

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–2]

Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.; Decision and Order

On April 29, 2015, Administrative Law Judge Gail A. Randall (hereinafter, ALJ) issued the attached Recommended Decision.¹ Therein, the ALJ found that “Respondents violated recordkeeping requirements by failing to record whether Jones Pharmacy’s biennial inventory was taken at the opening or close of business, and by failing to indicate the number of tablets per opened commercial container, the number of tablets shipped in each commercial container, and the number of commercial containers that [were] on hand.” R.D. at 59 (citing 21 CFR 1304.11(e)(3)).

Most significantly, the ALJ further found that Respondent’s (Jones Pharmacy) pharmacists dispensed controlled substance prescriptions in violation of their corresponding responsibility, *see id.* at 60–64, pursuant to which it is a violation of federal law for a pharmacist to knowingly dispense a controlled substance prescription which was not “issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.” 21 CFR 1306.04(a). The ALJ credited the testimony of the Government’s Expert that the prescriptions presented various red flags, *i.e.*, indicia that the prescriptions were not issued for a legitimate medical purpose. These included that: (1) The patients were traveling long distances (and many came from out-of-state) to obtain the prescriptions; (2) that the patients were prescribed cocktails which included narcotics such as oxycodone, benzodiazepines such as Xanax (alprazolam), and muscle relaxants such as Soma (carisoprodol) which were known to be highly abused; (3) that on some occasions, two patients came from the same out-of-state location and presented identical or nearly identical prescriptions; (4) that purported pain patients presented only prescriptions for short-acting but not long-acting narcotics; and (5) that the patients paid for their prescriptions with cash. *Id.* at 61–62. The ALJ further credited the testimony of the Government’s Expert in pharmacy practice that the red flags presented by

many of the prescriptions could not be resolved by the pharmacists. *Id.* at 64.

The ALJ specifically rejected Respondent’s contention that its owner (Ms. Chereese Jones) was simply naïve or unaware of various indicia (otherwise known as red flags) that the prescriptions her pharmacy filled lacked a legitimate medical purpose as well as its contention that during the relevant time period, Florida pharmacists were generally “unaware of the . . . concept of ‘red flags.’” R.D. at 66–69. The ALJ was unpersuaded by the testimony of Respondent’s Expert that pharmacists were generally unaware of the concept of red flags during the relevant time period, noting that while Respondent’s Expert claimed to have based her opinion on a review of the Agency’s administrative decisions, those decisions contradicted her testimony. *Id.* at 68–69.

Finding that the Government met its burden of proof, the ALJ then addressed whether Respondent had put forward sufficient evidence to show why it could be entrusted with a registration. The ALJ specifically found that Ms. Jones had “carefully avoided any admission that she failed to exercise her corresponding responsibility” and that her “wavering responses on cross-examination undoubtedly show her lack of understanding of a pharmacist’s corresponding responsibility.” R.D. 71–72 & n.27. Based on her conclusion that Ms. Jones “had not accepted responsibility for the unlawful dispensing that occurred at” Respondent, the ALJ declined to consider Respondent’s testimony regarding its remedial efforts. *Id.* at 73. And while finding that Jones Pharmacy and SND Healthcare “are separate entities,” *id.*, the ALJ found that Ms. Jones was the owner and operator of both entities and that “there is no dispute that SND Healthcare and Jones Pharmacy are one integrated enterprise.” *Id.* at 74. The ALJ thus “conclude[d] that the unlawful dispensing practices at Jones . . . Pharmacy, L.L.C., are an appropriate basis to deny the pending application” of SND Healthcare for a registration. *Id.* The ALJ thus recommended that I revoke Jones Pharmacy’s registration and deny any pending application by Jones to renew or modify its registration. *Id.* at 75. With respect to SND Healthcare, the ALJ recommended that I deny its pending application.

Respondent filed Exceptions to the ALJ’s Recommended Decision and the Government filed a Response to Respondent’s Exceptions. Thereafter, the record was forwarded to me for Final Agency Action.

Having considered the record in its entirety including Respondent’s Exceptions, I find that while several of its contentions with respect to the ALJ’s factual findings are not without merit, I adopt the ALJ’s credibility findings and conclude that most of the ALJ’s factual findings are supported by a preponderance of the evidence. I further conclude that the ALJ’s factual findings support her legal conclusions that: (1) Respondent’s pharmacists dispensed numerous controlled substance prescriptions in violation of the Agency’s corresponding responsibility rule, *see* 21 CFR 1306.04(a); (2) Respondent has not accepted responsibility for its misconduct; and (3) that there is sufficient overlap in the ownership and control of Jones Pharmacy and SND Healthcare such that Jones’ misconduct supports the denial of SND’s application.²

Accordingly, I adopt the ALJ’s legal conclusions, as well as her implicit conclusions that granting Jones’ renewal application and SND’s application “would be inconsistent with the public interest.”³ 21 U.S.C. § 823(f). I will therefore also adopt the ALJ’s recommendations that I deny Jones Total Health’s renewal application and SND’s pending application. A discussion of Respondent’s Exceptions follows.

Exceptions to the ALJ’s Findings of Fact*Exceptions to Findings Related to the DOH Inspection*

Respondent first takes exception to several of the factual findings made by the ALJ with respect to the June 2012 inspection which was conducted by the Florida Department of Health (DOH).

² I also adopt the ALJ’s conclusion that Respondent Jones Pharmacy’s inventories were non-compliant with DEA regulations. R.D. 59–60.

³ While the ALJ also recommended that I revoke Jones Total Health Pharmacy’s registration, R.D. at 75, I take official notice of the Agency’s registration records which show that Jones did not submit a renewal application until December 30, 2015, the day before its registration was due to expire. Because Jones had previously been issued the Show Cause Order, to continue its registration past the expiration date, it was required to file its renewal application “at least 45 days before the date on which [its] existing registration [was] due to expire.” 21 CFR 1301.36(i). Respondent did not seek to continue its registration past the expiration date, and based on the evidence in this record, I find that extension of its registration was not “consistent with the public health and safety.” *Id.* I therefore find that Jones Total Health Pharmacy’s registration expired on December 31, 2015. *See, e.g., Ralph J. Chambers*, 79 FR 4962, 4962 (2014); *Paul H. Volkman*, 73 FR 30630, 30641 (2008). However, Jones Total Health Pharmacy’s application does remain pending before the Agency. Respondent may dispute this finding (as well as any other finding which is the subject of official notice) by filing a properly supported motion within ten days of the date of this Order. 5 U.S.C. § 556(e).

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

Exceptions, at 3–7. Specifically, Respondent excepts to the ALJ's finding (FoF #69) that during the inspection, the DOH Inspector (who testified at the hearing) "found that the majority of [its] business was the sale of controlled substances, which the pharmacy was filling for cash and that very little business was for non-controlled substances." *Id.* Respondent argues that "[t]his finding is erroneous and contradicted by the record." *Id.*

While Respondent argues "that objective evidence contradicts [the inspector's] testimony," the ALJ found the Inspector's testimony credible and the Government produced a second page of the inspection report on which the Inspector listed "Additional Remarks" and stated in part:

Inspection reveals that the pharmacy fills mostly CII narcotics. They are charging \$9.00 per tablet for Oxycodone 30 mg or \$1620/180. CII dispensing is cash though they take insurance for other medications. Profits on the CII run between \$2,000 and \$6600 per day. The non-controls are mostly filler RXs and some HIV meds filled with insurance. Profit on the non-controls are [sic] usually less than \$200/day, often less than \$50/day. The primary business of the pharmacy is the cash sale of narcotics. The total number of prescriptions filled daily is extremely low.

GX 12, at 2.

Respondent asserts that the Inspector's testimony that this page of the report "was created at the time of such inspection is not credible" because it "was never shown to Ms. Jones, [and] was . . . [n]ever signed by Ms. Jones" during the inspection. Exceptions, at 4. Respondent further argues that "[t]he fact that [the DOH Inspector] never shared page 2 . . . with Ms. Jones contradicts her testimony that if she saw things that a pharmacist was doing wrong, she would tell" the pharmacist. *Id.* Respondent ignores, however, that the Inspector testified that the notes on page two were created so that the inspector on any subsequent inspection "would know what to look for." Tr. 166. The Inspector also explained that her comments about Respondent's dispensing of narcotics were not placed on the first page of the inspection form because "[w]e had had complaints about us putting things about narcotics on the front of an inspection, because people hang them, so we were told to put them on another page." *Id.* at 165–66.⁴

⁴ Respondent also argues that the Inspector's failure to provide page 2 to Ms. Jones violated Florida DOH's "Licensee Bill of Rights, which . . . requires that a pharmacy be presented for review . . . all inspection reports at the time of the inspection." Exceptions, at 4. Even if the Inspector's failure to provide this page to Ms. Jones violated the State's Licensee Bill of Rights, Respondent cites no

However, even if page 2 of the report was not shown to Ms. Jones, I find no reason to reject the Inspector's testimony that she made the notes based on her observations during the inspection she conducted on June 7, 2012. *Id.* at 165–67.

Respondent further attempts to question the validity of page two of the report. It asserts that the DOH Inspector "testified that the date field on the top of the document could not be altered on reports after they are finalized." Exceptions, at 5. Respondent then notes that the "[t]he report marked as Respondents' Exhibit 8 [at p. 5] contains a typewritten data field, while the" first page of the report submitted by the Government "contains a blank in the date field next to Ms. Jones' signature." *Id.* Respondent then maintains that "[t]his appears to contradict testimony that any date field on the report cannot be changed or manipulated and creates further doubt that page 2 . . . was created contemporaneous to the June 7, 2012 inspection." *Id.*

Respondent, however, failed to cite to the portion of the transcript which purportedly contains this testimony. *See id.* While this is reason alone to reject its contention, *see* 21 CFR 1316.66(a),⁵ Respondent ignores that the blank date field next to Ms. Jones' signature is located at the bottom of the page and not "on the top of the document." Thus, I find no reason to reject the testimony of the Inspector regarding when she created the document.

Respondent also argues that the Inspector's testimony and the report's statement that "the majority of Jones' Pharmacy's business was the sale of schedule II controlled substances . . . is inconsistent with the objective evidence." Exceptions, at 5. Putting aside that the report actually used the word "primary" rather than "majority" to describe the nature of Respondent's business, I find the contention unavailing. While Respondent points to data showing that during 2012, Respondent "made a gross profit of \$58,123 on sales of non-controlled substances" and notes that it filled "over 2,956 prescriptions" for non-controlled drugs and filled "only 769 prescriptions" for controlled substances, *id.* at 5–6, Respondent ignores that its

authority pursuant to which the document would be rendered inadmissible in either administrative or judicial proceedings, and even if there is such authority, it would not be controlling in this proceeding.

⁵ This regulation provides that "[t]he party shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) . . ."

own prescription log report for the year shows that its gross profit on its sales of controlled substances was \$316,942.⁶ RX 17, at 19. Thus, the objective evidence shows that in terms of Respondent's gross profit, its primary business during 2012 was the sale of controlled substances.

Respondent also takes issue with the ALJ's crediting of the DOH Inspector's "annotation in her report that [Respondent] sold a 180 pill prescription for \$1620, when [in the Inspector's] opinion the more reasonable price to pay was \$200 to \$250." Exceptions, at 6 (citing ALJ FoF #70). While it is unclear whether Respondent is challenging the Inspector's annotation as to the price Respondent was charging at the time of the inspection or what the Inspector testified as being the "more reasonable price," or both, the "objective evidence" shows that in this time period, Respondent was, in fact, charging \$1620 for 180 dosage units of oxycodone 30. *See* GX 23, at 5 (RX for 180 Roxicodone 30 issued on July 2, 2102 and dispensed the same day as oxycodone 30⁷ for \$1620 cash); *see also* GX 24, at 11–14 (RXs for 180 oxycodone 30 dispensed on May 29, 2012 and June 26, 2012, each for \$1620 cash).

Respondent further argues that the DOH Inspector "conceded on cross-examination that she had no basis to know what an appropriate mark-up would be" and her "testimony in this regard should have been rejected." Exceptions, at 6 (citing Tr. 136). However, Respondent wrongly attributes this testimony to the DOH Inspector rather than the Supervisory Diversion Investigator who provided it. *See* Tr. 136.

As for the DOH's Inspector's testimony that a "more reasonable

⁶ So too, the data for Respondent's previous years in business (2010 and 2011) supports the view that its primary business was the sale of controlled substances. Specifically, in 2010, it dispensed 1847 controlled substance prescriptions and had a gross profit on these of \$530,483. RX 13, at 40. By contrast, during 2010, it dispensed a total of 1072 prescriptions (including refills) for non-controlled drugs and had a gross profit of only \$10,189 on these dispensings. RX 14, at 25. And while during 2011, the number of non-controlled prescriptions (including refills) it filled (3053) clearly overtook the number of controlled prescriptions it filled (1093), its gross profit on controlled substances was \$439,990, more than 11 times its gross profit of \$38,242 on the non-controlled drugs it sold. *Compare* RX 15, at 25, with RX 16, at 66.

⁷ Of note, the prescription label lists the National Drug Code number of 0406–8530–01. GX 23, at 5. I take official notice that, according to the FDA's National Drug Code Directory website, this is the drug code for generic oxycodone 30 mg tablets marketed by Mallinckrodt, Inc. Respondent may refute this finding by filing a properly supported motion within ten (10) days of the date of this Decision and Order.

price” to pay for a 180 oxycodone 30 prescription was \$200 to \$250, it is true that she testified that did not know what price Respondent was paying for oxycodone in June 2012. *Id.* at 183. She also testified that she did not prepare a written analysis of the prevailing prices being charged for controlled substances during the period of February 2010 through July 2012. *Id.* at 181. However, the Inspector also testified that, based on her “experience as an inspector of pharmacies⁸ in the same area as [Respondent] on or around that time,” “less than \$200” and “at most \$250” was a more typical price for 180 dosage units of oxycodone 30. *Id.* at 168. Notwithstanding that the Inspector did not know what price Respondent was paying for oxycodone and did not prepare a written report, based on her experience as a pharmacy inspector, she was clearly competent to testify as to the prices being charged by other pharmacies for 180 dosage units of oxycodone 30. *See also* Tr. 161–62 (Inspector’s testimony that in determining whether pharmacies are filling legitimate controlled substances she looks at the prices being charged). I thus reject Respondent’s contention on this issue as well.

Next, Respondent argues that “[t]he ALJ incorrectly found based on [GX] 14 that sales of controlled substances were in the top ten products that [Respondent] sold from January 1, 2010 through August 29, 2014.” Exceptions, at 6 (citing FOF # 72). Respondent contends that “[t]he finding was erroneous and misleading because [the Exhibit] was an aggregate report of [its dispensing] for multiple years.” *Id.*

The ALJ’s finding was neither erroneous nor misleading as it specifically stated that this “report indicated that controlled substances were in the top 10 products that [Respondent] sold from January 1, 2010 to August 29, 2014.” R.D. at 15 (emphasis added). And even crediting Respondent’s evidence that shows that after 2010, the number of non-controlled prescriptions it dispensed “far exceeded the number of controlled” prescriptions that were dispensed, the evidence is what it is—a report of the dispensings during that time period. I thus reject Respondent’s challenge to this finding.

Respondent also challenges the ALJ’s finding that “[d]uring the four inspections conducted by the [DOH], [Respondent’s] dispensing and

corresponding responsibilities were discussed.” Exceptions, at 7 (citing FOF #76). Respondent maintains that “only two of the reports shown to Ms. Jones could be argued to relate to [the] corresponding responsibility—the reports of May 14, 2014 and August 29, 2014.” *Id.* Respondent discounts the inspection of April 14, 2011, during which the Inspector noted on the report (a copy of which was provided to Respondent’s representative) that:

[t]his pharmacy is filling and dispensing what appears to be a large amount of Schedule II Controlled Substance[] written prescriptions, especially for OXYCODONE Tablets, from patients whose home addresses are in Ohio, Kentucky, Tennessee, Connecticut, Indiana, Georgia, Massachusetts, South Carolina, New Jersey, West Virginia, New Hampshire, as well as from out of area locations in Florida such as Panama City, Fernandina Beach, Kissimmee, Sanford, Orange Park, Gainesville, Crestview, Port Orange, Daytona Beach, St. Cloud, Wesley Chapel, and Tavares.

GX 13, at 1.

In Respondent’s view, this report apparently does not establish that the corresponding responsibility was discussed at the inspection because Respondent “ceased filling prescriptions for out-of-state residents on April 1, 2011.” Exceptions, at 7 n.8. Respondent ignores, however, that the Inspector’s concerns were not limited to the oxycodone prescriptions dispensed to persons who came from other States and included the prescriptions it dispensed to Florida residents who came from out-of-area. Thus, even if the Inspector’s remarks did not specifically use the words “corresponding responsibility,” the remarks nonetheless put Respondent on notice that the Inspector was concerned about whether it was dispensing legitimate prescriptions.

In any event, the Agency’s corresponding responsibility rule has been in force for decades and numerous decisions of both the courts and the Agency have provided ample guidance as to the scope of a pharmacist’s duty under the rule. *See, e.g., Medicine Shoppe-Jonesborough v. DEA*, 300 Fed. Appx. 409, 412 (6th Cir. 2008); *United States v. Henry*, 727 F.2d 1373, 1378–79 (5th Cir. 1984); *United States v. Seelig*, 622 F.2d 207 (6th Cir. 1980); *United States v. Hayes*, 595 F.2d 258 (5th Cir. 1979); *see also Frank’s Corner Pharmacy*, 60 FR 17574 (1995); *Medic-Aid Pharmacy*, 55 FR 30043 (1990); *Ralph J. Bertolino*, 55 FR 4729 (1990). Having obtained a DEA registration and commenced dispensing controlled substance prescriptions, Respondent’s pharmacists were obligated to not fill

prescriptions when they either knew or were willfully blind to the fact that the prescriptions lacked a legitimate medical purpose. 21 CFR 1306.04(a). Thus, it is irrelevant whether the DOH Inspectors discussed with Respondent’s pharmacists their obligations under the Agency’s corresponding responsibility rule.

Exceptions to Findings Regarding the 2013 DEA Inspection

Respondent asserts that “[t]he ALJ’s finding of fact that [Respondent’s] inventory only indicated the name of the controlled substances, the strength of the controlled substances, the quantity, and ‘one’ of the NDC number was also erroneous.” Exceptions, at 8 (citing FOF #84). The ALJ’s Finding of Fact No. 84 stated:

DI Gonzales also noted that Ms. Jones’ biennial inventory was missing some of the required information. The inventory was supposed to indicate amounts of finished form in each container and the amount of commercial bottles that she had on hand during her inventory. Ms. Jones’ inventory only indicated the name of the controlled substances, the strength of the controlled substances, the quantity, and one of the NDC numbers.

R.D. at 17–18 (citing Tr. 35). According to Respondent, this finding was erroneous because the evidence “reflect[s] [that] the entire NDC number for the particular strength was listed on the biennial inventories not just ‘one’ of the NDC numbers.” Exceptions, at 8 (citing Tr. 472–73; 687; GX 5).

To be sure, the DI actually testified that Ms. Jones “only listed the name of the controlled substances, the strength of it, the quantity, and I believe on one of them the NDC number,” Tr. 35, thus suggesting that the ALJ misread the testimony. Nonetheless, the Agency’s regulation which sets forth the information which must be included on a pharmacy’s inventory does not require that the pharmacy list the NDC number for any drug. *See* 21 CFR 1304.11(e)(3) (requiring that a dispenser’s inventory include “the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section,” which does not include the NDC number). As Respondent was not required to list any NDC number, to the extent the finding erroneously states that the inventory “only indicated . . . one of the NDC numbers,” it is immaterial.

What is material is that the inventories were missing required information. Specifically, the inventory was required to include “[t]he number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

⁸The DOH Inspector had previously worked as a pharmacist for 33 years. Tr. 161. She also testified that in the three and a half years that she has been a DOH Inspector, she had inspected “[c]lose to 1,500” pharmacies in the Dade and Broward County areas. *Id.* at 160.

[t]he number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials)." *Id.* § 1304.11(e)(1)(iii)(C) & (D). Neither Respondent's November 3, 2011 inventory nor its April 13, 2013 inventory listed this information. *See* GX 5, at 1–14; Tr. 34–36, 38. Moreover, neither inventory indicated whether it was "taken either as of the opening of business or as of the close of business on the inventory date" as required by 21 CFR 1304.11(a). Tr. 36, 38.

Respondent nonetheless argues that Ms. Jones provided "unrebutted testimony . . . that the last two digits of the NDC number represent the bottle size of the medication (i.e., the number of tablets per bottle)." Exceptions, at 8. Respondent further asserts that when it fills prescriptions, it uses "the contents of open containers first, before opening another closed container of the same controlled substance," and thus, "while the biennial inventory did not contain a column for the number of containers, that number was easily derived from the information on . . . the biennial inventory." *Id.* Respondent then contends that "any factual finding that the DEA was unaware of the number of containers of controlled substances on hand is simply an argument of form over substance." *Id.* at 8–9.

This argument does not, however, establish that the ALJ's factual findings as to what information was missing from the inventory were not supported by substantial evidence. Rather, it is an argument which goes to the weight to be given to the violations. With the exception of the discussion in Finding of Fact No. 84 that the inventories contained just "one NDC" number, I find that the rest of the ALJ's findings as to what required information was missing from the inventories are supported by substantial evidence.

Respondent also takes exception to the ALJ's Finding of Fact No. 91, which was based on the testimony of a Diversion Investigator, that upon reviewing Respondent's electronic schedule II orders forms (DEA E222 forms), he found "480 line items that were done incorrectly."⁹ Exceptions, at 9 (quoting R.D. 19, FOF #91). Respondent submits that this finding is erroneous, because while the DI "testified to this, . . . DEA . . . bears the burden of proof [and] provided no independent evidence of the 480 line

items that were allegedly inappropriate." *Id.*

According to the DI, these E222 forms were not properly completed because while the distributor shipped the orders, Respondent's owner did not go back online and "input[] how many packages she received or the date she received them." Tr. 43. The Government also introduced various records showing several instances in which this occurred. GX 6, at 1–2; 3–5.

As evidenced by her factual finding, the ALJ clearly found credible the DI's testimony as to the number of line items that were not properly completed. Contrary to Respondent's contention, the DI's testimony alone provides substantial evidence to support these violations. I therefore reject this contention.

Exceptions to the Testimony of the Government's Expert

Respondent challenges several of the ALJ's factual findings that are based on the Government's Expert's testimony regarding a pharmacist's obligations in dispensing controlled substance prescriptions, and that in 2010, Florida pharmacists were generally aware of various red flags of abuse and diversion. R.D. 22–31; Tr. 240. First, Respondent challenges the ALJ's finding that "[i]n her role as a retail pharmacist, [the Expert] interacted frequently with other pharmacists in the area." R.D. 23, FOF #108 (citing Tr. 216) (cited in Exceptions, at 9–10). Respondent contends that the ALJ should not have credited this testimony because "[o]n cross-examination it became clear that [the Expert] could not identify any specific pharmacist she had talked to regarding the particular issues." Exceptions, at 10. However, the ALJ specifically addressed this portion of the Expert's testimony and while she noted that the Expert became hostile, the ALJ nonetheless found the Expert's testimony credible based on her years of experience. R.D. 24 n.13. Because the ALJ was in the best position to observe the Expert's testimony, and her testimony is not inherently implausible or inconsistent, I find no reason to reject the ALJ's credibility finding.

Next, Respondent challenges the ALJ's factual finding No. 113, which was based on the Expert's testimony that in determining whether a controlled substance prescription is issued for a legitimate medical purpose, one of "the biggest [signs] is when a patient asks you not to bill their insurance company and to pay cash for the prescription." Tr. 226; *see also* R.D. at 24; Exceptions, at 10. According to Respondent, "[t]his finding is erroneous

as the record is devoid of any evidence that anyone associated with the prescriptions at issue or otherwise, paid cash and simultaneously requested that [Respondent] not bill their insurance." Exceptions, at 10.

While it is true that there is no evidence in the record that any particular patients asked Respondent's pharmacists not to bill their insurance for the prescriptions, that does not render the finding erroneous. Indeed, other testimony, which stands unrefuted, is that drug seekers are willing to pay high prices in cash to obtain controlled substances and that "[o]ften the addicts will sell part of their prescription in order to pay this exorbitant amount of money¹⁰ for the prescription. So they take some and they sell some." Tr. 170. Moreover, a Supervisory Diversion Investigator, with 35 years of experience as a Diversion Investigator, testified that "paying cash" is a "red flag[] of diversion." Tr. 124. This witness further testified that:

Normally people pay with insurance. And these type of narcotics don't cost that much money, so that is usually an indication that the patient and the pharmacist know that these drugs are going to be diverted, that they'd be willing to pay more than \$1,000 for one prescription, for instance.

Id. at 125. *See also id.* at 33 (testimony of DI that upon review of Respondent's schedule II prescriptions, "we started discussing what we call as red flags, which a majority of [the prescriptions] were for Oxycodone 30 milligram And then we also noticed that they were all being paid for in cash."); *id.* at 51 (DI's testimony that upon reviewing the dispensing records, one of the concerns was that "a majority of the prescriptions were being paid [for] by cash.").

The evidence further shows that 93 percent of the controlled substance prescriptions dispensed by Respondent from February 15, 2010 through July 3, 2012 were paid for with cash or cash equivalents. Tr. 57; *see also* GX 2 (spreadsheet of the controlled substance prescriptions showing, *inter alia*, the method of payment). The Government's Expert testified that in her experience, "only . . . maybe five percent of the patients pay cash," Tr. 285, a figure which is consistent with other evidence provided by the Government, specifically, an April 2012 report prepared by the IMS Institute for Healthcare Informatics, which, based on

⁹ Prior to testifying as to the number of line items that were done incorrectly, the DI testified regarding several E222 order forms that were submitted for the record, noting that the forms "did not indicate how many packages Ms. Jones received or the date that she received the ordered packages." Tr. 39–43; *see also* GX 6.

