a condition precedent for the Respondent to prevail once the Government has established its *prima facie* case. *Matthew,* 75 Fed. Reg. at 66140. This feature of the Agency's interpretation of its statutory mandate on the

[74] Inexplicably, that portion of the Government's post-hearing brief designated as a discussion of Factor Five deals exclusively with the exercise of discretion. Gov't Brief at 16–18.

[75] 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 Fed. Reg. 49888 n.12.

[76] Tr. 95–96.

exercise of its discretionary function under the CSA has been sustained on review. *Mackay,* 664 F.3d at 822.

The Respondent's owner, Mr. Sanders, has accepted no measure of responsibility for the established misconduct in the record. The preponderant evidence that the Respondent's owner and PIC had actual knowledge that the pharmacy was providing large amounts of dangerous controlled substances to drug-dealer runners presenting illegitimate scrips and photocopied driver's licenses on a regular basis. That actual knowledge, which was supplied, not by an anonymous source, but by an employee, was met with a dismissive rejection at the time it was provided and at the hearing. There is nothing in the record to rebut the persuasive record evidence that the conduct of the owner and PIC exceeded inaction and rose to the level of willing complicity in controlled substance diversion on a massive scale. The equally persuasive evidence that multiple audits demonstrated alarming shortages and overages, profound recordkeeping issues, and pervasive incompetence was met in these proceedings with an attempt to deflect the blame to subordinates. Based on his testimonial performance at the hearing, a decision to rely upon the expertise of PIC Grape to ensure that the Respondent pharmacy fulfilled its obligations as a DEA registrant (to the extent that the *bona fides* of such reliance is accepted) is patently unreasonable. Mr. Sanders' inconsistent positions as to whether an initial inventory ever existed have amplified the probative value of this recordkeeping shortcoming in support of the Government's case. The Respondent pharmacy did not have the paperwork required for inventory control or transfer, and its personnel were bereft of any means to discern how much controlled substance the enterprise should have on board when the audits took place and when theft/loss reports were prepared. The evidence here does not show a reduced level of control demonstrated by imperfect paperwork, but rather an absence of any measure of control. Indeed, the most credible aspect of Mr. Sanders' testimony is that he has no training or expertise in the field of pharmacy. Tr. 262–63; *see also,* Resp't Brief at 11. The continuation of the Respondent's COR under the circumstances is untenable.

On the issue of remedial steps, Mr. Sanders offered a new computer software system and a new PIC.[77] Regrettably, the software system addresses none of the pernicious issues related to supplying runners with controlled substances that the Respondent (through its owner and PIC) knew were authorized on a large scale through illegitimate prescriptions. Regarding the replacement of PIC Grape, Mr. Sanders' testimony made it clear that he does not acknowledge that PIC Grape was ever part of the problem. Tr. 264, 287–88. Thus, his replacement cannot be perceived as a cognizable remedial step.

[77] In his post-hearing brief, the Respondent states that a new PIC has been hired. Resp't Brief at 3. This fact is not a matter of record, and, based on the posture of the case wherein the Respondent has consistently embraced PIC Grape's qualifications and abilities, would be unavailing in any event.

To be clear, this is not a case like *Terese,* where recordkeeping violations were acknowledged and addressed with alacrity. 76 Fed. Reg. at 46848. There has been no acceptance of responsibility or any demonstration of genuine attempts at remedial action. The Respondent's owner, Mr. Sanders, has consistently claimed that the runners did not exist, that his employees should have known better, or (in the case of Ms. Tippie) have fabricated lies against him, and that any auditing issues were a natural result of the hiccups associated with a nascent pharmacy. In short, the posture taken by Mr. Sanders has made it virtually impossible for the Agency to continue to entrust the Respondent pharmacy with a DEA registration.

Accordingly, in view of the fact that the Government has established its *prima face* case by a preponderance of the evidence, and the Respondent has declined to accept responsibility, the Respondent's Certificate of Registration should be REVOKED and any pending applications for renewal should be DENIED.

Dated: November 8, 2012

s/John J. Mulrooney, II

Chief Administrative Law Judge

[FR Doc. 2013–10550 Filed 5–2–13; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Revision to a Currently Approved Information Collection; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collection to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). This information collection is published to obtain comments from the public. NCUA is proposing a data collection change to the credit union Profile as well as the 5300 Call Report. NCUA is proposing to add fields to the General, Information Systems and Technology, Regulatory, Disaster Recovery, Member Services and Grant sections of the Profile. This data will assist NCUA in monitoring and supervising credit unions. On the 5300 Call Report, NCUA is proposing to add fields to the Miscellaneous Loan Information, Additional Share Information, Miscellaneous, Delinquency, Loan Charge Off and Recoveries, Liquidity, Commitments and Sources, Purchased Credit Impaired Loans, and Supplemental Investment Information sections. The new data collection provides more detailed delinquent, charge off and recovery loan information. Additionally, these fields provide information for offsite monitoring of risks to the National Credit Union Share Insurance Fund.

DATES: Comments will be accepted until June 3, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*.

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, a copy of the information collection request, or a copy of submitted comments should be directed to Tracy Crews at the National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428, or at (703) 518–6444.

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is amending the currently approved collection for 3133–0004. Two specific forms are used, NCUA Form 5300 and NCUA Profile Form 4501A, also known as the Call Report and Profile, respectively. Section 741.6 of the NCUA Rules and Regulations requires all federally insured credit unions to submit a Call Report quarterly. 12 CFR 741.6. The information enables the NCUA to monitor credit unions whose share accounts are insured by the National Credit Union Share Insurance Fund. NCUA uses the information collected from these Call Reports to fulfill its mission of supervising credit unions and the Federal Reserve Board uses it to monitor and control the nation's money supply and the system of financial institutions. Congress and various state legislatures use this information to monitor, regulate, and control credit unions and financial institutions. The changes made to the Profile and Call Report form for June 2013 will provide data to assist the National Credit Union Administration in assessing regulatory compliance and financial and operational risks. There is a decrease of 6,045 hours from the last submission