¹⁰ This testimony was provided by the DOH Inspector in reference to the \$1,620 price for 180 oxycodone 30 which Respondent was charging at the time of the June 2012 inspection. *See generally* Tr. 165–67.

its National Prescription Audit, found that out of 4.024 billion prescriptions dispensed during 2011, cash was the method of payment for only 258 million prescriptions or 6.4 percent. GX 29, at 42.

Respondent takes issue with the ALJ's having allowed the Government's Expert "to testify about the . . . report." Exceptions, at 11. It argues that the Government's Expert "had no personal knowledge to how the report was compiled and the report was not reflective of the South Florida community [sic] which [Respondent] was located." *Id.* Respondent also argues that the report "did not address the record evidence that Florida had one of the highest uninsured rates for individuals." *Id.*

While Respondent is correct that the Government's Expert did not have personal knowledge as to how the report was compiled and the report does reflect nationwide data, Respondent ignores that the Expert testified that in her experience, which includes 17 years as a retail pharmacist and a substantial period working at pharmacies in Broward and Dade County, only five percent of patients pay cash for their prescriptions. Respondent also ignores that its Expert agreed that six percent was an accurate figure for the nationwide average.

Moreover, while Respondent produced a Census Bureau Report which shows that in 2012, 20.1 percent of Floridians did not have what the Census Bureau defines as "comprehensive health insurance" coverage, the Report clearly stated that "[t]his definition excluded single service plans, such as accident, disability, dental, vision or prescription medicine." RX 33, at 7, 24. Thus, the actual percentage of persons lacking insurance covering their prescriptions is likely less than the 20.1 percent figure.¹¹ Moreover, even ignoring that 49 percent of the prescriptions in GX 2 were filled for out-of-state customers, there is still a wide disparity between the percentage of prescriptions that were paid for with cash and what one would expect based

¹¹ Respondent also produced a reprint of an article from the Kaiser Health News which was attributed to the Miami Herald; the article states that Broward County's uninsured rate was 26 percent and was purportedly based on census data. RX 33, at 1. However, this document is hearsay and actually contains hearsay within hearsay. In contrast to the figure provided in the IMS Report, which has been corroborated by both the Government's and Respondent's experts, Respondent has made no showing to establish the reliability of the statements in the Miami Herald article. See *J.A.M. Builders v OSHA*, 233 F.3d 1350 (2000). Nor is there any tradition of courts accepting newspaper articles as reliable evidence of the statements contained in them.

on the Census Bureau's figure regarding the percentage of uninsured Floridians.

Finally, Respondent takes exception to the ALJ's crediting the Government Expert's "testimony that 'a pharmacist could also go to the [DOH's] website and lookup the prescriber's specialty.'" Exceptions, at 10 (citing FOF #115). According to Respondent, the Government's Expert "was impeached" on cross-examination "and conceded that with regard to the cited example the DOH website only lists the training that a particular physician had and not necessarily their area of expertise." *Id.* at 10–11 (citing Tr. 339).

To be sure, in this portion of the transcript, Respondent's counsel questioned the Government's Expert about a physician whose profile showed that he had done a residency in pediatrics but did not list any specialty certification. See GX 35, at 3. However, the DOH profiles for other physicians do include their "certifications from specialty boards recognized by the Florida board which regulates the profession for which he/she is licensed." GX 36, at 2–3 (profile of Dr. S.K. showing that he was board certified in "Family Practice" by the "American Board of Family Medicine."); see also, e.g., GX 37, at 2–3 (profile of Dr. J.F. showing that he was board certified in "Family Practice" by the "American Osteopathic Board of Family Physicians"); GX 38, at 2–3 (profile of Dr. R.T. showing that he was board certified in "Obstetrics and Gynecology" by the "American Board of Obstetrics & Gynecology"); GX 42, at 2–3 (profile of Dr. R.W. showing that he was board certified in "Emergency Medicine" and "Internal Medicine" by the American Boards of Emergency Medicine and Internal Medicine).

Moreover, many of the prescriptions in the record also listed the prescriber's NPI (National Provider Identifier) number and the Government's Expert provided unrefuted testimony that a pharmacist can use an NPI number and look up a physician's specialty. Tr. 228. Notably, Respondent did not take exception to this portion of the ALJ's factual finding number 115. See Exceptions, at 10.

Respondent also argues that the Government's Expert acknowledged on cross-examination that the prescriptions contained, in the words of Respondent's counsel, "no indication that a doctor is practicing within any particular scope," Tr. 337, and that "there is no prohibition in the medical field [against] a physician writing a prescription for a particular drug regardless of the area in which they may specialize." Exceptions, at 11 (citing Tr. 337, 339). As for the

first concession, while it is true that the prescriptions typically did not list the doctor's specialty, the Government's Expert provided testimony which the ALJ found credible that it is important for a pharmacist to know the scope of the physician's practice because a doctor's deviation from his specialty "could indicate a possible red flag." R.D. 25 (FOF# 115). So too, even assuming that in Florida, a physician is not prohibited from prescribing a particular drug regardless of the area in which he/she specializes, certainly when physicians issue prescriptions for large quantities of highly abused controlled substances such as oxycodone 30, alprazolam 2, and in many cases carisoprodol, and these drugs are not usually prescribed by physicians with a particular specialty, there is a compelling reason to question the legitimacy of the prescription. I thus reject Respondent's challenges to the testimony of the Government's Expert.¹²

Exceptions to "Alleged Red Flags Within Jones Pharmacy's Prescriptions"

Next, Respondent argues that the ALJ erred in finding that Respondent "filled prescriptions for patients that 'traveled from North Carolina to see doctors in Deerfield Beach.'" Exceptions, at 12 (quoting R.D. 28, FOF # 123 and citing GXs 16 and 44). Respondent argues that "there was no evidence in the record that any particular patients travelled from North Carolina" and that the Government provided "no evidence that such individuals had traveled to Florida for the purposes of obtaining the prescription as opposed to already staying in Florida for an extended period of time." *Id.* Continuing, Respondent maintains that "[t]he only

¹² For the same reason, I reject Respondent's Exceptions to the ALJ Factual Findings Nos. 128 and 130. As for Finding No. 128, it discussed prescriptions written by one Dr. K., who was affiliated with "The Pain Center of Broward," for D.T., a male patient whose address was in West Virginia. Exceptions, at 13. Specifically, Dr. K. prescribed 107 du of oxycodone 30, 41 du of oxycodone 15, and 30 alprazolam 2mg, which D.T. filed at Respondent paying \$791 in cash for the drugs. GX 48.

While Respondent argues that the Government presented no evidence concerning Dr. K.'s "then current practice area," the DOH website shows that he was board certified in Obstetrics and Gynecology. See GX 40, at 4. And even though the prescription did not indicate that Dr. K. was practicing in an area different than his specialty, the Government's Expert provided credible testimony that a pharmacist needs to know a prescriber's practice area when evaluating whether a controlled substance prescription has been issued for a legitimate medical purpose. Indeed, the circumstances attendant with D.T.'s prescriptions provided compelling evidence that the prescriptions lacked a legitimate medical purpose and should have prompted additional investigation into Dr. K.'s background.

evidence in the record concerning these individuals [sic] residence was the fact that the individuals presented licenses from the State of North Carolina.” *Id.*

With respect to these two patients (L.S. and J.S.), whose driver’s licenses showed that they had the same last name and resided at the same residence in Charlotte, North Carolina, the prescriptions they presented raised numerous other red flags. Specifically, each of these individuals went to the same pain clinic in Deerfield Beach and obtained prescriptions for large quantities of oxycodone and alprazolam that were frequently identical and paid approximately \$500 to \$600 in cash (or cash equivalents) for their drugs when they filled the prescriptions. *See* GX 16; GX 44; Tr. at 230 (discussing red flags). Moreover, at each visit, the patients obtained prescriptions for two short-acting formulations of oxycodone. According to the Government’s Expert, this is a red flag because with legitimate chronic pain management, “the patient should present a prescription for a long acting plus a short acting,” with the latter being used for breakthrough dosing. Tr. 229. The Government’s Expert further explained that “drug seekers tend to want the short acting medications because those are the ones that will give them those immediate highs” and you “don’t get the high you do from the long acting that you do from the short.” *Id.*

As the evidence shows, on March 11, 2010, L.S. and J.S. received the exact same three prescriptions from the same doctor, Rene Casanova,¹³ which Respondent filled the next day: 210 oxycodone 30, 90 oxycodone 15 and 75 alprazolam 2. *See* GX 16, at 1–11. At their April 8, 2010 visit to the clinic, L.S. and J.S. saw Dr. Randall Wolff.¹⁴ While Dr. Wolff did not prescribe alprazolam to them, he nonetheless issued both of them prescriptions for 210 oxycodone 30 and 90 oxycodone 15. *Id.* at 13–19. While at their next visit (May 6, 2010) to the pain clinic, a different doctor, Charles Neuringer,¹⁵ issued them slightly different prescriptions for oxycodone 30 (210 du

to L.S. and 180 to J.S.), he provided them with identical prescriptions for 90 oxycodone 15 and 60 alprazolam 2, at their June 2, 2010 visit, Dr. Neuringer provided them with identical prescriptions for 180 du of oxycodone 30, 90 oxycodone 15, and 60 alprazolam 2.¹⁶ *Id.* at 21–44. Thus, even if the Government did not produce evidence that these two persons were travelling from North Carolina each time they obtained the prescriptions, there were ample other red flags that provided compelling evidence that the prescriptions they presented and Respondent filled lacked a legitimate medical purpose.

Moreover, even if the Government did not show that L.S. and J.S. were travelling from North Carolina each time they obtained prescriptions and filled them at Respondent, the evidence shows that between February 15, 2010 and April 1, 2011, Respondent dispensed more than 1,500 controlled substance prescriptions to more than 500 patients whose addresses indicated that they did not live in Florida. GX 2. The patients came from such States as North Carolina, Ohio, West Virginia, Kentucky, Tennessee, Mississippi, Georgia, and others. *Id.* Given the number of these patients, I find it likely that many of them were traveling to Florida in search of controlled substances.

Respondent also takes exception to the ALJ’s crediting of the testimony of Government’s Expert regarding prescriptions issued by Dr. M. to R.H. for 180 oxycodone 30, 112 Endocet (oxycodone/acetaminophen) 10/325, and 90 carisoprodol 350. Respondent dispensed the prescriptions, and charged R.H. \$945 for the oxycodone 30, \$196 for the Endocet, and \$41.08 for the carisoprodol, for a total of \$1182 in cash. GX 19; GX 47. According to the prescriptions, R.H. resided in Panama City, Florida, which is in the Florida panhandle and on the other side of the State from Fort Lauderdale. *Id.*

Respondent objects to the ALJ’s finding that these medications were “prescribed to a 56 year old man¹⁷ by a pediatrician,” arguing that the prescriptions “on their face solely indicated that the physician . . . was associated with the Intercoastal [sic] Medical Group” and did not reflect that the doctor was a pediatrician. Exceptions, at 12. Respondent further contends that Dr. M.’s DOH Physician Profile indicated only that he had done

a residency in pediatrics and there was no testimony as to his current practice. *Id.*

However, even ignoring that Dr. M.’s DOH profile did not list Dr. M. as having any specialty certification, *see* GX 35, at 3; let alone certification in a specialty such as pain management, oncology, or hospice and palliative medicine, *see* Tr. 229, these prescriptions raised numerous other red flags which provided compelling evidence that the prescriptions likely lacked a legitimate medical purpose. These included the drugs, strength of the dosage units and quantities prescribed; the distance R.H. likely travelled to obtain the prescriptions; and R.H.’s willingness to pay nearly \$1200 in cash for the drugs. Indeed, were R.H. a legitimate chronic pain patient, these prescriptions would have cost him more than \$14,000 a year. Thus, I reject Respondent’s exception to the ALJ’s Finding of Fact No.128.

Next, Respondent takes exception to the ALJ’s crediting of the Government’s Expert’s testimony regarding Respondent’s dispensing of prescriptions for 180 oxycodone 30 and 30 Xanax 2 which were written by a doctor in Sunrise, Florida for three persons from West Palm Beach. Exceptions, at 13 (citing R.D. 30–31, FOF# 130). Respondent states that “[t]he ALJ accepted [the Expert’s] statement that the doctor was ‘rubberstamping the prescriptions and there was no individualized treatment.’” *Id.* (quoting FOF #130). Respondent argues that the Expert’s testimony was “wholesale speculation” because she did not review patient files, or interview the patients or the doctors. *Id.*

Putting aside that ALJ’s actual finding was that “this *appeared* to be an instance where the doctor was ‘rubber stamping’ the prescriptions,” R.D. at 30 (emphasis added), Respondent does not address other portions of the ALJ’s findings, including that the prescriptions were for cocktail medications and that Xanax 2 mg is a high dose of Xanax. *Id.*; *see also* Tr. 270–71. Moreover, the prescription numbers assigned by Respondent show that the prescriptions were presented sequentially, and the evidence shows that each of the patients paid \$900 in cash for the oxycodone 30 prescriptions. GX 50, at 2; GX 2 (line items 2541–2546). Respondent also fails to explain why legitimate patients would be willing to travel from West Palm Beach

¹³ I take official notice that following a hearing, on September 19, 2012, the former Administrator revoked Dr. Casanova’s registration based on her findings that he issued controlled substance prescriptions which lacked a legitimate medical purpose in violation of 21 CFR 1306.04(a). *See Rene Casanova*, 77 FR 58150, 58151–52 (2012).

¹⁴ Following a hearing, on January 19, 2012, the former Administrator revoked Dr. Wolff’s registration based on her findings that he issued controlled substance prescriptions which lacked a legitimate medical purpose in violation of 21 CFR 1306.04(a). *See* GX 42, at 1; *see also Randall L. Wolff*, 77 FR 5106, 5121–22 (2012).

¹⁵ On or about December 17, 2010, Dr. Neuringer surrendered his registration for cause. GX 41, at 1.

¹⁶ Respondent filled the May 6 and June 2 prescriptions the same day they were issued.

¹⁷ The prescription label lists R.H.’s birthdate as April 2, 1954. GX 19, at 2.

down to Sunrise¹⁸ to obtain prescriptions and pay \$900 cash for just the narcotic, which was highly sought after by drug abusers and diverters. Thus, even accepting that three persons presenting the same prescriptions on a single day from the same doctor does not conclusively establish that the latter was engaged in “rubber stamping” or “pattern prescribing,” there were ample other indicia which created a strong suspicion that the prescriptions lacked a legitimate medical purpose.

Exceptions to the ALJ’s Findings Regarding the Testimony of Respondent’s Expert

Respondent also argues that in her Finding of Fact #190, “[t]he ALJ erroneously made findings . . . concerning [its Expert’s] testimony as it relates to corresponding responsibility.” Exceptions, at 14. According to Respondent, “the ALJ made findings . . . that [its Expert] indicated that she has not done any research about the corresponding responsibility of a pharmacist; had not given any presentations about the corresponding responsibility of a pharmacist since 2007; and has not published any research on corresponding responsibility issues.” *Id.* (citing R.D. 46). Respondent contends that these findings are contrary to its Expert’s un rebutted testimony that “she sat on the National Association for Board of Pharmacy and sat on a task force for the DEA” on “the implementation of prescription monitoring programs.” *Id.* (citing Tr. 795). According to Respondent, its Expert testified that “it was very conceivable that [the] corresponding responsibility did come up in this context.” *Id.* Respondent further notes that its Expert “testified that she has done research on the area of corresponding responsibility” because she teaches students in simulated pharmacy dispensing exercises and “needed to know that knowledge as well for regulatory compliance in the stores I supervise.” *Id.* (quoting Tr. 799).

As an initial matter, Respondent’s Expert actually testified that she “needed to know that knowledge as well for regulatory compliance in the stores I supervised.” Tr. 799 (emphasis added). Notably, the evidence shows that the Expert last supervised retail pharmacy stores in 2006, when she went to work for the Institute for Safe Medication Practices. Tr. 717; RX 24 (Expert’s Resume). Thus, as of the

hearing, Respondent’s Expert had not worked in regulatory compliance in nearly a decade.

As for her participation on the task force on prescription monitoring programs, her actual testimony was: “I don’t know if we ever discussed that . . . that term [*i.e.*, the corresponding responsibility], but we had a task force with DEA, so to the extent that the DEA wanted to bring that up, we would talk about it.” Tr. 794. When pressed by the Government if the term came up, Respondent’s Expert answered: “But I can’t remember it. I don’t remember,” after which she testified that she did not remember one way or the other but stated that it was “very conceivable that the term would have come up.” *Id.* at 794–95.

Respondent also cites to other portions of its Expert’s testimony regarding her knowledge of a pharmacist’s corresponding responsibility, including her testimony that she has reviewed administrative decisions published by the Agency, the DEA Pharmacist’s Manual, and “pharmacy journals to the extent that they’ve published anything about that.” Tr. 800; *see also* Exceptions, at 14. Respondent also notes that its Expert “is a member of the American Society of Pharmacy Law.” Exceptions, at 14–15. However, when asked whether the corresponding responsibility had been discussed at any of the Society’s meetings, Respondent’s Expert answered: “I don’t remember.” Tr. 801.

The ALJ specifically found that “the testimony of Respondent’s Expert . . . is not credible as it relates to the general knowledge of Florida pharmacists from 2010 to 2012.” R.D. 68. Having reviewed the record and ALJ’s findings, I agree with the ALJ and her reasons for declining to credit the testimony of Respondent’s Expert.

As explained above, Respondent’s Expert has not supervised retail pharmacies in nearly a decade and, in her own testimony, she acknowledged that she has not filled a prescription in 15 years. Tr. 794. Moreover, Respondent’s Expert is licensed only in Massachusetts and while she “did a consulting job in Florida,” she has not worked as a dispensing pharmacist in the State.¹⁹ RX 24, at 1; Tr. 737.

Also, much of her testimony as to how she has become knowledgeable on a pharmacist’s corresponding responsibility was vague. While Respondent’s Expert claimed to have reviewed various Agency decisions including *East Main Street Pharmacy*,

75 FR 66149 (2010), in determining what red flags of abuse and diversion were generally known to pharmacists during the period of 2010 through 2012, she then opined that she did not believe that many of the red flags identified in that decision²⁰ were widely known to be indicators of diversion and abuse.

For example, Respondent testified that in her opinion, the combination of prescriptions for a narcotic, a benzodiazepine, and carisoprodol “would [not] signify a pattern of drug abuse to pharmacists in 2010.” Tr. 865. Yet, based on the expert testimony in *East Main Street Pharmacy*, the Agency found that “the combination of a benzodiazepine, a narcotic and carisoprodol is ‘well known in the pharmacy profession’ as being used ‘by patients abusing prescription drugs.’”²¹ 75 FR at 66163.

Respondent also testified that she did not believe that it was widely known in 2010 that a patient paying cash was an indicator of abuse or diversion. Tr. 864. However, in *East Main Street*, the Agency found, based on expert testimony, that “any reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect.” 75 FR at 66158.

Respondent’s Expert also opined that she did not believe that patients travelling long distances to obtain prescriptions was widely known in 2010 to be an indicator of abuse or diversion of prescription drugs. Tr. 864. However, in *East Main Street*,²² the Agency found that “the fact that the patients were driving so far to get their prescriptions filled ‘would be a major red flag to any pharmacist.’” 75 FR at 66164; *see also id.* at 66158 (discussing testimony of expert witness that the fact that patients were “driving 2 + hours” to fill prescriptions “would be a major red flag to any pharmacist and that a reasonable pharmacist would seriously question why these patients were driving such a long distance to have their prescriptions filled” and that “the number one reason” consumers shop at certain pharmacies “is proximity to where they live”).

²⁰ Of note, the *East Main Street* findings were based on the testimony of an expert witness for the Government. 75 FR at 66156.

²¹ In *East Main Street*, the Agency also noted the Government Expert’s testimony that “these cocktails would have a synergistic effect on a person’s central nervous system and could cause respiratory depression.” 75 FR at 66163.

²² In *East Main Street*, the patients were generally travelling from the Portsmouth, Ohio and northern Kentucky to Columbus, Ohio, a considerably shorter distance than that travelled by many of the patients in this matter. *See* 75 FR at 66158.

¹⁸ According to a query conducted on Mapquest, of which I take official notice, Pt. W.F. resided approximately 47 miles from Dr. A.M.’s office.

¹⁹ Respondent’s Expert did not further explain what the “consulting job” involved. Tr. 737.

As for whether, in 2010, pattern prescribing was also an indicator that prescriptions were not issued for a legitimate medical purpose, Respondent's Expert opined that she did not believe that this "was widely known by pharmacists" to be "happening." Tr. 865. Yet, in *East Main Street*, the Agency found that "in the prescriptions he reviewed, the Government's Expert observed that there was 'no individualization of dosing based on pain in these patients' with respect to the hydrocodone and alprazolam prescriptions and that 'any pharmacist would have known that this was a problem and a strong indicator of a doctor operating a controlled substance prescribing mill.'" 75 FR at 66163.

Finally, when asked whether in her view, it was widely known in 2010 that Xanax in the two milligram dosage was to be used in "only very rare circumstances," Respondent asserted that "it was not widely known that Xanax should be reserved for certain circumstances." Tr. 865–66. However, in *East Main Street*, the Agency found that "with respect to the alprazolam, the Government's Expert explained . . . that the two-milligram strength . . . is generally only prescribed for a patient with post-traumatic stress disorder." 75 FR at 66163.

Respondent's Expert further maintained that the first time DEA publicly addressed the issue of out-of-state patients coming to pharmacies was in the 2012 *Holiday CVS* decision. Tr. 752–53; see also *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 FR 62316, 62321 (2012). However, in *East Main Street*, the Agency had noted that "approximately half" of the pharmacy's patients "were coming from Kentucky," which "was more than two hours away," and that this "would be a major red flag to any pharmacist." 75 FR 66164. Beyond this, it is obvious that patients travelling great distances to obtain large quantities of potent narcotics such as oxycodone 30 are likely seeking the drugs to either abuse them or divert them to others.²³

²³ Respondent's Expert also testified that the first reference to the term "red flag" that she could find in DEA's public pronouncements was in the *Holiday CVS* decision. Tr. 753. However, the term appears in DEA administrative decisions involving practitioners including pharmacies even earlier than in *East Main Street*. See *Paul J. Caragine*, 63 FR 51592, 51600 (1998); see also *Medicine Shoppe-Jonesborough*, 73 FR 364 (2008); *United Prescription Services, Inc.*, 72 FR 50397 (2007). It also has appeared in federal court decisions that predate 2010. See *United States v. Johnston*, 322 Fed. Appx. 660, 666–68 (11th Cir. 2009); *Medicine Shoppe-Jonesborough v. DEA*, 300 Fed. Appx. 409, 413 (6th Cir. 2008); *United States v. Alerre*, 430 F.3d 681, 686 (4th Cir. 2005); *United States v. Chin*, 795 F.2d 496, 502 (5th Cir. 1986).

Respondent also argues that the ALJ "erroneously made findings that suggested [that its Expert's] opinions in this case that [it] should maintain its . . . registration was based solely on her 'conversations with Ms. Jones.'" Exceptions, at 15 (quoting R.D. 47, FOF#194). The ALJ did not, however, find that the Expert's Opinion was based "solely" on her conversations with Ms. Jones. See R.D. 47, FOF#194. Indeed, the ALJ specifically noted the Expert's testimony that Respondent "has displayed a 'positive trend downwards as to the amount of controlleds that are dispensed per non-controlleds.'" *Id.* (quoting Tr. 785). And the ALJ also acknowledged that Respondent's Expert had reviewed Respondent's policies and "opined that Ms. Jones has changes 'policies and procedures as she [has] learned about things.'" R.D. 48, FOF#197 (citing Tr. 832–33 and quoting Tr. 850).

However, the ALJ also noted that Respondent's Expert "did not offer any opinions as to whether or not [Respondent's] dispensing of controlled substances was abnormal in 2010 [through] 2012." R.D. 47, FOF #195. Indeed, when asked if she was offering any opinion as to whether Respondent's dispensing in this period "was atypical or abnormal," Respondent's Expert answered: "No, but I do think she did exercise her corresponding responsibility in 2014." Tr. 809. Respondent's Expert further admitted that she was not "offering any opinions . . . on whether . . . any specific prescriptions was or was not filled by [Respondent] in compliance with [its] corresponding responsibility." *Id.* Respondent's Expert also testified that she was not offering any opinions as to whether the extent to which Respondent filled prescriptions for cash or for out of state patients was atypical or abnormal. *Id.* at 810–812.

In short, having reviewed Respondent's exceptions to the ALJ's findings as to the testimony of its Expert, I find no reason to reject the ALJ's credibility finding.²⁴

In any event, the term "red flag" has been part of the lexicon for more than 200 years, and whether the Agency has used this term, or such terms as "warning signs" or "suspicious circumstances," is of no consequence. See III The Compact Edition of the Oxford English Dictionary 1132 (1987) (noting term's use "[a]s a sign of danger, a warning, or a signal to stop"); *Jayam Krishna-Iyer*, 74 FR 459, 460–61 n.3 (2009). What matters is whether Respondent's pharmacists either knew or were willfully blind to the fact that the controlled substance prescriptions they dispensed lacked a legitimate medical purpose. 21 CFR 1306.04(a).

²⁴ In this section of its Exceptions, Respondent also takes issue with the ALJ's finding that "[t]he Florida E-FORSCE website indicated that the system was created in 2009 by the Florida

Exceptions to the ALJ's Conclusions of Law

Exceptions to the ALJ's Legal Conclusion as to Factor One

In discussing Factor One—the recommendation of the state licensing board—the ALJ found that the record did not contain a recommendation from the Florida Board or any evidence of disciplinary action taken against Respondent or Ms. Jones. R.D. at 57–58. Noting that under DEA precedent, "[t]he ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA [and] not to entities within state government," the ALJ held that the absence of a recommendation or disciplinary action against Respondent (or Ms. Jones) is not dispositive and neither weighs in favor of, or against, a determination as to whether Respondent's continued registration is consistent with the public interest. R.D. at 58 (citing *Top Rx*, 78 FR 26069, 26081 (2013); *Edmund Chein*, 72 FR 6,580, 6590 (2007), *pet. for rev. denied Chein v. DEA*, 533 F.3d 828 (D.C. Cir. 2008)).

Respondent argues that the actions of the DOH in conducting six inspections, which found that "in virtually all of those exams, and certainly all exams subsequent to 2012," Respondent "was in compliance with all rules and regulations including those relating to the maintenance of ordering forms and inventory," "should be deemed as persuasive for continued registration." Exceptions, at 16. However, this statement is contradicted by the record evidence related to the DOH inspections.²⁵

legislature." Exceptions, at 15 (citing R.D. 41 n. 21). Respondent argues that "[i]t appears the ALJ may have performed independent research concerning the E-FORSCE system because it does not appear that either party introduced the website" into evidence. *Id.* Respondent notes that neither party requested that the ALJ to take judicial notice of the website. *Id.* Respondent further argues that the E-FORSCE system did not become operational until September 1, 2011. Exceptions, at 15–16 (citing a fact sheet at the website).

The ALJ did not, however, base her finding that Respondent's pharmacists violated their corresponding responsibility on their failure to use the E-FORSCE system in determining whether to dispense the prescriptions. Nor do I. Thus, the ALJ's noting that the Florida legislature enacted the legislation creating the system in 2009 is not a material fact and no error was committed. See 5 U.S.C. § 556(e) ("When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.').

²⁵ For example during the June 10, 2013 Inspection, the Inspector found that Respondent was non-compliant with the requirement that it report controlled substance dispensings to the PDMP within 7 days. RX 8, at 3. Also, during the

Respondent also argues that because “the State has taken no action adverse to [it], the ALJ should have found that this factor weighed in favor of continued registration.” *Id.* (citing *Physicians Pharmacy, L.L.C.*, 77 FR 47096 (2012)). However, while Respondent retains its state authority, the Agency has long held that possession of state authority is a prerequisite for obtaining and maintaining a registration.²⁶ Whether a registrant retains its state license is not a factor in determining whether it has committed acts which render its registration inconsistent with the public interest.²⁷ Thus, in the absence of a recommendation regarding Respondent’s registration, Respondent’s continued possession of its State authority is not dispositive and neither supports nor refutes the Government’s contention that its registration is “inconsistent with the public interest.” 21 U.S.C. § 823(f). Accordingly, I agree with ALJ’s ruling that factor one “does not weigh for or against a determination as to whether the Respondents’ continued registration is consistent with

August 29, 2014 inspection, the DOH Inspector found that Respondent was non-compliant with Florida law requiring that it maintain controlled substances records “for 4 years.” *Id.* at 1. Also at the latter inspection, the Inspector noted that “controlled substance invoices are mixed in with non-controlled” and that “CII should be separate and CIII–V should be marked if filed with noncontrols [sic] [and] must be readily retrievable from all other records.” *Id.* Of note, under 21 CFR 1304.04(h)(1), “[i]nventories and records of all controlled substances listed in schedule I and II shall be maintained separately from all other records of the pharmacy.”

²⁶ Thus, consistent with the structure of section 823(f), determining whether an applicant possesses state authority is an inquiry which is required before the Agency considers the public interest factors. See 21 U.S.C. § 823(f). And in revocation proceedings, a registrant’s loss of state authority is a basis for revoking a registration which is independent from the determination of whether a registrant has committed such acts as to render its registration inconsistent with the public interest. Compare *id.* § 824(a)(3) with *id.* § 824(a)(4).

To be sure, there are cases in which the Agency has adopted a recommended decision which endorsed the view that the possession of a valid state license “weighs against a finding that Respondent’s registration would be inconsistent with the public interest.” However, whether an applicant possesses the requisite state authority is properly viewed as a threshold matter which is to be considered before the public interest determination is made.

²⁷ Certainly conduct which causes a State Board to suspend or revoke a practitioner’s controlled substances authority may involve controlled substances and provide a basis to revoke under the public interest standard. But a State Board may also suspend or revoke a practitioner’s state authority for reasons having nothing to do with a registrant’s controlled substance activities; while such cases do not implicate the public interest standard, they are nonetheless grounds to revoke based solely on the registrant’s loss of state authority. 21 U.S.C. § 824(a)(3).

the public interest,” R.D. 58, and reject the exception.

Exceptions to the ALJ’s Legal Conclusions as to Factors Two and Four

In her decision, the ALJ found that Respondent “violated recordkeeping requirements by failing to record whether [its] biennial inventory was taken at the opening or close of business, and by failing to indicate the number of tablets per opened commercial container, the number of tablets shipped in each commercial container, and the number of commercial containers that Ms. Jones had on hand.” R.D. at 59 (citing 21 CFR 1304.11(e)(3)). Reasoning that without “a complete inventory, the DEA is unable to conduct an accurate accountability audit,” the ALJ, while acknowledging that “the inventory was complete in other aspects,” then explained that “Ms. Jones’ partial compliance does not obviate her failure to record the required the information on the biennial inventory.” *Id.* at 60. The ALJ further explained that “Respondent’s lack of attention to detail with its accountability of the controlled substances received and dispensed is adequate grounds for recommending [the] revocation of [its] registration.” *Id.* (citing *Alexander Drug Co.*, 66 FR 18299, 18303 (2001) (citing *Singers-Andreini Pharmacy, Inc.*, 63 FR 4668 (1998))).

Respondent argues that the ALJ’s conclusion “was one of form over substance” and that “the un rebutted testimony of Ms. Jones, the biennial inventories presented, [its] expert[s] testimony . . . , and the DOH inspections, all establish that Jones Pharmacy was in substantial compliance with the applicable regulation,” and that this standard “is recognized in DEA regulations.” Exceptions, at 17, 19 (citing 21 CFR 1301.71(b)). Respondent further argues that revocation is not warranted based on “these minor deficiencies.” *Id.* at 19.

Contrary to Respondent’s understanding, the “substantial compliance” standard applies only with respect to the Agency’s assessment of an applicant’s/registrant’s “overall security system.” 21 CFR 1301.71(b). Moreover, in the Controlled Substances Act, Congress set the standard for assessing the adequacy of a registrant’s inventories by requiring that “every registrant . . . make a complete and accurate record of all stocks thereof on hand.” 21 U.S.C. § 827(a)(1) (emphasis added). See also *id.* § 827(a)(3) (requiring that “every registrant . . . shall maintain . . . a complete and accurate record of each such substance

. . . received, sold, delivered, or otherwise disposed of”).

Under DEA’s regulations, Respondent’s inventories were neither complete nor accurate. They were not complete because they did not list the number of commercial containers on hand and the number of units in each such container. See 21 CFR 1304.11(e)(3); *id.* § 1304.11(e)(1)(iii)–(iv). Nor were they accurate because they did not indicate whether the inventory was taken “as of [the] opening of business or as of the close of business.” *Id.* § 1304.11(a). In the absence of the inventories indicating whether they were taken at the opening or close of business, DEA personnel conducting an audit would not know whether to count the prescriptions dispensed and any shipments received (as well as any returns or other dispositions) on the dates that the inventories were taken.

Respondent nonetheless argues that because the inventories listed the NDC number of the controlled substances, and “the last two digits of the NDC number represent the bottle size,” the inventories contained the required information. Exceptions, at 18. While it may be that the last two digits of an NDC number indicate the bottle size, there are a multitude of different manufacturer’s controlled drug products on the market and DEA personnel had no obligation to investigate what bottle size corresponded with the various NDC numbers listed on Respondent’s inventories.²⁸

Moreover, despite her factual finding that 480 line items on Respondent’s schedule II order forms were not completed correctly, the ALJ did not draw a legal conclusion as to whether Respondent was in compliance with DEA’s regulations. Compare R.D. at 18–19 (FOF Nos. 89–91), with *id.* at 58–60 (discussing legal conclusions with respect to recordkeeping). I find that Respondent violated DEA regulations by failing to properly record “the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.” 21 CFR 1305.13(e).

²⁸ Respondent also asserts that its Expert “found it compelling that the DOH remarked in the October 12, 2011 DOH report that [it] had a zero (0%) percent error rate on its physical inventory.” Exceptions, at 18. Putting aside that the Inspector’s comment pertained to an audit he conducted and not an inventory, see RX 8, at 7; the Inspector’s Report noted that Ms. Jones had not provided a controlled drug report and that the software company had to be contacted “in order to figure out how to print the report.” *Id.* Thus, the DOH Inspector’s audit likely did not include controlled substances.

While Respondent argues that the violations found by the ALJ do not support revocation, I need not decide whether these violations, including those based on its failure to properly complete the order forms, would support the revocation of Respondent's registration as opposed to some lesser sanction. This is so because the evidence shows that Respondent has committed egregious dispensing violations which fully support the denial of both its and SND's applications.

Exceptions to the ALJ's Findings That Respondent Violated Its Corresponding Responsibility

Respondent raises five arguments as to why I should reject the ALJ's legal conclusion that it violated 21 CFR 1306.04(a). The first three of these are based primarily on the ALJ's reliance on the testimony of the Government's Expert that many of the prescriptions presented red flags which were unresolvable. They include that: (1) Government's Expert was not qualified to testify as an Expert; (2) the Expert was biased; and (3) its right to due process was violated when the ALJ denied its request for a copy of the Expert's report. Exceptions, at 20–24. As for its other contentions, Respondent argues that: (4) Substantial evidence does not support a finding that Respondent knew or should have known of the various red flags, *id.* at 24–29; and (5) this proceeding “may have been brought for punitive reasons” because Respondent's owner complained to her congressional representatives when DEA failed to approve her request to change her registered location. *Id.* at 30. I find that none of these contentions have merit.

Respondent's Challenges to the Government's Expert

Respondent first challenges the ALJ's ruling accepting the Government's Expert as an Expert in retail pharmacy. Tr. 224. According to Respondent, the Government's Expert was not qualified to testify as such because she has “no expertise of ever serving on pharmacy boards,” has “never taught pharmacy,” has “never worked at an independent pharmacy . . . or testified about any expertise with independent pharmacies,” and “is not currently working in a capacity where she [is] dispensing.” Exceptions, at 21. Respondent also argues that the Government's Expert's “retail pharmacy experience was limited to that of an assistant manager at Publix [a supermarket chain]—and before that [as] a pharmacist at Walgreens,” these being

“large retail institutions that had significant resources.” *Id.* And Respondent argues that the Expert “had never before been qualified as an expert,” that she “has not published any articles relating to red flags of diversion,” nor written “any policies or procedures relating to diversion” or “controlled substances.” *Id.* at 21–22.

The evidence shows, however, that Government's Expert holds both a Bachelor of Science in Pharmacy and a Doctor of Pharmacy degree. GX 25, at 1. She testified that she had 17 years of experience working in retail pharmacies, Tr. 214, and her CV shows and she has 10 years of experience working a pharmacist, an assistant manager and a pharmacy manager at retail pharmacies. GX 25, at 2, 4. She testified to having dispensed an estimated five million prescriptions. Tr. 216.

She also testified that based on her education and professional experience she was familiar with a pharmacist's responsibilities in dispensing controlled substances and issues involving the diversion and abuse of controlled substances. *Id.* at 218–19. Thus, the Government's Expert's experience and education provided an ample basis for the ALJ to deem her qualified to testify as an expert witness. *See, e.g., United States v. Roach*, 644 F.3d 763, 764 (8th Cir. 2011) (physician qualified to testify as expert on issues based on knowledge acquired “solely from on-the-job observations and attendance at conferences and seminars”); *American General Life Ins. Co. v. Schoenthal Family, LLC*, 555 F.3d 1331, 1338–39 (11th Cir. 2009) (rejected argument that “[e]xperience alone . . . can never form the basis for expert testimony,” and noting that expert's education and experience rendered him qualified to testify as expert on insurance industry standards). I therefore reject Respondent's argument to the contrary.²⁹

²⁹ While Respondent invokes Rule 702 of the Federal Rules of Evidence (which provide only guidance in this proceeding, *see Rosalind A. Cropper*, 66 FR 41040, 41041 (2000)), even under Rule 702, the Government's Expert would have been deemed qualified to testify as such based on her experience and knowledge. There is no requirement that an expert has served on a Board of Pharmacy, has written articles on or taught the subject matter, or has previously testified as an expert. *See Fed. R. Evid. 702* (Advisory Committee Notes 2000 Amendments) (“Nothing in this amendment is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert testimony.”); *Beins v. United States*, 695 F.2d 951, 609 (D.C. Cir. 1982) (expert's lack of publications in field not disqualifying). As for Respondent's argument that the Expert's experience was limited to working “in large retail institutions” and not

Respondent further maintains that the Expert was biased because she “testified that she helped write the Order to Show Cause.” Exceptions, at 22. Respondent also notes that the Expert testified that she had provided a report to DEA, which was in existence when it sought discovery from the Government, but that the ALJ denied its request for discovery. Respondent further argues that the ALJ's ruling denying its request for the Expert's report was a denial of its right to due process. *Id.* at 23 (citing *McClelland v. Andrus*, 606 F.2d 1278, 1286 (D.C. Cir. 1979)). Respondent then asserts that the Expert's report “likely contained the identity of other witnesses and may have lead [sic] to the discovery of additional evidence.” *Id.* at 24.

As for Respondent's claims that the Government's Expert was biased because she “testified that she helped write the Order to Show Cause,” the Expert's testimony was: “Yes, I provided a report of my findings and my opinion only.” Tr. 303. And when then asked by Respondent if she had “seen that report in any documents that have been shown to you in this proceeding,” the Expert “I think they showed it to me after the fact. This is what we submitted to you. They showed me the Order after, yes. After they gave it to you, they forwarded it to me too, but I'm going to be honest, I don't read all that stuff.” *Id.*

Of note, the record contains no indication that the Show Cause Order (which was in the record as ALJ Ex. 1) was presented by Respondent to the Expert when this colloquy occurred. *See id.* And when the Government objected to this line of questioning on the ground that “we're using terms here . . . in a confusing manner” and asked that Respondent's counsel “show her the document,” the ALJ instructed Respondent's Counsel that “if you would be precise in what you're referring to, that would be very helpful,” before adding that “[i]t is confusing.” Tr. 304. Respondent's Counsel then proceeded to ask the Government's Expert about the report she submitted. *Id.* at 305. As I also find the record confusing, I do not find it established that the Government's Expert helped to write the Order to Show Cause other than in the sense that she reviewed the prescriptions and provided a report to the Government.

I also reject Respondent's contention that it was entitled to discovery of the Expert's report. As several courts of appeals have recognized, “[t]he

independent pharmacies, the Agency's corresponding responsibility rule applies in the same manner to all pharmacies.

Administrative Procedure Act contains no provision for pretrial discovery in the administrative process . . . and the Federal Rules of Civil Procedure for discovery do not apply to administrative proceedings.” *Silverman v. CFTC*, 549 F.2d 28, 33 (7th Cir. 1977); see also *Mister Discount Stockbrokers, Inc.*, v. SEC, 768 F.2d 875 (7th Cir. 1985). Rather, “[t]he extent of discovery that a party is entitled to is primarily determined by the particular agency.” *Mister Discount Stockbrokers*, 768 F.2d at 878 (quoting *McClelland*, 606 F.2d at 1285).

DEA’s regulations do not, however, provide for broad-based discovery. Rather, consistent with the Due Process Clause, they provide only the right to receive in advance of the hearing a summary of the anticipated testimony of the Government’s witnesses and copies of the Government’s proposed exhibits.

To be sure, the Agency has recognized that “discovery must be granted if in the particular situation a refusal to do so would so prejudice a party as to deny [it] due process.” *Margy Temponeras*, 77 FR 45675, 45676 n.4 (2012) (quoting *McClelland*, 606 F.2d at 1285)). See also *Goldberg v. Kelly*, 397 U.S. 254, 270 (1970) (“where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, the evidence used to prove the Government’s case must be disclosed to the individual so that he has an opportunity to show that it is untrue”) (int. quotations and other citation omitted). However, “the party seeking discovery must rely on more than speculation and must show that the evidence is relevant [and] material, and that the denial of access to the documents is prejudicial.” *Beau Boshers*, 76 FR 19401, 19403 (2011) (citing *Echostar Comm. Corp. v. FCC*, 292 F.3d 749, 756 (D.C. Cir. 2002); *Silverman*, 549 F.2d at 34). The prejudice must be of such “a significant degree so as to result in a denial of due process.” *Mister Discount Stockbrokers*, 768 F.2d at 878.

While Respondent contends that the denial of its right to the report of the Government’s Expert violated its right to due process, I conclude that Respondent has failed to identify any prejudice, let alone prejudice resulting in the denial of due process. Notably, in advance of the hearing, the Government provided Respondent with a thorough disclosure of the testimony it expected to elicit from its Expert regarding the various red flags of diversion present in the prescriptions she reviewed and it also identified those sets of prescriptions which its Expert would testify were

unresolvable red flags for diversion.” ALJ Ex. 11, at 16–19 (Govt. Prehearing Statement). Moreover, Respondent makes no claim that the Government failed to provide copies of its proposed exhibits in advance of the hearing as required by the ALJ’s Prehearing Ruling. ALJ Ex.16, at 3. Thus, Respondent was fully apprised of the Government’s theory of the case and the evidence it intended to rely on and Respondent had ample opportunity to prepare a defense.

While Respondent asserts that by denying it “access to [the Expert’s] report, [it] was denied access to part of the evidence on which the DEA relies [on] to revoke its license,” Exceptions, at 24; the Government did not introduce the report into evidence and thus did not rely on it to prove its case. Moreover, Respondent was able to thoroughly cross-examine the Government’s Expert as to the basis of her opinions that the prescriptions presented unresolvable red flags. See Tr. 289–359; 375–79.

Respondent further asserts that it has been prejudiced because the Expert’s report “likely contains the identity of other witnesses and may have lead [sic] to the discovery of additional evidence.” Exceptions, at 24. However, earlier in its Exceptions, Respondent argued that I should reject the ALJ’s findings as to the prescriptions in GX 22 because the Government’s Expert acknowledged that “she had not . . . spoken with the doctors, or the patients or any physicians that had issued the prescriptions at issue in this action.” Exceptions, at 13 (citing Tr. 317). As Respondent has not even suggested what other type of witnesses it believes the Expert’s report refers to, its claim of prejudice rests on pure speculation. I therefore reject its exception.³⁰

Respondent’s Contention That Substantial Evidence Does Not Support a Finding That It Knew or Should Have Known of the Red Flags

Respondent argues that “[t]he ALJ improperly concluded that [Respondent] knew or should have

³⁰In light of my conclusion that Respondent has not shown that the denial of the Expert’s report is so prejudicial as to deny it due process, I do not address the Government’s argument that the report was a draft report which even under the Federal Rules of Civil Procedure need not be disclosed to the opposing party. Govt. Resp. to Respondents’ Exceptions, at 20–21 (citing Fed. R. Civ. P. 26(b)(4)(B)). Nor do I address the Government’s contention that the parties agreed that the only documents subject to disclosure were the prehearing summaries of the expected testimony, the experts’ CVs, and any documents that their experts would be expected to refer to on direct examination and that Respondents “are complaining about a document they abandoned months before the hearing.” *Id.* at 19.

recognized a red flag prior to the time the controlled substances were dispensed.” Exceptions, at 24. Noting the ALJ’s reliance on *Holiday CVS*, Respondent argues that “unlike the *Holiday CVS* case, there was no evidence in the record of this case that any controlled substance was diverted, or any prescription [was] issued by a prescribing physician who lacked authority to prescribe controlled substances.” *Id.* at 24–25. Respondent further argues that in *Holiday CVS*, the pharmacies “were specifically advised by DEA staff on more than one occasion of prescribing patterns to look out for as potential indicators of diversion.” *Id.* at 25 (citing 77 FR at 62326, 62331). Respondent thus contends that “[n]one of these facts are [sic] present in this action.” *Id.*

While it is true that in *Holiday CVS*, the Agency found that pharmacies knowingly filled prescriptions issued by two physicians who were no longer registered and did so well after the pharmacies should have known that the physicians were no longer registered, that was only a small part of the case. See 77 FR at 62316–317. Rather, the heart of the Government’s case was that the pharmacies’ pharmacists had repeatedly violated their corresponding responsibility by dispensing prescriptions when they either knew or were willfully blind to the fact that the prescriptions lacked a legitimate medical purpose. See *id.* at 62317–322; see also *id.* at 62332–334.

Contrary to Respondent’s contention, the Government’s proof was similar to that put forward in this case in that it was based entirely on circumstantial evidence. More specifically, the evidence showed that: (1) The patients were travelling long distances (and frequently from out-of-state) to obtain their prescriptions; (2) the prescriptions were for large quantities of such highly abused drugs as oxycodone 30 and alprazolam; (3) the doctors issued prescriptions for combinations of oxycodone (including two dosage strengths both oxycodone 30 and 15) and alprazolam; and (4) the patients were paying cash for the prescriptions. See *id.* at 62332–34.

As in this matter, in *Holiday CVS*, the Government did not put forward any witness who testified that he/she had “personal knowledge” that the drugs were being diverted. While Respondent further argues that the Government did not put on any evidence “that any diagnosis was not legitimate . . . or that any controlled substance was diverted after a prescription was filled,” Exceptions, at 29; the Government did introduce evidence showing that several

of the physicians either surrendered their registrations or had their registrations revoked after a hearing in which they were found to have issued prescriptions in violation of 21 CFR 1306.04(a). See *Rene Casanova*, 77 FR at 58151–52; GX 42, at 1 (registration printout for *Randall L. Wolff*); *Wolff*, 77 FR at 5121–22; GX 41, at 1 (registration printout showing Dr. Neuringer surrendered his registration for cause).³¹

Nor do I find persuasive Respondent's attempt to distinguish *Holiday CVS* because in that matter, agency Investigators met with CVS employees and discussed both a pharmacist's corresponding responsibility and various red flags attendant with illegitimate prescriptions. To the extent Respondent suggests that its owner and pharmacists were entitled to a similar briefing, and should be excused from liability because they did not receive such a briefing, it is mistaken. DEA does not have the resources to personally brief every registrant following its discovery of new patterns of diversion.³² Rather, as a participant in a

³¹ The evidence also shows that Respondent filled controlled substance prescriptions issued by Drs. Jacobo Dreszer (4 Rxs), Michael Aruta (7 Rxs), Beau Boshers (12 Rxs), and Cynthia Cadet (2 Rxs). See GX 2 (line entries nos. 25, 41, 53–60, 70–83, 87). I take official notice that on February 25, 2010, the former Administrator ordered the immediate suspension of each of these doctor's registrations, and following a consolidated hearing before an ALJ, the former Administrator found that each of these doctors had issued controlled substance prescriptions outside of the usual course of professional practice and which lacked a legitimate medical purpose and revoked their respective registrations. See *Cynthia M. Cadet*, 76 FR 19450, 19451, 19465 (2011); *Michael J. Aruta*, 76 FR 19420, 19420, 19434 (2011); *Beau Boshers*, 76 FR 19401, 19404, 19419 (2011); *Jacobo Dreszer*, 76 FR 19386, 19389–90, 19401 (2011).

³² In *Holiday CVS*, one of the Government's Investigators (who also testified in this proceeding) testified that the DEA Weston Office had decided in 2005 "to interview all new pharmacy applicants and also treat all new pharmacy applications the same and alert the chains. So when there was a new pharmacy opening up, I would contact them and they would come in for a discussion of the situation." 77 FR at 62331. Respondent cites to this testimony and argues that "[t]here was no testimony from DEA staff that the DEA ever provided similar information to [it] during the . . . time period covering the prescriptions at issue in this action." Exceptions, at 29 n.32. Respondent thus suggests that "there was a disparity of treatment between types of pharmacies despite the DEA seeking to impose the same knowledge on [it] that was given to *Holiday CVS*." *Id.*

To the extent Respondent raises the lack of such a briefing as an affirmative defense, the burden of production was on Respondent to show that it did not occur and Respondent produced no evidence as to whether DEA Investigators visited it prior to granting its initial application, let alone that they failed to conduct a briefing on red flags associated with unlawful prescriptions. Second, even if Respondent had established that it was treated differently than chain pharmacies because it was an independent pharmacy, the Government's basis for treating it differently would only be subject to rational basis review. Cf. *FCC v. Beach Comm., Inc.*,

highly regulated profession, Respondent's owner had an obligation to keep herself informed regarding regulatory developments which affected her profession. Cf. *Holiday CVS*, 77 FR at 62317 (citing *United States v. Southern Union Co.*, 630 F.3d 17, 31 (1st Cir. 2010) ("[T]hose who manage companies in highly regulated industries are not unsophisticated. . . . It is part of [a company's] business to keep abreast of government regulations.")).

Moreover, even prior to Respondent's first engaging in the dispensing of controlled substances, this Agency had identified several of the same red flags that are present here, such as the prescribing of drug cocktails of narcotics (oxycodone), benzodiazepines (alprazolam), and carisoprodol and patients obtaining large doses and multiple prescriptions for narcotics. See *Paul H. Volkman*, 73 FR 30630, 30637 (2008) (discussing testimony of expert in pain management that physician's practice of prescribing drug cocktails of opioids, which often included multiple opioids, a benzodiazepine and carisoprodol, "greatly increased the chance for drug abuse, diversion, [and]/or addiction");³³ see also *Your Druggist Pharmacy*, 73 FR 75774, 75775 n.1 (2008) (discussing carisoprodol's use by drug abusers as a part of a drug cocktail which also includes an opiate and benzodiazepine).

Also, as discussed above, on October 27, 2010, the Agency identified additional red flags in the *East Main Street Pharmacy* case such as patients paying cash, patients travelling long distances to obtain prescriptions, and patients obtaining prescriptions for alprazolam in the two milligram dosage. To the extent Respondent believes that it should be excused for its dispensing violations which occurred prior to this date because no Agency decision had explicitly found that these circumstances were red flags, the circumstances of patients, who had traveled long distances and frequently from out-of-state, presenting

508 U.S. 307, 316–17 (1993). Finally, because the regulation provides constitutionally adequate notice of a pharmacist's legal obligation to not knowingly dispense prescriptions which lack a legitimate medical purpose, see *United States v. Hayes*, 595 F.2d 258, 260–61 (5th Cir. 1979), and the red flags themselves are simply factual circumstances which provide evidence to suspect that a prescription was not issued for a legitimate medical purpose, Respondent cannot claim that it has been denied fair notice that its filling of the prescriptions at issue was unlawful.

³³ Indeed, the Government's Expert in *Volkman* discussed at length six patients who received multiple controlled substance prescriptions from the doctor and died of overdoses only a few days later. See 73 FR at 30637 n.23.

prescriptions for multiple controlled substances including large quantities of oxycodone (and frequently prescriptions for both 30 and 15 milligrams dosages), alprazolam 2mg, and at times also carisoprodol, for which they paid large sums of cash (or cash equivalents), created an obvious and compelling level of suspicion that the prescriptions lacked a legitimate medical purpose. See *Holiday CVS*, 77 FR at 62322 ("[T]he red flags presented by the circumstances of patients travelling from Kentucky or Tennessee to South Florida to obtain prescriptions, including for a schedule II narcotic, which by definition has the highest potential for abuse of any drug that may be lawfully prescribed, and then travelling to Respondents to fill them, are so obvious that only those who are deliberately ignorant would fill these prescriptions.") (citation omitted).³⁴ Because I conclude that these red flags rendered it obvious that the prescriptions likely lacked a legitimate medical purpose, I reject Respondent's further contention that "the ALJ . . . improperly concluded that there was a general knowledge of 'red flags' among . . . independent pharmacies." Exceptions, at 29.

Respondent further argues that the ALJ erred in "credit[ing] the DEA's argument that cash and high prices charged are evidence of knowledge [on Ms. Jones's part] that her 'acts were illegal.'" *Id.* According to Respondent, this "argument turns the principles of due process and burden of proof on their head," apparently because both parties' Experts testified that there are no "prohibitions of pharmacies charging any particular price on controlled substances." *Id.* (citing Tr. 758).

Respondent, however, cites no authority for its contention. Moreover, even granting that there are no prohibitions on the prices a pharmacy can charge for controlled substances, when those prices far exceed what other pharmacies would charge, the Agency may properly draw the inference that

³⁴ In this exception, Respondent also repeats its argument that the Government's Expert "provided no credible evidence that the term [red flags] was known by pharmacists [sic] the State of Florida other than her unsubstantiated testimony." *Id.* at 27. Respondent also relies on the discredited testimony of its Expert to the effect that the first reference she found on the Agency's website to the term red flag was in the *Holiday CVS* decision and that she did not believe that in 2010, such circumstances as patients paying cash or traveling to obtain prescriptions was widely known by pharmacists to be an indicator of abuse or diversion. *Id.* at 28. I reject these arguments for the reasons explained in my discussion of Respondent's exceptions to the ALJ's factual findings and credibility determinations regarding the parties' experts.

the pharmacy is charging those prices because it knows it is supplying persons who are seeking the drugs to either abuse them or divert them to others. See *United States v. Leal*, 75 F.3d 219, 223 (6th Cir. 1996) (holding that evidence that pharmacist “marked up controlled substance prices 788% as compared to a national average of 86%” supported finding that pharmacist knew prescriptions were unlawful”); *United States v. Cooper*, 868 F.2d 1505, 1512 (6th Cir. 1989) (evidence that pharmacy charged prices well in excess of average prices supports an inference that the pharmacist knew drugs were prescribed illegally); *Hayes*, 595 F.2d at 261 (holding that evidence that “the prices charged by [pharmacist] for drugs were unusually high” supported conclusion that pharmacist “knew that the prescriptions were not issued for a legitimate medical purpose”).

Here, the evidence shows that Respondent was charging prices as high as \$1620 for 180 dosage units of oxycodone 30 mg when it paid \$58.66 for the drugs. See, e.g., GX 2 (line entries Nos. 3172, 3192, 3249). Moreover, the DOH Inspector, who had inspected approximately 1,500 pharmacies in Broward and Dade counties and who had 33 years of experience as a practicing pharmacist, testified that the typical price for 180 oxycodone 30 was “less than \$200” and “at most \$250.” Tr. 168. The Inspector further testified that the \$1620 price Respondent was charging at the time of the 2012 DOH Inspection was “extraordinary” and that “in charging that amount of money,” Respondent’s owner knew the prescriptions were not issued for a legitimate medical purpose. *Id.* at 167. I agree and I reject Respondent’s contention to the contrary.

Respondent’s Contention That This Proceeding May Have Been Brought For Punitive Reasons

Respondent further argues that “the objective evidence indicates that the instant action may have been brought for punitive reasons.” Exceptions, at 30. As support for its contention, Respondent cites to the evidence showing that in March 2012, Ms. Jones leased a new location; that on June 2, 2012, she applied to change her registered address to her new location; and that in both July and October 2012 she had sent DEA Investigators the dispensing report (GX 2), but that DEA did not approve the modification until April 2, 2013, several weeks after Respondent’s owner had written her congressional representatives to complain about the delay. *Id.* at 30–33.

In its Exceptions, Respondent further quotes from Ms. Jones’ letter to her congressional representatives in which she asserted that “I can only think of negative reason of why someone would sit on our file so long,” that “[i]t feels like an abuse of power for someone in this position,” and “I feel this is an adult version of being bullied. I am emailing and calling and I can’t get any response on the status of our application and why it is taking so long.” RX 7 (quoted in Exceptions, at 32–33). Noting that one of the Government’s Investigators testified that when he conducted the April 2, 2013 inspection, he was aware that Ms. Jones had sent this letter to her congressional representatives, Respondent thus suggests that the proceeding was brought to retaliate against Ms. Jones for complaining to her representatives. Exceptions, at 32–33 & n.33.

I reject the contention that the proceedings were brought to retaliate against Respondent’s owner. Here, notwithstanding that Ms. Jones engaged in constitutionally protected speech when she complained to her congressional representatives, the Government’s case for seeking the revocation of Respondent’s registration is amply supported by the evidence showing that Respondent’s pharmacists filled numerous controlled substance prescriptions in violation of 21 CFR 1306.04(a) thus rendering its registration inconsistent with the public interest. In the related context of a *Bivens* action for a retaliatory criminal prosecution, the Supreme Court has held that a plaintiff must show that the prosecutor lacked probable cause. See *Hartman v. Moore*, 547 U.S. 250, 265–66 (2006); see *United States v. Armstrong*, 517 U.S. 456, 464 (1996) (holding that “a presumption of regularity” supports prosecutorial decisionmaking, and where probable cause exists the decision to bring a charge “generally rests entirely” in the prosecutor’s “discretion”) (int. quotations and citations omitted). Because there is no evidence in the record, other than Ms. Jones’ assertion, that the proceeding was brought to punish her for having complained to her congressional representative, and because the case against Ms. Jones is amply supported by the evidence in the record, I reject her contention.

Respondent’s Exception That the ALJ Failed To Consider Respondent’s Evidence as to Ms. Jones’ Acceptance of Responsibility and Remedial Actions

The ALJ further found “that Ms. Jones has not unequivocally accepted responsibility for” the “unlawful dispensing that occurred at

[Respondent] from 2010 [through] 2012.” R.D. at 73. Based on this finding, the ALJ applied Agency precedent which holds that a registrant’s acceptance of responsibility and showing that it has undertaken adequate remedial measures are independent and “essential requirements for rebutting the Government’s *prima facie* showing that continuing an existing registration would be ‘consistent with the public interest,’” and declined to consider Respondent’s evidence of remedial measures. *Id.* (citing *Holiday CVS*, 77 FR at 62346 (quoting 21 U.S.C. § 823(f))).

Respondent takes exception to the ALJ’s finding that Ms. Jones failed to unequivocally accept responsibility for its misconduct. It argues that the ALJ erred in concluding that Ms. Jones’ testimony that she believed “that she was dispensing in accordance with appropriate methods, demonstrates a lack of acceptance of responsibility.” *Id.* at 33–34. Respondent argues that “there is no specific language that is required to ‘unequivocally accept responsibility’ because “not all individuals are the same and different individuals express themselves in different ways.” *Id.* at 34. Respondent then argues that “Ms. Jones repeatedly indicated that she accepted responsibility for her actions that she felt bad in that she would not want to have done something to hurt anyone.” *Id.* Respondent further points to Ms. Jones’ testimony “that knowing what she knows now, she could have done more to determine if prescriptions were written for legitimate purposes” but that “she did not believe any of the prescriptions in 2010 that were issued were not for legitimate medical purpose at that time . . . [a]lthough knowing what she knows now, she concedes it is possible they may not have been.” *Id.* After discussing two older agency cases which Respondent asserts stand for the proposition “that there is no specific way in which a party may accept responsibility,” Respondent all but acknowledges the insufficiency of its showing on this issue when it argues that “[i]n the instant action, there was substantial evidence on the record that Ms. Jones *equivocally* took responsibility for her actions.” Exceptions, at 34–36 (emphasis added and citing *Barry H. Brooks*, 66 FR 18305 (2001) and *Mary Thomson*, 65 FR 75969 (2000)).

While it is true that in these two cases the Agency granted registrations to persons whose acceptance of responsibility was less than unequivocal, in subsequent cases the Agency has made clear that where the Government has proved that a registrant

has engaged in intentional or knowing misconduct, revocation is warranted in the absence of the registrant's unequivocal acceptance of responsibility for its misconduct. See *Jayam Krishna-Iyer*, 74 FR 459, 464 (2009). As the former Administrator explained:

While some isolated decisions of this Agency may suggest that a practitioner who committed only a few acts of diversion was entitled to regain his registration even without having to accept responsibility for his misconduct, the great weight of the Agency's decisions are to the contrary. . . . Because of the grave and increasing harm to public health and safety caused by the diversion of prescription controlled substances, even where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct.³⁵

Id. See also *Michael A. White*, 79 FR 62957, 62958, 62967–68 (2014) (adopting ALJ's finding that physician did not accept responsibility when his "acceptance of responsibility was tenuous at best," "not once during the hearing did [he] unequivocally admit fault for his improper . . . prescriptions," and he "minimized the severity of his misconduct"); *The Medicine Shoppe*, 79 FR 59504, 59508–10 (2014) (adopting ALJ's finding that pharmacy had not accepted responsibility for its misconduct when its owner/pharmacist initially testified that he accepted responsibility but on cross-examination denied ever having filled an unlawful prescription notwithstanding proof to the contrary); *Holiday CVS*, 77 FR at 62323 (rejecting challenge to ALJ finding that pharmacy registrants had failed to acknowledge their misconduct when corporate official testified only that company "takes its responsibility seriously, and given . . . the elevated level of drug abuse that's being observed broadly in Florida, we don't want to contribute to that").³⁶

³⁵ In *Krishna-Iyer*, the Agency further overruled any case to the contrary. 74 FR at 464 n.9.

³⁶ The Agency's rule has been upheld on review. See *MacKay v. DEA*, 664 F.3d 808, 820 (10th Cir. 2011) ("The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his . . . behavior in the future. And that consideration is vital to whether continued registration is in the public interest."); *Chein v. DEA*, 533 F.3d 828, 837 (D.C. Cir. 2008) (upholding revocation of physician's registration based on physician's failure to accept responsibility where physician "continued [to] insist[] that his dispensing of anabolic steroids to

Here, Respondent's evidence falls well short of the mark and even putting aside the egregious nature and scope of Respondent's misconduct, Ms. Jones' testimony establishes that she still does not understand what her obligations are under the CSA. Notably, when asked on cross-examination about specific sets of prescriptions, Ms. Jones maintained that at the time she dispensed the prescriptions she thought she was properly exercising her corresponding responsibility. Tr. 578–79. She further denied that she had reason to believe the prescriptions were not issued for a legitimate medical purpose, explaining that "I did what I had done at other pharmacies and I thought that was enough." *Id.* Ms. Jones further testified that her process for checking the legitimacy of the prescriptions was limited to "calling the doctor and verifying that the prescription was written by the office." ³⁷ *Id.* at 581.

While Ms. Jones further testified that "[k]nowing what I know today, I think I could have done more digging to test the legitimacy of the prescriptions," *id.* at 583, she then explained that "there are doctors who will still write prescriptions like this and who are still practicing. So, I feel like we have to be the police of the legitimacy of the prescriptions, even though that should be their responsibility to make sure legitimate prescriptions are written based on the diagnosis of the patient." *Id.* at 585 (emphasis added).

Throughout the cross-examination, Ms. Jones continued to maintain her

the undercover agents was proper"); *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005).

³⁷ Contrary to Ms. Jones' understanding, it has been settled law for years that a pharmacist's obligations under the corresponding responsibility rule requires more than just calling the prescriber. As the Fifth Circuit has explained:

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

United States v. Hayes, 595 F.2d 258, 261 (5th Cir. 1979). See also *United States v. Seelig*, 622 F.2d 207, 213 (6th Cir. 1980) (violation of 21 CFR 1306.04(a) "may be inferred from proof that [pharmacists] deliberately closed their eyes to what would otherwise be obvious to them"); *Medicine Shoppe-Jonesborough v. DEA*, 300 Fed. Appx. 409 (2008). And not only is ignorance of the law no excuse, those who choose to participate in a highly regulated profession cannot reasonably claim ignorance of the legal obligations imposed on them as a practitioner in that profession. See *David A. Ruben*; 78 FR 38363, 38387 n.54 (2013); cf. *Hageseth v. Superior Court*, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007).

belief that she had complied with her obligations under 21 CFR 1306.04(a) when she filled the prescriptions while denying that she had any obligation to do anything other than call the doctor's office. For example, when asked if her "due diligence include[d] assessing whether" the prescriptions in Government Exhibit 17 and 45³⁸ (which were presented by two persons who provided the same address in Tennessee and were for three controlled substances) were issued "for legitimate medical purposes," Ms. Jones answered: "Well we call the office to verify the prescription and to make sure it was valid. I disagree with what you're saying that we didn't make sure that the prescription was legitimate. I don't agree to that. I'm sorry, I don't." Tr. 593–94. When then asked whether there was "reason to believe that" the prescriptions were not issued for a legitimate medical purpose, Ms. Jones answered:

At face value of the prescription, no, because they're actual medications. They're written by a doctor. I've done a lot of training. Pain is what the patient says it is. Someone can, I have a patient who has sickle cell and has told me he's went to the hospital and sat there and waited and they asked him what his pain level was and he told them ten and it wasn't until they took his vitals that they actually believed him. So, I don't think you could look at someone to say you're not in pain and that's not a legitimate prescription.

Id. at 595. However, even if a pharmacist cannot look someone in the eye and determine whether she is actually in pain, a pharmacist can certainly evaluate the likelihood that prescriptions are legitimate when two patients, who provided the same address in Tennessee, presented essentially identical prescriptions for large quantities of oxycodone 30 and 15, as well as alprazolam 2, which they obtained from the same doctors, paid cash for the prescriptions and just happened to drop by her pharmacy to fill the prescriptions.

Next, the Government pursued the same line of questioning regarding the 49 prescriptions which were presented by 22 patients and filled by Respondent on April 19 and 20, 2010. Tr. 596; GXs 46 and 18. Of note, none of the 22

³⁸ These prescriptions were obtained by two patients (D.H. and K.S.) who provided the same residence address in Harriman, Tennessee and obtained prescriptions on same day (on two occasions) from a clinic in Opa Locka which Respondent filled for oxycodone 30 (three of the prescriptions being for 180 du, one being for 150 du), oxycodone 15 (all four prescriptions being for 90 du), and alprazolam 2 (all four prescriptions being for 60 du). GXs 17, 45. D.H. and K.S. paid for each prescription with cash. GX 45, at 2.

patients who filled these controlled substance prescriptions was from Florida. Rather, the patients were from Ohio, West Virginia, Georgia, Tennessee, Kentucky, and Mississippi. Moreover, 40 of the prescriptions were written by Dr. Wolff of Deerfield Beach, who registration was revoked by this Agency following a hearing at which he was found to have violated 21 CFR 1306.04(a).³⁹ Each of the patients filled a prescription for oxycodone 30, with sixteen of the patients obtaining 180 dosage units or more, fourteen of the patients also obtained prescriptions for alprazolam 2mg, and thirteen of the patients also obtained a third prescription for oxycodone 15. See GX 46. Moreover, each of the patients paid cash for their prescriptions. *Id.* at 3–4. Here, as well, these out-of-state patients just happened to know to go to Respondent, out of all the pharmacies in South Florida, and which had been opened for just over two months, to fill their prescriptions.⁴⁰

Asked whether she thought she was exercising her corresponding responsibility to ensure that these prescriptions were issued for a legitimate medical purpose, Ms. Jones testified: “I think I was at the time, yes.” Tr. 599. When subsequently asked if she “understand[s] those responsibilities differently today,” Ms. Jones answered:

Differently today—differently in the sense of I can do more; differently, no, in the sense if the prescription is written by the prescriber, I don’t think it makes it an illegitimate, not a legitimate prescription for medical purposes. I think I can do more digging to make sure that the patient is going to use it appropriately and not make it so that somebody else has access to it. I do that by looking at their history that the inspector

³⁹The other nine prescriptions were written by a doctor in Miami. GX 46, at 12.

⁴⁰A review of the spreadsheet of Respondent’s controlled substance dispensings shows that even in the initial months of its dispensing activity, filling prescriptions for persons who provided non-Florida addresses predominated over filling prescriptions for Florida residents. For example, from February 15, 2010 through the end of May 2010, Respondent filled 706 controlled substance prescriptions for persons who provided a non-Florida address and only 152 prescriptions for Florida residents. See GX 2 (line entries 2–706). Indeed, between February 15 and March 12, 2010 (its first month of dispensing as no dispensings occurred on March 13–14), it filled controlled substance prescriptions for 42 persons who provided addresses in Kentucky, Ohio, West Virginia, Tennessee, and North Carolina but only eight Florida residents. *Id.* (line entries 2–102). With the exception of three carisoprodol prescriptions, the prescriptions were comprised entirely of oxycodone in both 30 and 15 milligram dosage forms and alprazolam in either the 2 or 1 milligram dosage form. Of the patients who filled controlled substance prescriptions at Respondent during its first month of dispensing, 43 of them obtained prescriptions for oxycodone 30 and each paid cash.

made me aware of in August of 2014, but I still do rely on the prescriber to write prescriptions for legitimate medical purposes.

Id. at 599–600. Here again, notwithstanding the obvious and compelling evidence that the prescriptions lacked a legitimate medical purpose, Respondent continued to deny that the prescriptions were unlawfully dispensed.⁴¹

Moreover, at other points in her testimony, Ms. Jones left no doubt that she still does not understand her obligations under 21 CFR 1306.04(a). To be sure, Ms. Jones testified that she “would shy away” from filling a prescription for a patient who is paying cash. *Id.* at 623. However, when then asked if she “believe[s] there are circumstances where a pharmacist should refuse to fill a prescription after making the judgment that it is not issued for [a] legitimate medical purpose,” she testified:

That still leaves us diagnosing whether the patient has pain or not. I wouldn’t say for legitimate medical purpose. I would say by looking at the totality of what the situation is and as much information as you can collect and then deciding if you’re okay, if you feel comfortable filling it or not.

Id. at 624. While on further questioning Ms. Jones testified that “[t]here are circumstances that would cause me to reject a prescription,” she then added that “I don’t think I can make the determination whether it’s for legitimate medical purposes because I would have to say that I’m in that person’s body and I know how they feel if we’re just speaking about pain medications.” *Id.* at 625. And subsequently, Ms. Jones testified that with respect to pain medications, “I might question the quantity, maybe the duration, but for legitimate medical purpose, that would lead me into me having to diagnose because I’m someone who will give recommendations and tell you what I think, but I can’t, I don’t think it’s a fair statement that you could say someone is not in pain.” *Id.* at 628.⁴²

⁴¹Asked about additional sets of prescriptions, Ms. Jones adhered to the same theme that she believed that when she filled the prescriptions she properly exercised her corresponding responsibility, but today, she “would do more digging.” Tr. 606. She did so no matter how strong the indicia of suspicion were with respect to the prescriptions, such as when she was asked about an oxycodone prescription that cost her \$58.56 and for which she charged the patient \$1620. *Id.* at 611–12.

⁴²The federal courts have also rejected this view. As the Fifth Circuit has further explained: “a pharmacist can fulfill [her] responsibility under [21 CFR] 1306.04 without practicing medicine. . . . [A] pharmacist can know that prescriptions are issued for no legitimate medical purpose without [her] needing to know anything about medical science.”

Subsequently, Ms. Jones was asked after if she understood her corresponding responsibility under the Controlled Substances Act. *Id.* at 639. Ms. Jones answered:

Well, I understand that I have a responsibility to make sure that patients are safe with the medication they receive. But, you, you’re saying medical legitimacy. The law is saying that we had a—to make sure it says medical, it’s—the law says medical legitimacy? That’s what I’m not understanding.

Id.

When then asked whether she knew “one way or another” if she had a corresponding responsibility, Ms. Jones answered: “I did not know that the law said that I had to make sure that prescriptions said it was legitimate, medically legitimate.” *Id.* at 639–40. Ms. Jones then admitted that she did not know this even while “sitting here today.” *Id.* at 640. When then asked for her “understanding of what the law requires of . . . a pharmacist [who] dispens[es] controlled substances,” Ms. Jones testified “that I need to make sure that the patients are safe and that I need to make sure that the prescription is a, a true and correct prescription. That’s my understanding of my responsibilities.” *Id.* at 640–41. And when asked if she has “any responsibility to ensure that the prescription is issued for a legitimate medical purpose,” Ms. Jones testified: “I thought that was the prescriber’s responsibility. The person actually writing the prescription.” *Id.* at 641.

Thereafter, Ms. Jones was asked whether she “acknowledge[s]” that she did not exercise her responsibility to ensure that that prescriptions at issue “were issued for a legitimate medical purpose?” *Id.* at 642. Ms. Jones answered: “[i]n my scope of what I did I, that was not a part of what I was doing anyway if that makes sense. That was not something that I thought was my responsibility to make sure they were medically legitimate.” *Id.* Indeed, when asked whether there was any category of the prescriptions discussed in the hearing that she thought were medically legitimate, Ms. Jones replied: “I can’t say that they weren’t medically legitimate because I didn’t have conversations with the patients. So, I can’t say that they were or were not.” *Id.* at 646.

The ALJ was not impressed by Ms. Jones’ testimony. As the ALJ explained:

Ms. Jones purported to accept responsibility for [Respondent’s] dispensing practices by repeatedly asserting that she did

United States v. Henry, 727 F.2d 1373, 1378 (5th Cir. 1984) (quoting *Hayes*, 595 F.2d at 261 n.6).

what she knew at the time, but now she knows she could have done more. But then Ms. Jones demonstrated by her statements that she does not fully understand her corresponding responsibility even yet today. Thus, there remains no excuse for the Respondent's past dispensing conduct and continued lack of knowledge of [her and her pharmacists'] corresponding responsibility. . . .

R.D. 72–73 (citing 21 CFR 1306.04(a)).

I agree. And because Respondent has not credibly accepted responsibility for its misconduct, the ALJ did not err when she declined to consider Respondent's evidence of its remedial measures. *See* R.D. at 73 (citing cases).

As found above, the evidence shows that Respondent filled nearly 3,300 controlled substance prescriptions, the vast majority of which presented such compelling evidence that the prescriptions lacked a legitimate medical purpose as to support a finding that Respondent's pharmacists either knew or were willfully blind to the fact that the prescriptions were issued in violation of 21 CFR 1306.04(a). Given the scope and duration of Respondent's misconduct, Ms. Jones' failure to acknowledge its misconduct, as well as Ms. Jones' testimony which demonstrates that notwithstanding this proceeding, she still does not understand the scope of a pharmacist's obligations under the CSA, I have no confidence that either of Ms. Jones' entities (Total Health Pharmacy, L.L.C., and SND Healthcare, L.L.C.) will faithfully comply with the CSA if it was granted a registration.⁴³ Accordingly, I reject Respondent's exceptions and will adopt the ALJ's recommendation that I deny the application of Jones Total Health Pharmacy, L.L.C., to renew its registration and the application of SND Healthcare, L.L.C., for a registration. *See* R.D. at 75.

Order

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the application of Jones Total Health Pharmacy, L.L.C., for

⁴³ Indeed, this is a case where the proven misconduct is so extensive and egregious that even if the ALJ had found that Ms. Jones had credibly accepted responsibility (and given weight to the evidence of remedial measures), I still would have concluded that allowing Respondents to be registered "would be inconsistent with the public interest." 21 U.S.C. §§ 823(f) and 824(a)(4). *See also Hatem M. Ataya*, 81 FR 8221, 8244 (2016) ("[W]hile proceedings under 21 U.S.C. §§ 823 and 824 are remedial in nature, there are cases in which, notwithstanding a finding that a registrant has credibly accepted responsibility, the misconduct is so egregious and extensive that the protection of the public interest nonetheless warrants the revocation of a registration or the denial of an application.") (citing *Fred Samimi*, 79 FR 18698, 18714 (2014)).

a DEA Certificate of Registration as a retail pharmacy be, and it hereby is, denied. I further order that the application of SND Healthcare, L.L.C., for a DEA Certificate of Registration as a retail pharmacy be, and it hereby is, denied. This Order is effective immediately.

Date: October 31, 2016.

Chuck Rosenberg,

Acting Administrator.

Dana Hill, Esq., for the Government.

Daniel S. Newman, Esq., for the Respondent.

Findings of Fact, Conclusions of Law, and Recommended Decision

I. Introduction

Administrative Law Judge Gail A. Randall. This proceeding is an adjudication governed by the Administrative Procedure Act, 5 U.S.C. §§ 551 *et. seq.*, to determine whether the Drug Enforcement Administration ("DEA") should deny a pharmacy's application, and revoke an associated pharmacy's registration with pending applications for renewal of such registration denied under the Controlled Substances Act, 21 U.S.C. §§ 824(a)(4) and 823(f).

II. Procedural Background

The Deputy Assistant Administrator, Drug Enforcement Administration ("DEA" or "Government"), issued an Order to Show Cause ("Order") dated October 6, 2014, proposing to deny the application, number W13031979A, for SND Healthcare, LLC, ("SND"), pursuant to 21 U.S.C. § 823(f), and to revoke the DEA Certificate of Registration, number FJ1733725 for Jones Total Health Pharmacy, LLC, ("Jones Pharmacy"),⁴⁴ pursuant to 21 U.S.C. § 824(a)(4), because the registration of each entity is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f).⁴⁵ [Administrative Law Judge Exhibit ("ALJ Exh.") 1].

On November 5, 2014, the Respondents, through counsel, timely filed a request for a hearing in the above-captioned matter. [ALJ Exh. 2].

⁴⁴ The Order to Show Cause in this matter refers to a Jones Total Health Care Pharmacy, but the DEA certificate of registration history documents indicate the pharmacy's name as Jones Total Health Pharmacy. [*cf.* ALJ Exh 1 with Gov't Exh. 8]. DI Gonzales testified at the hearing that the Order to Show Cause misstated Jones Pharmacy's name. [Tr. 111–112]. Therefore, the correct full name of the entity involved in this matter is Jones Total Health Pharmacy, LLC. [Tr. 112; Gov't Exh. 8].

⁴⁵ SND Healthcare, LLC, and Jones Total Health Pharmacy, LLC, together will be referred to as "Respondents."

I, Gail A. Randall, Administrative Law Judge, have been designated as the presiding officer in the above-captioned case.

On January 14, 2015, a Protective Order was issued in this matter. [ALJ Exh. 17]. Upon joint request, I issued my Order Modifying The Protective Order on January 30, 2015. [ALJ Exh. 18].

On January 12, 2015, I issued a Prehearing Ruling, which includes the parties' stipulations. [ALJ Exh. 16]. On February 4, 2015, I issued the Notice of Hearing, informing both parties of the time and place for the hearing. [ALJ Exh. 20].

The hearing was conducted in this matter on March 3, 2015 through March 6, 2015, at the Miami Dade Courthouse, Miami, Florida. [*Id.*].

On April 20, 2015, the Government filed its Proposed Findings of Fact and Conclusions of Law ("Govt. Brief"). Also on April 20, 2015, the Respondents filed their Proposed Findings of Fact and Conclusions of Law ("Resp. Brief").

III. Issues

The issues in this proceeding are:

(1) Whether the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration ("DEA" or "Government") should revoke the DEA Certificate of Registration, number FJ1733725, of Jones Total Health Care Pharmacy as a retail pharmacy, pursuant to 21 U.S.C. § 824(a) (2006), and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f) (2006), because its continued registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f).

(2) Whether or not the record as a whole establishes by a preponderance of the evidence that the DEA should deny the application, number W13031979A for a DEA Certificate of Registration for SND Healthcare, LLC, as a retail pharmacy pursuant to 21 U.S.C. § 823(f), because to grant its application would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). [ALJ Exh. 16; Tr. 6].

IV. Findings of Fact

I find by a preponderance of the evidence the following facts:

A. Stipulated Facts

1. Stipulations About Controlled Substances Dispensed to B.F. and K.W.

1. On February 17, 2010, Jones Pharmacy dispensed 240 tablets of Oxycodone HCL 30 mg, 30 tablets of

Xanax 2 mg, and 120 tablets of Carisoprodol 350 mg to B.F.

2. On February 17, 2010, Jones Pharmacy dispensed 240 tablets of Oxycodone HCL 30 mg, 30 tablets of Xanax 2 mg, and 180 tablets of Oxycodone HCL 15 mg to K.W.

3. On March 17, 2010, Jones Pharmacy dispensed 240 tablets of Oxycodone HCL 30 mg, 180 tablets of Oxycodone HCL 15 mg, 60 tablets of Carisoprodol 350 mg, and 30 tablets of Xanax 2 mg to B.F.

4. On March 17, 2010, Jones Pharmacy dispensed 240 tablets of Oxycodone HCL 30 mg, 180 tablets of Oxycodone HCL 15 mg, and 30 tablets of Xanax 2 mg to K.W.

5. On April 14, 2010, Jones Pharmacy dispensed 240 tablets of Oxycodone HCL 30 mg, 180 tablets of Oxycodone HCL 15 mg, 60 tablets of Carisoprodol 350 mg, and 30 tablets of Xanax 2 mg to B.F.

6. On April 14, 2010, Jones Pharmacy dispensed 240 tablets of Oxycodone HCL 30 mg, 180 tablets of Oxycodone HCL 15 mg, and 30 tablets of Xanax 2 mg to K.W.

2. Stipulations About Controlled Substances Dispensed to L.S. and J.S.

7. On March 12, 2010, Jones Pharmacy dispensed 210 tablets of Roxycodone (Oxycodone HCL) 30 mg, 90 tablets of Roxycodone 15 mg, and 75 tablets of Xanax 2 mg to L.S.

8. On March 12, 2010, Jones Pharmacy dispensed 210 tablets of Roxycodone 30 mg, 90 tablets of Roxycodone 15 mg, and 75 tablets of Xanax 2 mg to J.S.

9. On April 9, 2010, Jones Pharmacy dispensed 210 tablets of Roxycodone 30 mg and 90 tablets of Roxycodone 15 mg to L.S.

10. On April 9, 2010, Jones Pharmacy dispensed 210 tablets of Roxycodone 30 mg and 90 tablets of Roxycodone 15 mg to J.S.

11. On May 6, 2010, Jones Pharmacy dispensed 210 tablets of Roxycodone 30 mg, 90 tablets of Roxycodone 15 mg, and 60 tablets of Xanax 2 mg to L.S.

12. On May 6, 2010, Jones Pharmacy dispensed 180 tablets of Roxycodone 30 mg, 90 tablets of Roxycodone 15 mg, and 60 tablets of Xanax 2 mg to J.S.

13. On June 2, 2010, Jones Pharmacy dispensed 180 tablets of Roxycodone 30 mg, 90 tablets of Roxycodone 15 mg, and 60 tablets of Xanax 2 mg to L.S.

14. On June 2, 2010, Jones Pharmacy dispensed 180 tablets of Roxycodone 30 mg, 90 tablets of Roxycodone 15 mg, and 60 tablets of Xanax 2 mg to J.S.

3. Stipulations About Controlled Substances Dispensed to D.H. and K.S

15. On April 13, 2010, Jones Pharmacy dispensed 150 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to D.H.

16. On April 13, 2010 Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 60 tablets Alprazolam 2 mg to K.S.

17. On May 17, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to D.H.

18. On May 17, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to K.S.

4. Stipulations About Controlled Substances Dispensed on April 19 and 20

19. On April 19, 2010, Jones Pharmacy dispensed 210 tablets of Oxycodone HCL 30 mg to J.C.

20. On April 19, 2010, Jones Pharmacy dispensed 210 tablets of Oxycodone HCL 30 mg to S.H.

21. On April 19, 2010, Jones Pharmacy dispensed 210 tablets of Oxycodone HCL 30 mg to C.L.

22. On April 19, 2010, Jones Pharmacy dispensed 210 tablets of Oxycodone HCL 30 mg to J.B.

23. On April 19, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg to J.S.

24. On April 19, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg to C.H.

25. On April 19, 2010, Jones Pharmacy dispensed 210 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to J.A.

26. On April 19, 2010, Jones Pharmacy dispensed 210 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to M.T.

27. On April 20, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 30 tablets of Oxycodone HCL 15 mg, 30 tablets of Endocet 10/650 mg, and 30 tablets of Alprazolam 2 mg to R.F.

28. On April 20, 2010, Jones Pharmacy dispensed 60 tablets of Oxycodone HCL 15 mg and 30 tablets of Alprazolam 2 mg to S.F.

29. On April 20, 2010, Jones Pharmacy dispensed 150 tablets of Oxycodone HCL 30 mg, 60 tablets of Oxycodone HCL 15 mg, and 30 tablets of Alprazolam 2 mg to S.T.

30. On April 20, 2010, Jones Pharmacy dispensed 150 tablets of Oxycodone HCL 30 mg and 30 tablets of Alprazolam 2 mg to J.K.

31. On April 20, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 60 tablets of Oxycodone HCL 15 mg, and 30 tablets of Alprazolam 2 mg to G.O.

32. On April 20, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg to J.T.

33. On April 20, 2010, Jones Pharmacy dispensed 150 tablets of Oxycodone HCL 30 mg, 60 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to B.C.

34. On April 20, 2010, Jones Pharmacy dispensed 20 tablets of Oxycodone HCL 30 mg to E.C.

35. On April 20, 2010, Jones pharmacy dispensed 150 tablets of Oxycodone HCL 30 mg, 60 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to J.H.

36. On April 20, 2010, Jones Pharmacy dispensed 120 tablets of Oxycodone HCL 30 mg, 60 tablets of Oxycodone HCL 15 mg, and 30 tablets of Alprazolam 2 mg to M.R.

37. On April 20, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 120 tablets of Oxycodone HCL 15 mg, and 60 Tablets Alprazolam 2 mg to R.J.

38. On April 20, 2010, Jones Pharmacy dispensed 200 tablets of Oxycodone HCL 30 mg, 100 tablets of Oxycodone HCL 15 mg, and 75 tablets of Alprazolam 2 mg to J.D.

39. On April 20, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 30 tablets of Alprazolam 2 mg to L.N.

40. On April 20, 2010, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg, 90 tablets of Oxycodone HCL 15 mg, and 60 tablets of Alprazolam 2 mg to A.T.

5. Stipulations About Controlled Substances Dispensed to R.H.

41. On October 26, 2010, Jones Pharmacy dispensed 90 tablets of Carisoprodol 350 mg, 180 tablets of Oxycodone HCL 30 mg, and 112 tablets of Oxycodone-APAP 10/325 mg to R.H.

6. Stipulations About Controlled Substances Dispensed to D.T.

42. On February 28, 2011, Jones Pharmacy dispensed 107 tablets of Oxycodone HCL 30 mg, 41 tablets of Oxycodone HCL 15 mg, and 30 tablets of Xanax 2 mg to D.T.

7. Stipulations About Controlled Substances Dispensed to R.C., J.C., and T.M.

43. On July 27, 2011, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg and 30 tablets of Xanax 2 mg to R.C.

44. On July 27, 2011, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg and 30 tablets of Xanax 2 mg to J.C.

45. On July 27, 2011, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg and 30 tablets of Xanax 2 mg to T.M.

8. Stipulations About Controlled Substances Dispensed to M.H., J.R., and W.F.

46. On August 1, 2011, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg and 30 tablets of Xanax 2mg to M.H.

47. On August 1, 2011, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg and 30 tablets of Xanax 2 mg to J.R.

48. On August 2, 2011, Jones Pharmacy dispensed 180 tablets of Oxycodone HCL 30 mg and 30 tablets of Xanax 2 mg to W.F.

9. Stipulations About Controlled Substances Dispensed to D.O.

49. On May 4, 2012, Jones Pharmacy dispensed 30 tablets of Clonazepam 1 mg and 180 tablets of Dilaudid (Hydromorphone) 8 mg to D.O.

50. On July 2, 2012, Jones Pharmacy dispensed 30 tablets of Clonazepam 1 mg and 180 tablets of Roxycodone HCL 30 mg to D.O.

10. Stipulations About Controlled Substances Dispensed to M.S./S.M.⁴⁶

51. On January 11, 2012, Jones Pharmacy dispensed 180 tablets of Oxycodone 30 mg to M.S./S.M.

52. On February 8, 2012, Jones Pharmacy dispensed 180 tablets of Oxycodone 30 mg to M.S./S.M.

53. On March 7, 2012, Jones Pharmacy dispensed 180 tablets of Oxycodone 30 mg to M.S./S.M.

54. On April 4, 2012, Jones Pharmacy dispensed 180 tablets of Oxycodone 30 mg to M.S./S.M.

55. On May 1, 2012, Jones Pharmacy dispensed 180 tablets of Oxycodone 30 mg to M.S./S.M.

56. On May 29, 2012, Jones Pharmacy dispensed 180 tablets of Oxycodone 30 mg to M.S./S.M.

57. On June 26, 2012, Jones Pharmacy dispensed 180 tablets of Oxycodone 30 mg to M.S./S.M.

11. Stipulations About Jones Pharmacy's Dispensing of Controlled Substances as Enumerated in the Order to Show Cause.

58. The prescriptions enumerated in the Order to Show Cause were issued and filled in the time period of February 15, 2010 through July 3, 2012.

59. There are no prescriptions enumerated in the Order to Show Cause that were issued or filled after July 3, 2012.

60. The controlled substances dispensed by Jones enumerated in the order to Show Cause were prescribed by physicians who were licensed to practice medicine in Florida at the time the prescriptions were written

61. The controlled substances referenced in Stipulations 1–57 were prescribed by physicians who were licensed to practice medicine in Florida at the time the prescriptions were written. [ALJ Exh. 21].

B. DEA Investigation

62. Domingo Gonzales is a Diversion Investigator (“DI”) who has worked for the DEA for two and a half years. [Transcript (“Tr.”) 25]. DI Gonzales works at the Miami Field Division in Miami, Florida. [*Id.*]. DI Gonzales has completed between 15–20 pharmacy inspections during his tenure with the DEA. [Tr. 26–27]. DI Gonzales was tasked with conducting an onsite inspection of Jones Total Health Pharmacy in April of 2013. [Tr. 27].

63. Group Supervisor Gayle Lane is a Miami Diversion Group Supervisor who has worked for the DEA for 38 years. [Tr. 115–117]. Group Supervisor Lane supervises six Diversion Investigators conducting investigations of pharmaceutical drug diversion. [Tr. 115]. Group Supervisor Lane's supervisory territory includes Monroe, Miami Dade, and Broward counties. [Tr. 116]. Recently Group Supervisor Lane has also done investigations in the Fort Meyers and Naples area. [Tr. 116]. In the last five years, Group Supervisor Lane has conducted close to 200 investigations. [Tr. 117]. Group Supervisor Lane testified that the DEA DI's look for red flags such as people coming in to the pharmacy at the same time with identical prescriptions from the same doctor, or exorbitant prices for controlled substances. [Tr. 124–125].⁴⁷

Exorbitant prices would indicate abuse or diversion because normally “people pay with insurance. And these type of narcotics don't cost that much money, so that is usually an indication that the patient and the pharmacist know that these drugs are going to be diverted, that they'd be willing to pay more than \$1,000 for one prescription, for instance.” [Tr. 125]. Group Supervisor Lane assigned the Jones Pharmacy case to DI Gonzales. [Tr. 122].

64. Brian Curtis is a Diversion Investigator who works for the DEA in the Miami Field Division. [Tr. 148]. DI Curtis filled in for Investigator Gonzales when DI Gonzales was on military leave. [Tr. 148–149]. DI Curtis was asked to assist with pulling prescriptions, and providing them to the pharmacist expert, Dr. Gordon, for review. [Tr. 149].

65. DI Curtis pulled all of the prescriptions for the respective customers indicated in Government Exhibits 15–24. [Gov't Exh. 15–24].

C. Florida Department of Health Inspector Mary Crane

66. Mary Crane is a Pharmacy Inspector for the Florida Department of Health who works in Broward County and Dade County, Florida. [Tr. 159]. Ms. Crane inspects pharmacies for compliance with the laws and rules of the State of Florida and for a pharmacy's adherence to federal laws as well. [Tr. 159]. Ms. Crane also checks to ensure that pharmacies are operating in a clean and safe manner, and that they comply with the standards of practice in Florida. [Tr. 160]. In the past three and a half years, Ms. Crane has completed close to 1,500 pharmacy inspections in Broward County and Dade County. [Tr. 160]. Before she was a pharmacy inspector, Ms. Crane practiced retail pharmacy for 33 years. [Tr. 161].

67. When Ms. Crane inspects prescriptions in the course of her duties, she looks for red flags. [Tr. 162]. In determining whether a red flag is present on a prescription, Ms. Crane looks at the pattern of prescribing, the profile of the patient to see if there is a progression from a low to high dose, other medications the individual is taking, type of physician that wrote the prescription, and other factors such as the patient's age, type of medication, and whether or not the prescription was purchased with cash. [Tr. 162]. Ms. Crane further testified that there is not a definitive list of things a pharmacist is supposed to check. [Tr. 163]. Ms. Crane stated that the concept of “red

⁴⁶ The parties agree on the stipulations related to the patient in question. There is some conflicting documentary evidence as to the ordering of this patient's first and last names.

⁴⁷ As a caveat, Group Supervisor Lane also testified that she did not have any personal knowledge of the controlled substances listed in the Order to Show Cause being diverted by the

individuals to whom they were dispensed to. [Tr. 140].

flags,” not the term, has been present for her entire tenure as a pharmacist, 36 years. [Tr. 206, 210].

68. In 2012, Ms. Crane inspected Jones Pharmacy. [Tr. 164]. Ms. Jones told Ms. Crane that she was moving her pharmacy because she was going to be compounding creams for the Miami Heat basketball team, and needed a store that looked better in a better area. [Tr. 167, 451, 671].

69. During the inspection, Ms. Crane found that the majority of Jones’ business was for Schedule II controlled substances which the pharmacy was filling for cash. There was little of the business that was for non-controlled substances. [Tr. 164]. Ms. Crane noted that when she drove up to Jones pharmacy “people were loitering in the parking lot. It was not in a really nice area, and I was a little bit, when I got out of my car, kind of looked around.” [Tr. 164]. During her discussion with Ms. Jones about the pharmacy’s proposed move, Ms. Crane told Ms. Jones “you need to leave these pill seekers at the old store because that clientele will not come if you have a lot of people hanging around that want narcotics.” [Tr. 167].

70. Pursuant to her inspection, Ms. Crane filled out an inspection form. [Tr. 165–166; Gov’t Exh 12]. Ms. Jones signed the first page of the report, but the second page including Ms. Cranes’ remarks was not provided to Ms. Jones. [Tr. 165, 181–182; Gov’t Exh 12]. Ms. Crane wrote that the “primary business of the pharmacy is the cash sale of narcotics.” [Tr. 166–167]. Ms. Crane also annotated in her report that Jones Pharmacy sold a 180 pill prescription for \$1,620. [Tr. 167]. Ms. Crane said that a more reasonable price to pay for this type of prescription would be \$200–\$250. [Tr. 168]. Ms. Crane stated that the “extraordinary price that people were paying cash for that prescription stood out to [her], that not only were the prescriptions . . . not [written] for [a] legitimate means but that [Ms. Jones] knew it in charging that amount of money.” [Tr. 167]. Ms. Crane did not note any deficiencies with Ms. Jones’ biennial inventory. [Tr. 185–186].

71. Ms. Crane testified that high prices were an indicator of abuse and/or diversion because addicts will often sell part of their prescription in order to pay the exorbitant amount of money the addicts paid to purchase the prescription. [Tr. 169–170]. Ms. Crane also testified that she never prepared a written analysis regarding the prevailing prices of controlled substances that were sold during the period February 2010 through July 2012. [Tr. 181]. Nor was Ms. Crane aware of the prices Ms.

Jones paid per pill for Oxycodone 30 mg in June of 2012. [Tr. 183].

72. During Ms. Crane’s inspection of Jones Pharmacy in August 2014, she asked Ms. Jones to produce a drug utilization report. [Tr. 174; Gov’t Exh 14]. The drug utilization report Ms. Jones produced listed the drugs Jones Pharmacy had dispensed by NDC number, and it also had the total number of units the pharmacy has dispensed. [Tr. 174; Gov’t Exh 14]. The report indicated that controlled substances were in the top 10 products that Jones Pharmacy sold from January 1, 2010 to August 29, 2014. [Tr. 175; Gov’t Exh. 14]. The amount of profit Ms. Jones made from schedule II narcotics during the three and a half year period was in excess of \$1.2 million. [Tr. 176].

73. Ms. Crane noted that there was an inspection conducted on April 14, 2011, where inspector Allen Miller noted that Jones Pharmacy was filling controlled substance prescriptions for patients whose home addresses were out of state. [Tr. 170–172; Gov’t Exh. 13]. Ms. Crane said that filling prescriptions for people traveling from out of state was a problem indicating diversion. [Tr. 173].

74. Ms. Crane noted during her inspection that Ms. Jones had reported a suspected forgery, and notified the police. [Tr. 186–187]. Ms. Crane advised Ms. Jones to keep her file and narrative of the event. [Tr. 186; Gov’t Exh. 12].

75. In August of 2014, Ms. Crane inspected Jones Pharmacy again and noted that there were no remarks relating to DEA 222 forms, the biennial inventory, filling prescriptions for out of state clients, or that the pharmacy was dispensing mostly controlled substances. [Tr. 190–191; Resp. Exh. 8].

76. During the four inspections conducted by the Florida Department of Health, Jones Pharmacy’s dispensing and corresponding responsibilities were discussed. [Tr. 204; Resp. Exh. 8].

D. 2013 DEA Inspection

77. The April 2013 inspection of Jones Pharmacy was prompted by Ms. Jones’ submittal of a request for a change of address. [Tr. 28].

78. When a registrant wishes to move location, the registrant is required to request a change of address with the DEA. [Tr. 28]. When a registrant sends a request for change of address to the Miami DEA office, the DEA will review data from the automated consolidation ordering system (“ARCOS”)⁴⁸ to see if

⁴⁸DI Gonzales testified that the ARCOS system is a system in which manufacturers and distributors are required to input “their transactions of Schedule 2 controlled substances and Schedule 1 in small cases and at the time any Schedule 3 narcotic drugs. [The manufacturers and

there is any issue with the respective pharmacy’s Schedule 2 and 3 narcotic ordering practices. [Tr. 29, 118]. Looking at the ARCOS data, the DEA reviews the quantity and type of controlled substances the pharmacy is ordering. [Tr. 120]. After the review of ARCOS data, DEA reviews the prescriptions at the pharmacy. [Tr. 118].

79. In April of 2013, the DEA approved the address change and Ms. Lane assigned the pharmacy to Domingo Gonzales. [Tr. 121].

80. In the summer of 2014, Domingo Gonzales was not able to take the lead role on the investigation due to military leave, so Ms. Lane assigned DI Brian Curtis to fill in for DI Gonzales. [Tr. 122].

81. During the April 2013 inspection, DI Gonzales presented Ms. Jones with a DEA 82, Notice of Inspection form. [Tr. 32]. Ms. Jones reviewed the document and declined to ask questions. [*Id.*]. DI Gonzales and Ms. Richards then asked Ms. Jones for her biennial inventories, invoices for schedule 2 or DEA 222 forms for purchases of Schedule 2 controlled substances, and her schedule 2 controlled substance prescriptions. [*Id.*].

82. DI Gonzales proceeded to review Ms. Jones’ biennial inventories, order forms, and invoices. [Tr. 32]. DI Gonzales was not able to review all of the orders, because Ms. Jones could not produce all of the orders. [*Id.*].

83. During his inspection, DI Gonzales reviewed the prescriptions for possible red flags. [Tr. 33]. DI Gonzales noticed that on the back of some of the prescriptions there was a copy of the purchaser’s driver’s license. In some instances, the license was an out of state license. [Tr. 33]. Also with some prescriptions, DI Gonzales noticed that they were paid for with cash. [Tr. 33–34]. These were an indication of red flags. [Tr. 34].

84. DI Gonzales also noted that Ms. Jones’ biennial inventory was missing some of the required information. [Tr. 35]. The inventory was supposed to indicate amounts of finished form in each container and the amount of commercial bottles that she had on hand during her inventory. [*Id.*]. Ms. Jones’ inventory only indicated the name of the controlled substances, the strength of the controlled substances, the quantity, and one of the NDC numbers. [*Id.*].

85. Specifically, Ms. Jones produced two inventories that she conducted on November 3, 2011, and April 13, 2013,

distributors] are required to indicate all their sales and purchases of controlled substances in those fields.” [Tr. at 30].

respectively. [Tr. 36; Gov't Exh. 5]. In the November 3, 2011 inventory, Ms. Jones did not indicate whether the inventory was conducted at the beginning, or close of business, as required by the Federal Code of Regulations. [*Id.*]. The time the inventory is taken is important for auditing purposes. [Tr. 37]. Ms. Jones also did not "indicate the number of tablets per commercial container, that come in each commercial container, or the number of commercial containers in each that she had on hand." [Tr. 36; Gov't Exh. 5]. The number of tablets is important for auditing reasons and the prevention of diversion. [Tr. 36].

86. With regard to the April 13, 2013 inventory, the same deficiencies as noted in the November 3, 2011 inventory were present. [Tr. 38; Gov't Exh. 5].

87. Ms. Jones was not able to produce all of her orders for invoices, because a great deal of the invoices were saved in coded electronic format on her computer's desktop.⁴⁹ [Tr. 421; 687–690].

88. At the conclusion of the inspection, DI Gonzales took all of Ms. Jones' controlled substances prescriptions, her invoices for schedule 2 controlled substances, and all of Ms. Jones' DEA 222 forms for purchases of schedule 2 controlled substances. [Tr. 33].

89. DI Gonzales testified to orders that were indicated on DEA E222 forms. [Tr. 39]. These orders were three different orders placed on May 22, 2012, May 18, 2012, and November 15, 2011. [Tr. 39; Gov't Exh. 6]. DI Gonzales prepared the exhibit indicating the individual orders. [Tr. 39]. DI Gonzales indicated that the May 22, 2012 order, reflected on pages 7–10, was done correctly. [Tr. 40].

90. The order placed on November 15, 2011, was done incorrectly. There was no record of how much Ms. Jones received or the date on which the order was received. [Tr. 42–43; Gov't Exh. 6 at 1–2]. Likewise, the order placed on May 18, 2012, was also deficient. [Gov't Exh. 6 at 3–6]. It did not indicate how many packages Ms. Jones received or the date that she received the ordered packages. [Tr. 43; Gov't Exh. 6 at 3–6].

91. In total, there were 480 line items that were done incorrectly on Ms. Jones' orders. [Tr. 44].

92. DI Gonzales testified to reviewing Jones pharmacy's dispensing report from February 15, 2010, until July 3, 2012. [Tr. 46; Gov't Exh. 2]. The report

was provided in an electronic excel spreadsheet format. [Gov't Exh. 2]. Ms. Rodriguez, attorney for Ms. Jones at the time, provided DI Gonzales with the dispensing report, which included Jones Pharmacy's dispensing history as far back as the day the pharmacy opened. [Tr. 46; Gov't Exh. 3].

93. The dispensing report indicated line item numbers 1 through 3,300, and ranged from February 15, 2010 until July 3, 2012. [Tr. 47]. The report provides prescription information such as the date it was filled, the date it was written, the drug and patient information, to include the patient's name and date of birth, information regarding how much the prescription cost to the pharmacy, and how much the customer paid. [Tr. 47]. There were 834 instances where the patient paid above \$5.00 per pill. [Tr. 61; Gov't Exh. 4]. There were 415 instances where the markup was over 1,000 percent. [Tr. 61–62].

94. When reviewing information of this nature, DI Gonzales looks for red flags that stick out. [Tr. 49]. For example, DI Gonzales looks for the most popular drug dispensed from the pharmacy, the information regarding the customer, the price the pharmacy is actually charging, and what the DEA considers "cocktail drugs."⁵⁰ [Tr. 49–50].

95. DI Gonzales and the DEA hired Dr. Tracey Gordon to review the dispensing records.⁵¹ [Tr. 50]. To enable Dr. Gordon's analysis of the records, DI Gonzales created charts and pivot tables⁵² to succinctly display the information. [Tr. 55; Gov't Exh. 4].

96. Before Dr. Gordon reviewed the dispensing records, DI Gonzales discovered through his analysis of the information that 99% of the controlled substances Jones Pharmacy filled were

⁵⁰ DI Gonzales defined the term "cocktail drug" as pain medications such as Oxycodone or Hydromorphone combined with an Alprazolam 2 milligram or Soma 350 milligram or Carisoprodol. [Tr. 56]. When DI Gonzales did his calculation, he only used these drugs to calculate the total aggregate number of cocktail drugs dispensed. [Tr. 56–57].

⁵¹ Dr. Tracey Gordon holds a Bachelor's of Science degree in pharmacy from Florida A&M University, and a Doctorate in pharmacy from the University of Florida. [Tr. 216–217; Gov't Exh. 25]. Dr. Gordon currently works as a Clinical Hospice Pharmacist. [Tr. 214]. Prior to her Hospice experience, Dr. Gordon worked in retail pharmacy for 17 years as a pharmacist for Eckerd, Walgreens, and Publix in certain Florida Counties. [Tr. 214–215]. Dr. Gordon was recognized at the hearing as an expert in retail pharmacy. [Tr. 224; *see Infra* FOF 106–111].

⁵² DI Gonzales explained that a pivot table is a tool available in Microsoft Excel software that allows the user to sort through information by topic heading and establish a chart from the desired information. [Tr. 54–55].

for immediate release controlled substances, and 89% of the drugs were for pain medications that the DEA considers "cocktail drugs." [Tr. 48, 50; Gov't Exh. 4]. DI Gonzales further determined that 49% of the "cocktail drug" controlled substances were dispensed to out of state customers. [Tr. 57].

97. DI Gonzales also determined in his analysis of the dispensing records that 93% of the prescriptions for controlled substances were paid for with cash. [Tr. 57]. DI Gonzales calculated the markup on the controlled substances, and created a spreadsheet to display this information. [Tr. 58–59; Gov't Exh. 4]. DI Gonzales determined that there were 415 instances where Ms. Jones charged a 1,000% markup on these controlled substances. [Tr. 61–62; Gov't Exh. 4].

98. DI Gonzales also reviewed the top 10 doctors Jones Pharmacy dispensed for during the time frame covered in the dispensing report. [Tr. 62; Gov't Exh. 32]. The information revealed that Dr. Randall Wolff prescribed 261 prescriptions that Jones Pharmacy subsequently filled. [Tr. 63]. DI Gonzales then looked up Dr. Wolff's profile on the Florida Department of Health License Certification website, and he printed the profile. [Tr. 66; Gov't Exh. 42 at 2–5]. DI Gonzales then created a packet for Doctor Wolff that consisted of a printout from DEA's internal CSA2 database, and the report from the Florida Department of Health License Verification website. [Tr. 66; Gov't Exh. 42]. In total, the packet was five pages. [Gov't Exh. 42].

99. DI Gonzales created documents similar to Government Exhibit 42 for all of Jones Pharmacy's top ten prescribing physicians, including Randall Wolff. [Tr. 66–67; Gov't Exh. 33–42]. The purpose for compiling this data was to aid Dr. Gordon's analysis of the prescriptions. [Tr. 63].

100. DI Gonzales prepared individual dispensing histories for customers B.F. and K.F. from Ohio for the purpose of aiding Dr. Gordon's analysis of Jones Pharmacy's prescribing practices. [Tr. 69–70; Gov't Exh. 43].

101. DI Gonzales prepared similar documents in the same manner for the patients listed in Government Exhibits 44–52. [Tr. 72; Gov't Exh. 44–52]. These documents are printouts of the dispensing report for the individuals identified in the Government's Order to Show Cause. [Tr. 72; Gov't Exh. 44–52; ALJ Exh. 1]. The documents include records of all the prescriptions the respective patients obtained from Jones Pharmacy. [Tr. 72; Gov't Exh. 44–52].

⁴⁹ DI Gonzales testified that the electronic copy of orders for invoices appeared as a string of numbers followed by a little bit of information, followed again by a string of numbers. This sequence would then repeat itself. [Tr. 35].

102. Ms. Jones applied for a DEA license in 2013 for another pharmacy, SND Healthcare. [Tr. 73]. DI Gonzales was alerted to SND Healthcare's application by DEA Group Supervisor Gayle Lane. [Tr. 73]. DI Gonzales confirmed that Ms. Jones was the owner of both Jones Pharmacy and SND Healthcare by searching the Florida Division of Corporations' website, Sunbiz. [Tr. 74–75]. Sunbiz's records are publicly available. [Tr. 75].

103. DI Gonzales also reviewed the Certification of Authenticity from the Florida Department of State Division of Corporations for Jones Pharmacy, and SND Healthcare, LLC. [Tr. 76; Gov't Exh. 9]. These documents showed that Cherese Jones is the only corporate officer for both corporations. [Tr. 77; Gov't Exh. 9]. These corporations also share a mailing address. [Tr. 77].

104. DI Gonzales then searched the Florida Department of Health database which specifies the pharmacists in charge or pharmacists affiliated to the pharmacy. [Tr. 78; Gov't Exh. 10, at 34]. DI Gonzales procured these documents to verify the licenses and the owners of anyone affiliated with the pharmacy. [Tr. 79] The documents indicate that Cherise Jones was the individual applying for the license. [Tr. 79; Gov't Exh. 10, at 6].

105. In July of 2013, DI Gonzales had a meeting with Ms. Jones and her then attorney, Ms. Monica Rodriguez. [Tr. 79–80]. The purpose of the meeting was to discuss the red flags and issues that were found during DI Gonzales's inspection. [Tr. 80]. At the meeting, DI Gonzales offered Ms. Jones an opportunity to surrender her DEA number and withdraw the application that she had pending. [Tr. 80]. Ms. Jones declined. [Tr. 80].

E. Dr. Tracy Gordon (Government Expert)

106. Dr. Tracey Gordon is a Clinical Hospice Pharmacist, with a little over two years of practice. [Tr. 213–214]. Dr. Gordon works on an interdisciplinary team consisting of doctors and nurses. [Tr. 214]. The team works to help manage pain and symptoms in hospice patients. [Id.].

107. Dr. Gordon works alongside physicians and makes recommendations of controlled substances based on patient symptoms. [Id.]. Prior to becoming a clinical hospice pharmacist, Dr. Gordon worked in retail pharmacy for 17 years as a pharmacist. Before that, Dr. Gordon was a pharmacy tech, clerk, and an intern. [Id.]. As a retail pharmacist, Dr. Gordon worked for Eckerd, Walgreens, and Publix. [Id.]. Dr. Gordon worked in Leon, Broward, Palm

Beach, and Dade counties, respectively. [Tr. 215]. Dr. Gordon worked as a pharmacy manager and assistant pharmacy manager in some stores. [Id.]. For some employers, Dr. Gordon floated from one store to the next.⁵³ [Id.]. Dr. Gordon testified that she has probably worked in 200 pharmacies. [Id.]. Dr. Gordon estimated that she worked alongside at least 100 pharmacists during her career. [Tr. 215–216].

108. In her role as a retail pharmacist, Dr. Gordon interacted frequently with other pharmacists in the area. [Tr. 216]. Dr. Gordon currently holds a consultant license, and regular pharmacy license in Florida.⁵⁴ [Tr. 216]. Dr. Gordon obtained her Bachelors of Science degree in pharmacy at Florida A&M University, and a Doctorate in pharmacy from the University of Florida. [Tr. 216–217; Gov't Exh. 25].

109. In her professional experience, Dr. Gordon has become familiar with issues surrounding the abuse or diversion of controlled substances. [Tr. 218]. Dr. Gordon acknowledged that there is no comprehensive written list of issues a pharmacist may encounter during his practice. [Tr. 218]. Dr. Gordon stated "it's just what you do. You just see, you have to determine whether a prescription is for a legitimate medical purpose to protect your patient because that's what we're here to do." [Tr. 218].⁵⁵

⁵³ Dr. Gordon explained that in retail pharmacy, you can either have your own home store, or you can "float" to different stores. [Tr. 215]. In her retail experience, Dr. Gordon did both. [Tr. 215].

⁵⁴ At the hearing, Dr. Gordon testified that she was licensed as a pharmacist in Florida and Georgia. [Tr. 216; Gov't Exh. 25]. Dr. Gordon's Georgia license lapsed on December 31, 2014, however. [Tr. 290] When confronted on cross examination about this fact, Dr. Gordon became hostile and stated that "her Georgia license has nothing to do with this case." [Tr. 291]. At one point, Dr. Gordon interrupted a dialogue between counsel and the Judge attempting to show how her lack of a Georgia pharmacy license was irrelevant to this case. [Tr. 292]. As counsel for Respondents rightly pointed out, the Government highlighted certain credentials of Dr. Gordon on direct examination; one of those being that Dr. Gordon is licensed as a pharmacist in Georgia. While I recognize that this case deals with Dr. Gordon's expertise as a retail pharmacist in Florida, I find paramount to Dr. Gordon's credibility that her credentials accurately reflect the licenses she currently holds. If Doctor Gordon's Georgia Pharmacy license was so idle and irrelevant that she let it lapse, then surely it should be left off of her curriculum vitae. Despite this fact, I find Dr. Gordon's opinions credible to the limited extent that they deal with the practice of retail pharmacy in Florida.

⁵⁵ In a related part of her testimony, Dr. Gordon stated "[p]harmacists have known from the beginning of time that a prescription should be for a legitimate medical purpose. That's our purpose. That's one of our jobs." [Tr. 234]. Dr. Gordon also testified that Florida pharmacists were aware of red flags of abuse and diversion in 2010. [Tr. 240].

110. Dr. Gordon has not sat on any boards of pharmacy, a board or organization that sets educational policy for pharmacists, and is not currently dispensing pharmaceuticals. [Tr. 220–222].

111. Dr. Gordon was recognized as an expert in retail pharmacy.⁵⁶ [Tr. 224].

112. Dr. Gordon testified that in order to ensure that a prescription was issued for a legitimate medical purpose, a pharmacist must check the dose, check the quantity, see what type of doctor wrote the prescription, and look at the patient's address. [Tr. 226]. Dr. Gordon stated that in order to properly check the prescription, the pharmacist must be a "judge of the person too, to see the person, to make sure that's what they need."⁵⁷ [Id.].

113. Another concern to Dr. Gordon is when patients ask you not to bill their insurance company and to pay cash for the prescription instead. [Id.]. That to Dr. Gordon is one of the biggest signs of possible abuse or diversion. [Id.].

114. Dr. Gordon explained the tools that are available to the pharmacist in preventing diversion. [Tr. 227]. One such tool is E-FORCSE. [Id.]. E-FORCSE is a program that was created

⁵⁶ During her cross examination, Dr. Gordon was asked about Florida pharmacists' general knowledge of red flags. [Tr. 323]. Dr. Gordon stated that she knew of Florida pharmacists' general knowledge of red flags because she spoke to pharmacists in her network, and watched a reality show broadcast on national television that depicted diversion in Broward and Dade Counties. [Id.]. When asked about the identities of the independent pharmacists Dr. Gordon spoke to in 2010, Dr. Gordon became hostile stating "Well let's see, do you remember everyone you speak to back in 2010? I do remember there's this one pharmacist who used to come into Publix all the time and we talked about it all the time" and "[h]ow about my father? . . . My father is an independent. He worked for independent for years." [Tr. 324]. Notwithstanding the above listed statements, Dr. Gordon's experience infers that she had a great deal of interaction with Florida Pharmacists during her career, including the years 2010 through 2012. And despite her inability to articulate specific examples, it follows that Dr. Gordon was generally aware of Florida pharmacists' knowledge of red flags because she had extensive interaction with many pharmacists during the applicable time period. For this reason, I find Dr. Gordon's testimony regarding what Florida pharmacists knew from 2010–2012 credible and persuasive.

⁵⁷ Dr. Gordon testified that it was possible some of Jones' patients were drug dealers or drug addicts. [Tr. 340]. When asked about her experience with drug addicts or drug users, Dr. Gordon stated "[a]ctually I was in a group with a bunch of drug addicts in my church. Yes, I was with them for two years and I helped them." [Tr. 342]. Dr. Gordon admitted that she did not have any formal social work degrees or drug counseling training. [Id.]. In this vein, I afford Dr. Gordon's testimony no weight as it relates to whether or not Jones' patients were drug dealers or addicts because Dr. Gordon has no personal knowledge of Jones' patients. Dr. Gordon's testimony is only credible in that it shows the prescriptions Jones Pharmacy filled presented red flags for a variety of reasons. [Tr. 342].

by the state of Florida so that a pharmacist could see if a patient was either doctor shopping or pharmacy shopping. [*Id.*]. The program shows other pharmacies where the patient went to fill prescriptions, and the medication and controlled substances he received. [Tr. 228]. Dr. Gordon's normal procedure when she receives a prescription is to check if the patient has visited her pharmacy before. If the patient has not, then Dr. Gordon will look for the patient's profile in the E-FORCSE program. [Tr. 227–228].

115. Dr. Gordon also stated that it was important to know the scope of a physician's practice, because deviation from the practice area could indicate a possible red flag.⁵⁸ [Tr. 228–229]. Dr. Gordon stated that if a pharmacist does not know the prescriber, there are other tools the pharmacist can use to view a prescriber's specialty. [Tr. 228]. Dr. Gordon explained that Publix had a National Provider Identifier (“NPI”) system which allowed the pharmacist to look up a doctor and their specialty. [*Id.*]. For pharmacies without an NPI, Dr. Gordon stated that a pharmacist could also go to the Department of Health website and look up the prescriber's specialty as well. [Tr. 228].

116. Dr. Gordon explained that with proper pain management, “the patient should present a prescription for a long acting plus a short acting [medication]. And the rule of thumb is, you know, usually no more than two to three breakthrough doses per day. So really a short acting prescription if the patient is being managed chronically should not exceed maybe three tablets a day or 90 pills a month.” [Tr. 229].

117. Dr. Gordon further testified that some drugs, like Oxycodone and Hydromorphone can be a red flag themselves. [Tr. 230]. Dr. Gordon testified to an IMS Institute of Healthcare Informatics report that was admitted at the hearing. [Tr. 287–288;

Gov't Exh. 29]. Dr. Gordon stated that the IMS report indicates that the national average for cash sales of prescriptions dispensed between the years 2007 to 2011 is six percent. [Tr. 288; Gov't Exh at 42].

118. Dr. Gordon testified that there are circumstances where a pharmacist can fill prescriptions despite the presence of one or more of these red flags. [Tr. 231]. This can be accomplished by speaking to the patient, speaking to the caregiver, speaking to the physician's office. [Tr. 231].

119. Dr. Gordon stated that as a retail pharmacist, she never set prices for any medications. [Tr. 297].

120. In 2010, Dr. Gordon was asked by Group Supervisor Gayle Lane and DI Domingo Gonzales to look at Jones Pharmacy's prescriptions to determine if Cherise Jones did anything wrong in filling them. [Tr. 240]. Dr. Gordon was asked to look at Jones Pharmacy's prescriptions and dispensing report, and determine whether or not she would have filled the prescriptions at issue. [Tr. 240–241, 301]. Dr. Gordon prepared a report that described certain red flags that she saw with Jones Pharmacy's prescriptions. [Tr. 305]. Dr. Gordon testified that some of the prescriptions presented red flags that could not be conclusively resolved. [Tr. 241].

F. Red Flags Within Jones Pharmacy's Prescriptions

121. There is no one place where a registrant can go to view a published list of “red flags.” [Tr. 140]. This includes the DEA Pharmacy Manual, or the DEA's instructions on operating a pharmacy. [Tr. 140–141]. Supervisor Lane testified that there is no place where pharmacists can find a comprehensive list of “red flags” because the red flags are changing in various parts of the country. [Tr. 142]. Supervisor Lane said that recognizing these flags was “common sense on a pharmacist's part,” and that DEA cannot publish a definitive list of red flags because “[p]harmacy practice isn't a checkoff list, and the red flags change.” [Tr. 142–143].

122. Jones Pharmacy filled prescriptions for patients B.F. and K.W. These two individuals presented identification from Ohio on the same street. [Tr. 243; Gov't Exh. 15, 43].⁵⁹ The

patients were seeing the same doctor in Fort Lauderdale, the prescriptions were written on the same date, and the prescriptions were filled at the same time for common cocktail medications: Oxycodone 30, Oxycodone 15, Xanax 2, and Carisoprodol. Dr. Gordon stated that the dosing in these prescriptions were red flags because with proper pain management, a person normally has a long acting medication plus a short acting pain medication. [Tr. 244; Gov't Exh. 15, 43] In this case, both Oxycodone 30 and Oxycodone 15 were dispensed. [Tr. 244]. There is no need, however, to issue these two different strengths of this prescription because Oxycodone 30 could be split in half to achieve the proper dose. [Tr. 244–245; Gov't Exh. 15, 43]. Further, Dr. Gordon testified that a combination of Oxycodone and Xanax was a red flag because the two medications accentuate each other making euphoric effects. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve all of these red flags when presented together.⁶⁰ [Tr. 243; Gov't Exh. 15, 43].

123. Jones Pharmacy filled prescriptions for patients that traveled from North Carolina to see doctors in Deerfield Beach. [Tr. 247–248; Gov't Exh. 16, 44]. Dr. Wolff, a pulmonologist, and Dr. Nuanger, a urologist, issued multiple prescriptions for Oxycodone 15 mg, 30 mg, and Xanax 2 mg. [Tr. 248 Gov't Exh. 16, 44]. Each time, Jones Pharmacy was paid cash for these prescriptions. [Tr. 248]. Dr. Gordon testified that it was not normal to see prescriptions from a urologist for combinations of Oxycodone and Xanax month after month. [Tr. 249; Gov't Exh. 16, 44]. Likewise, Dr. Gordon testified that it was not typical to see a pulmonologist issue prescriptions for Oxycodone and Xanax, especially since these patients were receiving these prescriptions repeatedly, month after month. [Tr. 249; Gov't Exh. 16, 44]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve the red flags present in these prescriptions. [Tr. 248; Gov't Exh. 16, 44].

124. Jones Pharmacy filled prescriptions for D.H. and K.S. [Tr. 250; Gov't Exh. 17, 45]. These patients

were prepared this way to avoid the use of an electronic spreadsheet. [Tr.70].

⁶⁰ In Government Exhibit 15 at 1, there was a handwritten notation stating that the prescription was verified by Angie. [Tr. 243–244]. Dr. Gordon testified that this only indicated that someone at Jones pharmacy called to make sure the doctor wrote the prescription, not that Jones Pharmacy tested whether this prescription was for a legitimate medical purpose. [Tr. 244].

⁵⁸ During her cross-examination Dr. Gordon stated that it is “frowned upon” and “unethical” for a doctor to write a prescription for a reason outside of his particular scope of practice. [Tr. 334–335]. When questioned along these lines, Dr. Gordon could not produce a rule or authority for these contentions. [*Id.*]. Here, I afford no weight to Dr. Gordon's conclusions that it is “unethical” or “frowned upon” for a physician to write a prescription outside his normal scope of practice, for Dr. Gordon presented no authority, rule, or basis for her knowledge that would corroborate these assertions. I do, however, recognize and find credible Dr. Gordon's testimony that a physician prescribing outside their normal scope of practice presents a “red flag” when there is a high volume of controlled substances prescribed by a doctor repeatedly operating outside his scope of practice. [Tr. 228–229; 379]. In this instance, Dr. Gordon noted such a pattern by utilizing and sorting through DI Gonzales' Microsoft excel pivot tables. [Tr. 379–380].

⁵⁹ Government Exhibits 43 through 54 are printouts of the dispensing report that indicate the dispensing history for the customers whose prescriptions are identified in the order to show cause. [Tr. 72]. When counsel for the Government introduced a set of prescriptions in Government Exhibits 15 through 24, he also introduced the correlating customer's dispensing history in Government Exhibits 43–54. [Tr. 72] The exhibits

presented identification which indicated they lived at the same address in Tennessee. [Tr. 250; Gov't Exh. 17, 45]. Jones dispensed common cocktail drugs, Oxycodone 30 mg, Oxycodone 15 mg, and Xanax 2 mg to D.H. and K.S. [Tr. 250; Gov't Exh. 17, 45]. Both patients were seeing doctors in Opa Locka, Florida. [Tr. 250; Gov't Exh. 17, 45]. The patients paid for these prescriptions with cash. [Tr. 250]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve the red flags present in these prescriptions. [Tr. 250; Gov't Exh. 17, 45].

125. Ms. Jones testified to prescriptions for patient D.H. and patient K.S. which indicated the patients' diagnosis. [Tr. 515–517; Gov't Exh. 17, at 1, 9]. Both prescriptions listed “chronic back pain” on their front side in handwriting. [Gov't Exh. 17, at 1, 9]. The back of these prescriptions indicated that the patients had the same address. [Gov't Exh. 17, at 2, 10]. With regard to the similar addresses, Ms. Jones admitted that at the time these prescriptions were filled it was “not something that [she] actually probably noticed.” [Tr. 518]. Ms. Jones stated that looking at the addresses is something now that she looks at more closely. [Tr. 518–519]. Ms. Jones testified that she is not aware of this or any prescription dispensed at the pharmacy being diverted. [Tr. 517].

126. Jones Pharmacy filled prescriptions for patients on two dates in April of 2010 where red flags were present. [Tr. 251; Gov't Exh. 18,46]. All of the prescriptions filled on April 19, 2010 and April 20, 2010, were from patrons who lived out of state. [Tr. 251; Gov't Exh. 18,46]. Specifically, the patrons lived in Ohio, West Virginia, Georgia, Tennessee, Kentucky, and Mississippi. They were prescribed the typical cocktail medications Oxycodone 15, Oxycodone 30, and Xanax 2. [Tr. 251; Gov't Exh. 18, 46]. There was also some Percocet sporadically prescribed therein. [Tr. 251– 252; Gov't Exh. 18,46]. All of the patients were driving to either Miami or Deerfield Beach and seeing a couple of doctors, including Dr. Wolff, the pulmonologist. [Tr. 252; Gov't Exh. 18,46]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve the red flags present in these prescriptions. [Tr. 251–252; Gov't Exh. 18, 46].

127. Jones Pharmacy filled prescriptions where red flags were present on October 26, 2010. [Tr. 252–253; Gov't Exh. 19, 47]. The patient these prescriptions were dispensed to lived in Panama City, approximately 10 hours away from Jones Pharmacy. [Tr.

253; Gov't Exh. 19, 47]. The medications were prescribed to a 56-year-old man, by a pediatrician, and consisted of Oxycodone 30 mg, Oxycodone-APAP 10/325 mg, and Carisoprodol 350 mg. [Tr. 253; ALJ Exh. 21 at 4]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve these flags. [Tr. 257–258; Gov't Exh. 19, 47].

128. Jones Pharmacy filled prescriptions for patient D.T. on February 28, 2011. [Tr. 265; Gov't Exh. 20, 48]. The prescriptions were for Oxycodone 30 mg, Oxycodone 15 mg, and Alprazolam 2 mg. [Tr. 266]. The prescription indicated that the patient is from West Virginia. [Tr. 265–266; Gov't Exh. 20, 48]. The prescribing doctor, Dr. Karten, is a Gynecologist, or OB/GYN. [Tr. 268; Gov't Exh. 20, 40, 48]. Patient D.T., however, is a male. [Tr. 268]. This indicates that Dr. Karten is prescribing outside the scope of his practice. [Tr. 268]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve the red flags present in these prescriptions. [Tr. 268; Gov't Exh. 20, 48].

129. Jones Pharmacy filled prescriptions for three different individuals on July 27, 2011. [Tr. 269; Gov't Exh. 21, 49]. The prescriptions were filled for three different patients from West Palm Beach who traveled to Wilton Manors, Florida, to obtain similar prescriptions. [Tr. 269; Gov't Exh. 21, 49]. The prescriptions were prescribed on the same date for Oxycodone 30, Xanax 2, and Oxycodone 15. [Tr. 269; Gov't Exh. 21, 49]. The patients all paid for the prescriptions in cash. [Tr. 269; Gov't Exh. 21, 49]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve the red flags present in these prescriptions. [Tr. 270; Gov't Exh. 21, 49].

130. Jones Pharmacy filled prescriptions for three patients on August 1, 2011. [Tr. 270; Gov't Exh. 22, 50]. These prescriptions were filled for patients from West Palm Beach, Florida, who drove to Sunrise, Florida, to obtain these prescriptions for cocktail medications. [Tr. 270; Gov't Exh. 22, 50]. After obtaining identical prescriptions on the same day from the same doctor, these patients drove to Jones Pharmacy to have them filled. [Tr. 270; Gov't Exh. 22, 50]. The patients presented prescriptions for Oxycodone 30 mg and Xanax 2 mg. [Tr. 271; Gov't Exh. 22, 50]. Dr. Gordon stated that this appeared to be an instance where the doctor was “rubber stamping” the prescriptions, there was no individualized treatment. [Tr. 271; Gov't Exh. 22, 50]. Dr. Gordon further testified

that Xanax 2 mg is a very high dose of Xanax.⁶¹ Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve the red flags present in these prescriptions. [Tr. 272; Gov't Exh. 22, 50].

131. Ms. Jones testified that at the time the above described prescriptions were presented, she had no concerns with the prescriptions, including the distances the patients traveled to the pharmacy. [Tr. 528–529]. In fact, Ms. Jones testified that these prescriptions indicated that she and a pharmacy technician wrote on the prescriptions verifying the diagnosis. [Tr. 526–527]. Ms. Jones stated that with her current knowledge, if she was presented with the same prescription today, she would look at the patient's address, look at the type of doctor, the monitoring system E-FORCSE, and have the patient explain the reason for filling the prescription at Jones Pharmacy if he traveled a long distance. [Tr. 529–530].

132. Jones Pharmacy filled prescriptions for repeat customer D.O. on multiple occasions. [Tr. 273; Gov't Exh. 23, 51]. D.O. presented identification that indicated his address is in Pompano Beach, Florida. [Tr. 273; Gov't Exh. 23, 51]. D.O. drove to Miami to see a doctor, and then back up to Fort Lauderdale to Jones Pharmacy to have the prescription filled. [Tr. 273; Gov't Exh. 23, 51]. D.O. obtained Hydromorphone 8 mg and Clonazepam 1 mg. [Tr. 273; Gov't Exh. 23, 51]. Hydromorphone 8 mg and Clonazepam 1 mg are common cocktail medications. [Tr. 273]. The doctor who provided D.O. these medications, Ronald H. Thompson, M.D., specializes as an obstetrics and gynecologist, an OB/GYN. [Tr. 274; Gov't Exh. 38]. D.O. is a male patient. [Tr. at 274]. During his first visit to Jones Pharmacy, D.O. paid \$900 for 180 tablets of Hydromorphone. [Tr. 274]. On his second visit, he paid \$1620 for 180 tablets of Hydromorphone 8 mg. [Tr. 275]. Dr. Gordon stated that these factors indicated Jones Pharmacy knew that “these medications were diverted and [that] the patron was taken advantage of” by Jones Pharmacy by charging such high prices. [Id.]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve the red flags present in these prescriptions, and these prescriptions could not have been filled in compliance with Jones Pharmacy's duties. [Tr. 275; Gov't Exh. 23, 51].

⁶¹ Dr. Gordon testified that in her experience as a Clinical Hospice Pharmacist catering to terminal patients, she rarely sees prescriptions for Xanax 2 mg because it is such a high dose of Xanax. [Tr. 272].

133. Jones Pharmacy filled prescriptions for patient M.S./S.M. who lives in Deerfield Beach, Florida. M.S./S.M. traveled north to Boca Raton, Florida, to see a doctor, then traveled south to Jones Pharmacy to have the prescriptions filled. [Tr. 276; Gov't Exh. 24, 52]. The prescriptions filled were Oxycodone 30 mg, and the doctor's signature appeared to be stamped, not signed. [Tr. 276; Gov't Exh. 24]. Dr. Gordon testified that this indicates that Oxycodone 30 mg is a medication that this Doctor regularly prescribes. [Tr. 277]. M.S./S.M. paid between \$1080—\$1980 for a 180 pill prescription. [Tr. 277]. Dr. Gordon stated that this indicated that “the pharmacist was aware of what she was charging and [that she was] taking advantage of patrons, of drug addicts or drug dealers.” [Tr. 277]. Dr. Gordon further stated that there was nothing Jones Pharmacy could have done to resolve the apparent red flags in these prescriptions. [Tr. 279].

134. Ms. Jones testified about the verifications that were conducted for these prescriptions. [Tr. 533; Gov't Exh. 24]. Ms. Jones confirmed that the prescriptions were verified with the prescriber for the diagnosis. [Tr. 534]. Ms. Jones confirmed that the prescriptions appear to have been stamped with the prescribing Doctor's signature. [Tr. 534–536].

135. With regard to the above listed prescriptions at issue in this matter, Ms. Jones testified that “we may have made mistakes that people may call dumb, naive, stupid, but it was not our intent to put stuff in the hand of other people.” [Tr. 531]. Ms. Jones further stated “I would have done stuff different if it was, if it's now, I would do it different.” [Tr. 532]. Ms. Jones also expressed confusion about her corresponding responsibility when questioned on the topic. She stated “I did not know that the law said that I had to make sure that prescriptions said it was legitimate, medically legitimate.” [Tr. 640]. When asked if there were circumstances that would cause Ms. Jones to reject a prescription, Ms. Jones stated “[t]here are circumstances that would cause me to reject a prescription. I don't think I can make the determination whether it's for a legitimate medical purposes because I would have to say that I'm in that person's body and I know how they feel if we're speaking just about pain medications.” [Tr. 625].

136. Ms. Jones admitted that “she could have done things a lot different.” [Tr. 579]. Ms. Jones stated that she was aware of her responsibility for public safety, but that she didn't think at the time that the prescriptions were issued

for a non-legitimate medical purpose. Ms. Jones stated that she thought what she did was enough in reconciling the prescriptions. [Tr. 579] Now, however, Ms. Jones knows that she could have, and should have, done more.⁶² [Tr. 580].

137. In 2010, Jones Pharmacy made a total gross margin of \$530,483.06 on the sales of controlled substances. [Tr. 651; Resp. Exh. 13, at 40]. In 2010, Jones pharmacy made a total gross margin of \$10,188.89 on the sales of non-controlled substances. [Tr. 652; Resp. Exh. 14, at 25]. Ms. Jones testified that in 2010, controlled substance sales made up the primary sources of her income. [Tr. 653]. Ms. Jones stated that this amount of controlled substance sales for an independent pharmacy was normal in 2010. [Tr. 653]. In 2010, Ms. Jones conversed with a Walmart pharmacist in Jacksonville, an independent pharmacist in Fort Lauderdale, and an independent pharmacist in Miami on this topic. [Tr. 655–656]. These pharmacists told Ms. Jones that this level of controlled substance sales was normal. [Tr. 654–655].

138. In 2011, Jones Pharmacy filled slightly less than 1,100 prescriptions for controlled substances. [Tr. 666]. Jones Pharmacy made a total gross margin of \$439,990 on the sales of these controlled substances. [Tr. 666–667; Resp. Exh. 15, at 25]. In 2011, Jones Pharmacy made a total gross margin of \$38,241 on the sales of non-controlled substances. [Tr. 667; Resp. Exh. 16, at 66].

139. In 2012, Jones Pharmacy filled 720 controlled substance prescriptions for a profit of \$316,942. [Tr. 669–670; Resp. Exh. 17, at 19]. In 2012, Jones Pharmacy made a total gross margin of \$58,123 on the sales of non-controlled substances. [Resp. Exh. 18, at 64].

140. From April 2013 to December 2013, Jones pharmacy dispensed 213 prescriptions for controlled substances for a profit of \$25,556.69. [Tr. 670–671; Resp. Exh. 19, at 8].

141. In 2010, Jones pharmacy did not have any written policies related to the filling of prescriptions for controlled substances as it had to do with the legitimacy of prescriptions. [Tr. 656].

142. In 2011 and 2012, Jones Pharmacy filled more prescriptions for non-controlled substances than

⁶² On cross examination, Ms. Jones repeatedly stated that there was more she could have done to ensure the legitimacy of the prescriptions at issue. [Tr. 579–580, 582–583, 585–586, 588, 590–591, 593–596, 599–601, 608–609, 620–621, 623–624]. Ms. Jones admitted that her “process wasn't great for looking at if [a prescription] was issued for [a] legitimate medical purpose.” [Tr. 580]. The process Ms. Jones used in 2010 only involved her calling the prescribing doctor's office for verification that the doctor wrote the prescription. [Tr. 581].

controlled substances. [Tr. 708; Resp. Exh. 4, 15, 16, 17, 18].

143. In 2013, Jones Pharmacy filled more prescriptions in non-controlled substances than controlled substances. [Tr. 709; Resp. Exh. 4, 19, 20].

G. Ms. Chereese Jones

144. Ms. Jones is the sole owner of Jones Pharmacy and SND Healthcare. [Tr. 570; Gov't Exh. 9, 10]. Jones Pharmacy has always been under the management of Ms. Jones. [Tr. 571]. Ms. Jones is the Registered Agent, the Florida Community Pharmacy Permit applicant, managing member, and authorized representative who submitted the Applications By Foreign Limited Liability Company For Authorization To Transact Business in Florida for both Jones Pharmacy and SND Healthcare. [Gov't Exh. 9, 10].

145. Ms. Jones works at Jones Total Health Pharmacy. [Tr. 385]. Jones Pharmacy is a community pharmacy in Fort Lauderdale. [*Id.*]. Ms. Jones holds current pharmacist licenses in Florida, Pennsylvania, Nebraska, Arkansas, Tennessee and Kentucky. [Tr. 385–386; Resp. Exh. 1]. Jones Pharmacy has a current license with the Florida Department of Health, Division of Medical Quality Assurance. [Tr. 387; Resp. Exh. 2–3].

146. Ms. Jones sent a letter to her congresswoman and two senators in Florida based on the delay she was experiencing with the DEA approving her move from one location to the other. [Tr. 87]. DI Gonzales was aware of Ms. Jones' congressional inquiries at the time he conducted the pharmacy inspection. [Tr. 87]. In the letters to her congressional representatives urging action on behalf of the DEA to change her pharmacy's address, Ms. Jones stated that she was “‘lucky’ to move her business to a ‘better environment’ where she could ‘go in the parking lot and not worry about smelling urine or seeing people hanging out on the sidewalk.’” [Resp. Exh. 5 at 2, 6 at 2, 7 at 2].

147. Ms. Jones graduated from Florida A&M University with a doctor of pharmacy degree in 2000. [Tr. 392; Resp. Exh. 1].

148. After graduation, Ms. Jones completed two American Society of Health Systems (ASHP) Pharmacists residencies. [Tr. 392–393]. The ASHP residencies are post-graduate volunteer training that a candidate is matched for. [Tr. 392]. Ms. Jones did her ASHP residency at Jackson Memorial Hospital, Miami, Florida. [Tr. 393–394; Resp. Exh. 1].

149. Ms. Jones' first residency was in pharmacy practice, and it focused mainly on adults. [Tr. 394]. The second

residency Ms. Jones completed was for pediatrics. [Tr. 395]. Following her residency at Jackson, Ms. Jones moved to Pennsylvania where she worked at a children's hospital and did some part-time rotations at a Walgreens. [Tr. 396].

150. After ten months in Pennsylvania, Ms. Jones moved back to Florida and began working at Miami Children's Hospital. [Tr. 400]. Ms. Jones worked at Miami Children's hospital for two years. [Tr. 407]. Following Miami Children's Hospital, Ms. Jones worked as a pharmacist for various employers, including Target, until she was hired by Community Health of South Florida ("CHI"). [Tr. 408]. CHI is a federally qualified health center. [Id.]. At CHI, Ms. Jones supervised three pharmacy managers, and numerous staff pharmacists and technicians. [Tr. 408–409].

151. Ms. Jones has completed poster presentations, and presented her work at the mid-year ASHP meetings. [Tr. 412]. Ms. Jones has also conducted in-service lectures. [Tr. 412–413; Resp. Exh. 1].

152. Ms. Jones started Jones Total Health Pharmacy in February of 2010. [Tr. 410]. Ms. Jones has always had a strong interest in pediatrics, and she desired to bring that interest to her own pharmacy. [Tr. 411]. Ms. Jones had never operated a pharmacy on her own before starting Jones Total Health Pharmacy. [Tr. 414]. Jones Pharmacy's original location was on 300 West Sunrise Boulevard in Fort Lauderdale. [Id.].

153. When Jones Pharmacy opened in 2010, it opened using a wholesaler, H.D. Smith. [Tr. 416]. H.D. Smith provided the pharmacy with everything that Jones Pharmacy sold, including controlled substances. [Tr. 416]. After about three months with H.D. Smith, the company informed Jones Pharmacy that its purchase volume was not enough to keep it with H.D. Smith. [Tr. 417]. Jones Pharmacy was then referred to SmartSource, but SmartSource only sold non-controlled substances. [Id.]. At that point, Jones Pharmacy started using multiple companies to get everything that it needed for the pharmacy. [Tr. 417–418]. Jones Pharmacy has been using McKesson for its pharmaceutical needs since the end of 2011. [Tr. 417–418].

154. Ms. Jones initiated policies and procedures she had utilized at CHI when she started Jones Pharmacy. [Tr. 420]. These policies included recording a patient's information in the computer system, checking whether a patient had allergies, and recording patient demographics. [Tr. 419]. Then the prescription was scanned into the

computer and typed. [Tr. 419]. If a patient presented a prescription for a controlled substance, Ms. Jones would call the doctor's office to ensure the doctor authored and issued the prescription. [Tr. 420] At its inception, Ms. Jones ensured that most of the pharmacy's policies and procedures were in writing. [Tr. 421]. Ms. Jones stated that the policies and procedures change when changes are necessary. [Id.]. Later, Ms. Jones started asking the prescribing doctor for a patient's diagnosis. [Tr. 513]. This was not until after the pharmacy had operated for a while, because it was not something that Ms. Jones had done at the other pharmacies she had previously worked at. [Id.].

155. Ms. Jones was not present for the State of Florida Department of Health Investigative Services inspection on April 14, 2011. [Tr. 423; Gov't Exh. 13]. In the remarks section of the report, Investigator Alan Miller concluded that Jones pharmacy was "filling and dispensing what appears to be a large amount of Schedule II Controlled Substances written prescriptions" from out of state patients. [Tr. 425–426; Gov't Exh. 13].

156. Jones Pharmacy stopped filling out of state prescriptions on April 1, 2011. [Tr. 426]. At that time, Jones Pharmacy's policies and procedures were not modified in writing to reflect this new policy change. [Tr. 428].

157. Jones Pharmacy had a fraud policy in place, for the identification and process of fraudulent prescriptions, in October of 2011. [Tr. 430; Resp. Exh. 25].

158. Pursuant to deficiencies uncovered during inspections from the State of Florida Department of Health Investigative Service, Ms. Jones promptly corrected all noted deficiencies. [Tr. 431–436].

159. The State of Florida Department of Health Investigative Service conducted an inspection on October 12, 2011, at Jones Pharmacy. During this inspection, Ms. Jones was not told that any of Jones Pharmacy's DEA 222 forms were deficient. [Tr. 441; Resp. Exh. 8, at 7].

160. The State of Florida Department of Health Investigative Service conducted an inspection on June 7, 2012, at Jones Pharmacy, for a change of pharmacy location. [Tr. 440; Resp. Exh. 8, at 5–6]. During this inspection, the Florida Department of Health investigator did not tell Ms. Jones that any of Jones Pharmacy's DEA 222 forms were deficient. [Tr. 440–441; Resp. Exh. 8 at 5–6]. Also during the June 7, 2012 inspection, Ms. Jones notified the inspector that the pharmacy had

encountered a prescription that had been forged. [Tr. 442; Resp. Exh. 8, at 5]. In response, the pharmacy reported the forgery to the police. [Id.].

161. After the State of Florida Department of Health Investigation inspected the new location for a change of pharmacy location, Ms. Jones submitted a request of registration update to the DEA. [Tr. 446]. Ms. Jones called the DEA and was told how to request the change of location. [Id.]. Ms. Jones completed her request on June 20, 2012. [Id.].

162. Ms. Jones acquired the new location, 1150 West Sunrise Boulevard, Fort Lauderdale, FL, in March of 2012. [Tr. 446; Resp. Exh. 12]. At that time, Ms. Jones was paying rent for two pharmacy locations: the new location awaiting approval from the DEA, and the location where she was operating. [Tr. 446–447].

163. Ms. Jones submitted her application for address change online to the DEA on June 20, 2012. [Tr. 455]. She followed-up on her application on July 3, 2012, by calling the DEA call center. [Tr. 455] The call center transferred Ms. Jones to the DEA's Weston office, and Donna Richards responded to Ms. Jones inquiry. [Tr. 455]. Later that day, Susan Langston called Ms. Jones and asked for a dispensing report for controlled substances. [Tr. 455–456; Gov't Exh. 2]. After Ms. Jones submitted the requested information to Ms. Langston, she waited for a reply. [Tr. 457]. Jones Pharmacy was prohibited from moving its controlled substances to the new location until the DEA approved the registration at the new address. [Id.].

164. Because Ms. Jones did not hear anything from Ms. Langston after she submitted her dispensing report, Ms. Jones sent emails to the DEA asking if there was any update on her registration. [Tr. 457]. Then, in October of 2012, Ms. Donna Richards asked Ms. Jones to send her Jones Pharmacy's dispensing report. [Tr. 457]. Ms. Jones sent Ms. Richards the file that same day, and Ms. Richards confirmed receipt. [Tr. 458]. Thereafter, Ms. Jones emailed for updates but did not receive any. [Id.].

165. Due to the DEA's inaction on her registration request, on March 7, 2013, Ms. Jones wrote to her U.S. Congresswoman, and U.S. Senators explaining the delay and her frustration. [Tr. 460; Resp. Exh. No 5, 6,7]. Senator Nelson, Senator Rubio, and Congresswoman Wasserman Shultz wrote back to Ms. Jones. [Tr. 464–465; Resp. Exh. 5,6,7].

166. Then, on April 2, 2013, Ms. Jones had a site visit from DI Gonzales and DI Richards. [Tr. 467–468]. During the visit, Ms. Jones was asked for controlled

substance prescriptions and ordering records. [Tr. 469]. Ms. Jones produced a computer file with the controlled substance ordering system (“CSOS”)⁶³ records. [Id.]. The file was saved in a CSV format. [Tr. 470]. Ms. Jones sent a paper copy of the records to DI Gonzales on May 3, 2013, via FedEx. [Tr. 471]. DI Gonzales contended that he could not read the records, so Ms. Jones wrote a key on the first page of the packet to help DI Gonzales understand the CSV format for the finalized CSOS orders. [Tr. 471, 473–474; Gov’t Exh. 53].

167. Ms. Jones testified that during the April 2, 2012 inspection, the meeting “wasn’t a good overall tone. The meeting just, it didn’t really—it deteriorated after it started.” [Tr. 475]. Ms. Jones stated that DI Gonzales took with him Jones Pharmacy’s controlled substances prescriptions, schedules II–V. [Tr. 475]. He also took the controlled substance ordering receipts and records. [Tr. 475].

168. Later on April 2, 2012, Ms. Jones received a call from DI Gonzales, DI Langston, and DI Richards. [Tr. 476]. Ms. Langston talked with Ms. Jones about the inspection that had been conducted that day and the letters Ms. Jones wrote to her Senators and Congresswoman. [Tr. 477]. Ms. Langston said the Registration was done, and DI Richards confirmed it. [Id.]. The change of address was approved. [Tr. 477; Resp. Exh. 8].

169. The next time Jones Pharmacy was inspected was in June of 2013 by the Florida Department of Health [Tr. 478].

170. In July of 2013, Ms. Jones met with DI Gonzales. [Tr. 481]. At the meeting, DI Gonzales talked about pricing, specialties of prescribers, and drug cocktails. [Tr. 481].

171. Ms. Jones explained that Jones Pharmacy’s controlled substances are priced through Average Wholesale Pricing (“AWP”). [Tr. 481–482]. Jones pharmacy has formulas in its software system that are based off of AWP. [Id.]. Specifically, Jones Pharmacy uses a Rx30 pharmacy system that derives its pricing information from First Databank. [Tr. 482, 678]. First Databank is a service Rx30 uses to set AWP information. [Tr. 678–679]. First Databank publishes various pricing benchmarks and information, and the Rx30 software is driven from it. [Tr. 678]. Jones Pharmacy has always used First Databank pricing, but it was up to the Pharmacy to change the pricing to

what they wanted it to be. [Tr. 483]. In 2014, After DI Gonzales brought to Ms. Jones’ attention the high prices the pharmacy was charging for controlleds, Jones Pharmacy started using the First Databank pricing, AWP plus the dispensing fee. [Tr. 483]. Prices vary based on the AWP at the time. [Tr. 483–484]. Often times AWP prices can be high. [Tr. 483–484].

172. Jones Pharmacy started using E–FORCSE in 2011. [Tr. 615]. E–FORCSE is the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program monitoring system. The system shows which pharmacies a patient went to, and the medication and/or controlled substances the patient received. [Tr. 228].⁶⁴ Before E–FORCSE, Jones Pharmacy used wholesalers that required it to enter the patients into a prescription monitoring program (“PMP”) report. Ms. Jones testified that she thought the only people that order from those same wholesalers fed into the system, and then you could look at the patient’s fill history. [Tr. 615–616].

173. Ms. Jones first heard about red flags for diversion when Florida Department of Health Inspector Robert Di Fiore inspected the Jones Pharmacy on May 14, 2014. [Tr. 484–485; Resp. Exh. 8, at 2].

174. Jones Pharmacy dispensed controlled substances to patient H.L. up until July 2014. [Tr. 495–496; Resp. Exh. 11, at 2]. Jones Pharmacy noted that patient H.L. was taking the same medication every month, and patient H.L. became verbally abusive if her prescription was “not ready or done her way.” [Tr. 495]. Due to this Jones Pharmacy stopped filling prescriptions for patient H.L., but other pharmacies continued to fill prescriptions for her. [Tr. 496; Resp. Exh. 11, at 2].

175. Ms. Jones stated that when Jones Pharmacy opened, it was not calling the prescriber to ascertain a patient’s diagnosis. [Tr. 513]. This practice was consistent with Ms. Jones’ experience in retail pharmacy. [Tr. 514–515]. Later, Ms. Jones instituted a policy of calling the prescriber and asking for a patient’s diagnosis. [Tr. 513]. Ms. Jones presented examples of situations wherein the

pharmacy called the doctor to ensure he authored the prescription, ascertained the patient’s diagnosis, and recorded it on the prescription. [Tr. 512–517, 524–527; 532–534; Gov’t Exh. 17, 22, 24].

176. Ms. Jones testified that she did not believe in any way that any of the prescriptions at issue in these proceedings were going to be diverted after they were filled. [Tr. 517–518, 524].

177. Ms. Jones stopped filling prescriptions for certain individuals after the May 2014 Florida Department of Health Investigation. [Tr. 538]. Inspector Crane brought to Ms. Jones’ attention the fact that certain patients coming to Jones Pharmacy had drug related arrest records. [Tr. 537–538]. Ms. Jones used the Broward County court website to look up patient names and determine if a patient had an arrest record. [Tr. 538]. From this information, Ms. Jones determined that certain patients had drug charges in their criminal records, and she refused to fill prescriptions for these individuals. [Tr. 538, 540–541].

178. Ms. Jones credibly testified that her practices today are different from those when she first opened Jones Pharmacy. [Tr. 519]. First, Ms. Jones dispenses much less controlled substances. [Tr. 565; Resp. Exh. 4]. Her main business is from non-controlled substances that the pharmacy sells. [Tr. 564–565]. Second, in the event that Jones Pharmacy is presented with a prescription similar to the ones at issue in this proceeding, Ms. Jones stated that she would do things differently. [Tr. 520–523]. She would look at the prescribing doctor’s credentials, the patients history in the monitoring system, speak with the doctor’s office, questioning why a patient is coming from out of state to have a prescription filled, and require documentation substantiating an out of state patients reason for fill. [Tr. 520–523; Tr. 544–545]. Ms. Jones also stated that she will not fill for cash only patients unless the patient presents a “really good reason.” [Tr. 541]. Ms. Jones stated the number of patients paying with cash have diminished significantly. [Tr. 565, 568–569; Resp. Exh. 4].

179. Ms. Jones now has a written policy for how employees are to evaluate controlled substance prescriptions. [Tr. 555–556; Resp. Exh. 26]. Ms. Jones testified that Jones Pharmacy’s new operational policies and procedures establish clear guidelines for how the pharmacy receives controlled substances, dispenses them to patients, evaluates the legitimacy of a prescription, verifies the prescription, what is done for pick-

⁶³ The Controlled Substance Ordering System (“CSOS”) is the system pharmacies use to electronically order a controlled substance from their wholesalers. [Tr. 470].

⁶⁴ The Florida E–FORCSE website indicates that the system was created in 2009 by the Florida Legislature to “encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida.” *Florida Health E–FORCSE Homepage*, <http://www.floridahealth.gov/statistics-and-data/e-forcse/> (last visited Apr. 10, 2015). Specifically, E–FORCSE “collects, maintains, and stores controlled substance prescription dispensing information in its database and makes the information available to health care practitioners and law enforcement and regulatory agencies during active investigations.” [Id.].

ups, drop offs, and the protocol to follow if the pharmacy decides not to fill a prescription. [Tr. 555–556; Resp. Exh. 26]. The new policy and procedures guide is dated January 4, 2015. [Tr. 556; Resp. Exh. 26].

180. When testifying about pricing procedures, Ms. Jones admitted that she marked up controlled and non-controlled substances. [Tr. 680–681]. In fact, Ms. Jones stated that she marked up “most of the controlleds.” [Tr. 682].

H. Ms. Donna Horn (Respondents’ Expert)

181. Donna Horn testified for the Respondent, and was recognized as an expert in pharmacy, pharmacy operations, and regulatory compliance for pharmacies. [Tr. 725, 737; Resp. Exh. 24]. Ms. Horn lives in Norwood, Massachusetts. [Tr. 713]. Ms. Horn graduated from Massachusetts College of Pharmacy in Boston, Massachusetts in 1983. [Tr. 714]. She then worked for Osco, a national pharmacy chain, as a pharmacist and pharmacy manager for many years. [Id.]. Eventually Osco was sold to Brooks Pharmacy, and Ms. Horn worked for Brooks as a regional pharmacy manager. [Tr. 714–715]. It was her job to ready and transition 28 stores that she was supervising to the Brooks system of operations. [Id.]. When that was completed, Ms. Horn became the manager of regulatory affairs for Brooks. [Id.]. In that role, Ms. Horn ensured that the policies and procedures for the Brooks pharmacies were in compliance with the state regulations. [Tr. 716]. Then, in 2006, Ms. Horn went to work for the Institute for Safe Medication Practices. [Tr. 717]. The institute conducts studies in medication errors that occur in hospitals and pharmacies. The institute also does continuing education (“CE”). [Tr. 717]. Ms. Horn also writes articles for journals, and has served on the Massachusetts Board of Pharmacy for 11 years. [Tr. 717–718]. In 1995, Ms. Horn was elected to the executive committee of the National Association of Boards of Pharmacy (“NABP”). [Tr. 720]. All boards of pharmacy in the United States are members of NABP. [Tr. 720]. At NABP, Ms. Horn wrote model rules and regulations in conjunction with stakeholders and experts in the field. [Tr. 720–721]. When Ms. Horn was president of NABP, her platform was “reducing medication errors in community pharmacies.” [Tr. 735]. Ms. Horn currently holds a pharmacy license in Massachusetts. [Tr. 722]. Ms. Horn is also an adjunct faculty member of the Massachusetts College of Pharmacy. [Tr. 724]. She has been qualified as an expert in Federal and

State courts. [Tr. 725; Resp. Exh. 24]. Ms. Horn’s experience reflects that she is very experienced in the prevention of Medication safety and errors. [Tr. 723, 728, 730–731; Resp. Exh. 24 at 5–9]. In fact, Ms. Horn indicated that patient safety and medication risk management is a passion of hers. [Tr. 723]. The last prescription Ms. Horn filled was in 2000 or 2001. [Tr. 794].

182. Ms. Horn testified that she talked with Ms. Jones, reviewed the documents in this case, and noticed that Ms. Jones has adapted her pharmacy policies to make a much more comprehensive and complete approach to compliance with the applicable regulations. [Tr. 743–744].

183. Ms. Horn testified that Ms. Jones’ policies and procedures [are] “a great example of what should be done in order to prevent the, prevent the fraudulent filling of controlled substances.” [Tr. 744; Resp. Exh. 25].

184. With regard to the dispensing of prescriptions in 2010, Ms. Horn stated that the dispensing pharmacist should have looked at the patient who is getting the prescription and recorded a complete patient history. [Tr. 748]. Ms. Horn also stated that, in 2010, a pharmacist needed to know a patient’s drug allergies, what the patient was being treated for, and other medications the patient was on, and who the prescriber was. [Id.]. Ms. Horn further testified that the pharmacist would look at the actual prescription itself for the quantity and frequency of what’s being dispensed to see if it makes sense. [Tr. 749].

185. Prior to 2014, Ms. Horn had not seen anything published by the DEA concerning the dispensing of controlled substances to out-of-state customers. [Tr. 752]. In May of 2014, Ms. Horn attended a presentation at the NABP annual meeting where the DEA displayed a video vignette on “red flags.” [Tr. 751]. The intent of the video was to have every state board of pharmacy publish a link to the video on their respective websites. [Tr. 752]. Ms. Horn stated that she did not believe that the DEA had published anything relating to red flags on their website in 2010 or 2011 because there is nothing on it today. [Tr. 752–753]. Ms. Horn stated that the May 2014 meeting was the first time she “heard of the red flags and saw them played out in a movie.” [Tr. 752]. Ms. Horn did acknowledge that in 2012, the DEA published a legal opinion on its website that referred to “red flags.” [Tr. 753]. Ms. Horn consulted some of the DEA administrative opinions in determining what was generally known among pharmacists in 2009–2011. [Tr. 872–

873]. Ms. Horn claimed that the first time the concept of “red flags” was widely known among pharmacists was in relation to the video vignette released in May of 2014. [Tr. 751–752].

186. Ms. Horn opined that, in 2010, it was not widely known among pharmacists that patients travelling long distances, seeking to pay cash, presenting combinations of narcotics, benzodiazepines, and carisoprodol, and presenting pattern prescriptions were indicators of abuse and/or diversion of controlled substances. [Tr. 864–866].

187. Ms. Horn reviewed the State of Florida Department Of Health Investigative Services inspection reports in forming her opinions. [Tr. 759, 761; Resp. Exh. 8].

188. Ms. Horn stated that she looked at the DEA Form 222’s in this matter, and she believed that the forms were in compliance with the applicable regulations. [Tr. 773; Resp. Exh. 27]. She stated that Respondent’s method of recordkeeping is compliant with the regulations, both federal and state. [Id.].

189. Ms. Horn testified that some combinations of drugs that are labeled as “cocktail drugs” may be taken together for legitimate medical reasons, and often are taken together. [Tr. 777].

190. Ms. Horn did not opine on any of the Government-presented prescriptions. [Tr. 780; Gov’t Exh. 15–23]. Ms. Horn stated that she did not review any of the prescriptions at issue from 2010–2012. [Tr. 806]. Ms. Horn indicated that she has not done any research about the corresponding responsibility of a pharmacist. [Tr. 799]. Ms. Horn also indicated that she has not given any presentations about the corresponding responsibility of a pharmacist since 2007. [Tr. 799]. Further, Ms. Horn indicated that she has not published any research on corresponding responsibility issues. [Tr. 797–798].

191. Ms. Horn testified that she agreed with the procedures that Ms. Jones was using in 2010. [Tr. 781]. Ms. Horn stated that she believed Ms. Jones’ procedures were in conformity with what the DEA expected a pharmacist to do to prevent diversion in 2010. [Id.].

192. Ms. Horn testified that Jones Pharmacy has displayed a “positive trend downwards as to the amount of controlleds that are dispensed per non-controlleds.” [Tr. 785]. Ms. Horn further testified that she believed Ms. Jones is “aware now that people are not as honest as she thought that they were and that she’s made steps to get those people out of her business.” [Tr. 786].

193. Ms. Horn testified that she did not review any of the Florida rules regarding the use or misuse of

prescriptions in preparation for her testimony. [Tr. 805–806].

194. Ms. Horn stated that her opinion in this case, that Ms. Jones should maintain her DEA registration, is based on her conversations with Ms. Jones. [Tr. 806–808]. Ms. Horn stated that Ms. Jones has learned a lot from the time she opened Jones Pharmacy, and “she understands what her responsibilities are. They are much more clear to her now. The conversations that I’ve had with her, I truly believe she would not go to filling those prescriptions and she would certainly take into [sic] affect any other DEA red flags that you come up with, she would use those in determining, as long as she knows about them, in determining whether or not to fill a prescription. I truly believe that.” [Tr. 807]. Ms. Horn opined Ms. Jones’ current dispensing practices are “very much in line with what [Ms. Horn] would expect to see at a community pharmacy.” [Tr. 785–786].

195. Ms. Horn did not offer any opinions as to whether or not Jones Pharmacy’s dispensing of controlled substances was abnormal in 2010, 2011, and 2012. [Tr. 809]. Similarly, Ms. Horn did not opine about the practice of dispensing controlled substances to out of state persons and the prices charged for controlled substances for the timeframe 2010 through 2012. [Tr. 810–812]. Ms. Horn stated that she thinks Ms. Jones “did exercise her corresponding responsibility in 2014.” [Tr. 809].

196. Ms. Horn testified that Jones Pharmacy’s unwritten 2010 policy of calling the prescribing doctor—to certify that the doctor authored the prescription himself—indicated that the pharmacy was exercising its corresponding responsibility to ensure controlled substances were issued for a legitimate medical purpose under federal law. [Tr. 827; Resp. Exh. 25]. Ms. Horn further testified that merely calling the doctor was not enough, it “is also imperative that you have a discussion to talk about what is the diagnosis and what is the treatment going to be.” [Tr. 829]. Ms. Horn further stated that the above listed protocols are “all [she] knows about what was expected of a corresponding responsibility up until the time [the DEA] came up with these other red flags that would also help a pharmacist determine whether or not a prescription should be filled or not.” [Tr. 829].

197. Ms. Horn liked the Respondent’s more recent policies better than her earlier policies because the policies have been “updated to reflect new knowledge of diversion tactics.” [Tr. 832; Resp. Exh. 26]. This new policy

was enacted in 2015. [Tr. 833]. Ms. Horn opined that Ms. Jones has changed “policies and procedures as she [has] learned about things.” [Tr. 850].

198. Ms. Horn stated that in 2010 it was not widely known in the pharmacy community that certain drugs or combinations of cocktails were indicative of abuse or diversion. [Tr. 864]. Ms. Horn also stated that in 2010 it was not widely known in the pharmacy community that paying cash was an indicator of abuse or diversion rather than using insurance. [Tr. 864]. Ms. Horn stated that in 2010 it was not widely known in the pharmacy community that pattern prescribing—“patients going to the same doctor for the same ailments, receiving the same prescriptions in the same quantity without any difference in the treatment” [Tr. 865]—was an indicator of abuse or diversion. [Tr. 865]. Ms. Horn stated that in 2010 it was not widely known that Xanax 2 mg was only used in rare circumstances. [Tr. 865–866].

V. Conclusions of Law and Discussion

A. Position of the Parties

1. The Government’s Position

On April 20, 2015, the Government timely filed its lengthy (eighty-one page) Government’s Proposed Findings Of Fact And Conclusions Of Law (“Gov’t Brief”). In it, the Government urged me to accept the following conclusions of law: (1) the dispensing practices at Jones Total Health Pharmacy LLC are an appropriate basis to deny SND Healthcare LLC’s application for a DEA registration; (2) Jones Pharmacy committed acts that render its continued registration inconsistent with the public interest; and (3) Respondents have not credibly accepted responsibility or undertaken meaningful remedial measures. [Gov’t Br. 42–79].

First, as support for its argument that the dispensing practices at Jones Pharmacy are an appropriate basis to deny SND Healthcare LLC’s application for a DEA registration, the Government avers that Jones Pharmacy and SND Healthcare are appropriately treated as one integrated enterprise for purposes of this proceeding. [Gov’t Br. 42]. The Government states that “[t]he DEA has denied an application by one business entity for a DEA COR as being inconsistent with the public interest, 21 U.S.C. 823(f), based on a separate, related business entity’s dispensing conduct [sic] were it could find that the two were ‘nominally separate business entities.’” [Gov’t Br. 42 (*citing MB Wholesale, Inc.*, 72 Fed. Reg. 71,956, 71,958 (DEA 2007))]. The Government further states that SND Healthcare is

essentially an expansion of Jones Pharmacy into Miami and the two entities can fairly be considered one ‘integrated enterprise’ [because] . . . the ownership, management, and retail pharmacy operations of Jones Pharmacy and SND Healthcare are centralized with Chereese Jones.” [Gov’t Br. 43]. Due to this, the Government argues that there is “no basis in evidence or logic for imposing different sanctions for SND Healthcare and Jones Pharmacy or treating them as anything other than the integrated enterprise they are.” [Gov’t Br. 43–44].

Second, the Government argues that Jones Pharmacy committed acts that render its continued registration inconsistent with the public interest. [*Id.*]. Here, the Government avers that Jones Pharmacy filled over a hundred prescriptions for controlled substances that presented indicia of diversion and abuse. [Gov’t Br. 45]. As support, the Government cites prescriptions in Government Exhibits 15–24, and explains that these prescriptions displayed “red flags” that were indicators of diversion and abuse. [Gov’t Br. 45–46]. These “red flags” consisted of customers traveling long distances (often from out of state), cash payments, pattern prescribing, prescriptions for immediate release pain medications in two different strengths or with no accompanying long-acting pain medications, and prescriptions for common cocktail medications. [*Id.*]. The Government also contends that Jones Pharmacy charged exorbitant cash prices for its “highly diverted narcotics” by citing an example wherein Jones Pharmacy charged “one patient \$9, \$10, or \$11 a pill—mark-ups of over 3,000% over Jones Pharmacy’s cost to obtain these drugs—when it was filling prescriptions from a doctor who literally used a rubber stamp to prescribe oxycodone.” [Gov’t Br. 48]. The Government states that these “red flags” presented “were not feasibly resolvable by a pharmacist operating within the accepted bounds of the profession exercising the responsibility to ensure that they were filling only legitimate controlled substance prescriptions.” [Gov’t Br. 49].

Along these lines, the Government states that Jones Pharmacy’s dispensing patterns, prices, and profits show that filling suspicious controlled substance prescriptions was its chosen business model, and the filling of these controlled substances was Jones’ primary business. [Gov’t Br. 49–52]. The Government further avers that Ms. Jones knew or had reason to know of the Pharmacy’s unlawful dispensing, and her claimed ignorance of abuse and

diversion is neither a credible nor a legally viable defense. [Gov't Br. 53]. The Government then argues that Ms. Jones' purported naiveté "simply cannot be squared with the objective evidence," [Id.] and requests that I find that "Ms. Jones was not credible when she portrayed herself as 'dumb, naïve, [and] stupid' because this description cannot be squared with the profits she made and the prices she charged in 2010, 2011, and 2012." [Gov't Br. 58].

Next, the Government explains that the testimony of Respondent's expert, Ms. Horn, is neither credible nor grounded in any professional experience with regard to pharmacists' general ignorance of red flags. [Gov't Br. 59]. Here, the Government contests Ms. Horn's "professional exposure to issues involving a pharmacist's corresponding responsibility have been sparse, sporadic, and sparse." [Id.]. The Government cites facts such as Ms. Horn has never filled prescriptions in Florida, and Ms. Horn last practiced as a pharmacist filling prescriptions fifteen years ago. [Gov't Br. 60]. Finally, the Government states that accepting Ms. Horn's conclusion that "red flags" were a mystery in 2010 would upend this Agency's prior opinions and the expertise on which they were based. [Gov't Br. 65].

As additional support for its assertion that Jones Pharmacy committed acts that render its continued registration inconsistent with the public interest the Government states that Jones Pharmacy's inventories and records were deficient. [Gov't Br. 65]. Specifically, the Government alleges that the Respondent's inventories did not include whether they were taken at the beginning or end of the day, the number of commercial containers or dosage units per container, and what was received at the pharmacy for 480 orders of controlled substances. [Gov't Br. 66]. Citing these violations, the Government states "[a]lthough revocation and denial of Respondents' registrations is justified based on Jones Pharmacy's dispensing practices alone, recordkeeping deficiencies provide yet more reason to support this determination." [Gov't Br. 68].

Last, the Government argues that Respondents have not credibly accepted responsibility or undertaken meaningful remedial measures. [Gov't Br. 68]. The Government contends that Ms. Jones refused to admit responsibility for her past conduct, and revealed ignorance of her responsibilities that persists to this day. [Gov't Br. 69]. The Government avers that Ms. Jones' statements that she "could have done more" to prevent abuse and diversion" place her as a

third party bystander to wrongdoing. [Gov't Br. 72]. The Government states that Ms. Jones' testimony "that she viewed, and continues to view, this as a prescriber's responsibility is a blatant attempt to shift blame to others, not accept it for herself." [Id.]. Further, the Government states that Jones Pharmacy offered no credible evidence of remedial efforts because Respondent's attempt to show that it had a dramatic decline in controlled substances dispensing "coincided with (1) the decision to stop servicing out-of-state customers in April 2011 and (2) after the DEA started investigating Jones Pharmacy in April 2013." [Gov't Br. 78]. Finally, the Government urges me to find that "Jones Pharmacy's changes in dispensing practices reflect law enforcement's scrutiny of Jones Pharmacy rather than Jones Pharmacy's scrutiny of its customers." [Id.].

2. The Respondent's Position

On April 20, 2015, the Respondents timely filed their Respondents' Post-Hearing Brief. ("Resp. Brief"). Therein, the Respondent averred that Jones Pharmacy's continued registration is not inconsistent with the public interest, and that the Respondents have presented evidence to mitigate any evidence that shows that their registrations threaten the public interest. [Resp. Br. 29–37].

First, in addressing their contention that Jones Pharmacy's continued registration is not inconsistent with the public interest, the Respondents argue that public interest factors 1 and 3 clearly weigh in Respondent's favor. [Resp. Br. 29]. As support, the Respondents state that they currently hold a valid Florida license, and that the Florida Board of Pharmacy has not initiated any action against their license since its issuance in 2009. [Resp. Br. at 29–30]. Respondents also state that there is "no evidence in the record that the Respondent or its owner/operator has ever been convicted (or charged with) a crime related to the manufacture, distribution, or dispensing of controlled substances." [Resp. Br. 30].

Next, Respondents address public interest factor two by explaining that their experience in dispensing controlled substances has changed considerably from 2010 until now. [Resp. Br. 30]. The Respondents state that "[i]n 2010, controlled substance dispensing constituted 63% of Jones' dispensing. This percentage steadily declined and as of the end of 2014, controlled substance dispensing was only at seventeen percent (17%)." [Resp. Br. 30]. Respondents also state that their cash business has been

significantly reduced from 2010 to 2014, and that Jones Pharmacy has "completely changed the way that it conducts its business with regard to controlled substances." [Resp. Br. 31].

The Respondents also argue that public interest factor four is in their favor because "[a]t all times during the period at issue, Respondents sought to comply with state and federal laws relating to controlled substances." [Resp. Br. 31]. Here the Respondents argue that there was no specific legal standard that defined "red flags" that a pharmacist was expected to recognize and act upon. [Resp. Br. 32]. As support, the Respondents cite the testimony of Ms. Donna Horn, Respondents' expert witness. [Id.]. Respondents state that Ms. Horn "testified that it was her opinion that Ms. Jones complied with her corresponding responsibility as she understood it at the time by taking the actions that she took to check the validity of the prescriptions." [Id.].

These procedures included verifying the individuals presenting the prescriptions, verifying the physician's office and identifying who spoke on behalf of the physician, verifying that the physicians' licenses were active, and obtaining the diagnosis. [Resp. Br. 32].

Respondents further aver that public interest factor five also weighs in their favor. [Resp. Br. 33]. Respondents argue that their continued registration and granting of pending registration will not threaten the public safety because there is evidence in the record that reflects Jones Pharmacy's compliance with the law, including the Florida Department of Health inspections. [Resp. Br. 33–34]. Further, Respondents argue that their expert, Ms. Donna Horn, testified that Respondents' continued registration would not be inconsistent with the public interest. [Resp. Br. 33].

Last, Respondents argue that even though they do not concede that the DEA has met its burden in this instance, Respondents have met their burden to show that their registrations do not threaten the public interest. [Resp. Br. 34]. First, Respondents aver that they have accepted responsibility for their actions through the testimony of Ms. Jones. [Resp. Br. 34–35]. Second, Respondents state that they have "demonstrated through [their] actions that [they have] taken remedial measures to insure future compliance" with the law. [Resp. Br. 35]. The Respondents explain that their remedial measures include:

- (1) ceasing to fill out of state prescriptions;
- (2) implementing a policy to ensure prevention of fraudulent dispensing;
- (3) supplementing the procedure for calling physician offices;
- (4) verifying physician

practice areas; (5) reviewing the distances traveled between a patient and the physician writing the prescription; (6) reviewing the distance traveled between the customer and the Pharmacy; (7) reviewing on E-FORSCE other locations at which customers are filling prescriptions; (8) implementing new written policies and procedures; (9) ceasing to accept cash payments for controlled substance prescriptions; (10) refusing to fill prescriptions for certain individuals with criminal backgrounds; and substantially reducing business relating to the filling of prescriptions for controlled substances.

[Resp. Br. 36]. Respondents contend that the majority of these actions were taken without prompting from regulators. [*Id.*]. Third, Respondents claim that their recordkeeping also affects public interest factor four. [*Id.*]. To this end, the Respondents state that they have remedied the initial glitches in the ordering system, and that the “record evidence reflects that Jones Total Health now maintains inventories in accordance with [DEA] requirements.” [Resp. Br. 37].

In Conclusion, the Respondents request that I find that their continued registration is not inconsistent with the public interest, and that they have presented sufficient evidence to mitigate any evidence that shows that their registrations threaten the public interest. [Resp. Br. 29–37].

B. Statement of Law and Discussion

Pursuant to 21 U.S.C. § 824(a)(4), the Administrator⁶⁵ may revoke a registration, and deny a pending application for renewal or modification, if she determines that the continuation or issuance of such registration would be “inconsistent with the public interest” as determined pursuant to 21 U.S.C. § 823(f). Section 823(f) requires that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances.
- (3) The [registrant’s] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

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

[21 U.S.C. § 823(f); see also *Alexander Drug Co.*, 66 Fed. Reg. 18, 299, 18,302 (DEA 2001); *Nicholas A. Sychak, d/b/a Medicap Pharmacy*, 65 Fed. Reg. 75,959,

75,967 (DEA 2000)]. These factors may be considered in the disjunctive: the Administrator may properly rely on any one or a combination of these factors, and may give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. [*See Direct Wholesale*, 69 Fed. Reg. 11,654, 11,655 (DEA 2004); *Henry J. Schwarz, Jr., M.D.*, 54 Fed. Reg. 16,422, 16,424 (DEA 1989)].

The applicable regulations state that the test for the proper prescribing and dispensing of controlled substances is as follows:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

[21 C.F.R. § 1306.04(a)]. Thus, for a prescription to be lawful, it needs to be written for a legitimate medical purpose in the practitioner’s usual course of professional practice. *Id.* The pharmacist has a corresponding responsibility to verify the validity of a prescription, and if a prescription seems suspect, the pharmacist should not fill it. [*Id.* See also *United Prescription Services, Inc.*, 72 Fed. Reg. at 50,397, 50,407 (DEA 2007)].

DEA prohibits a pharmacist from filling a prescription for controlled substances when he either “knows or has reason to know that the prescription was not written for a legitimate medical purpose.” [*United*, 72 Fed. Reg. at 50,407; *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043, 30,044 (DEA 1990); see also *Frank’s Corner Pharmacy*, 60 Fed. Reg. 17,574, 17,576 (DEA 1995); *Ralph J. Bertolino*, 55 Fed. Reg. 4,729, 4,730 (DEA 1990); *United States v. Seelig*, 622 F.2d 207, 213 (6th Cir. 1980)]. This Agency has further held 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.” [*Bertolino*, 55 Fed. Reg. at 4,730 (*citations omitted*)].

With regard to a Pharmacy’s conduct, DEA has consistently held that a retail store operates under the control of its owners, stockholders, or other employees, and therefore the conduct of these individuals is relevant in evaluating the fitness of an applicant. [*See e.g., Rick’s Pharmacy*, 62 Fed. Reg.

42,595 (DEA 1997); *Big T Pharmacy*, 47 Fed. Reg. 51,830 (DEA 1982)].

In a pharmacy case to revoke a pharmacy registrant’s certificate, the DEA has the burden of proving that the requirements for revocation are satisfied. [21 C.F.R. § 1301.44(e)]. Once the Government has proven its prima facie case, the burden of proof shifts to the Respondent. [*Arthur Sklar, R.Ph., d/b/a King Pharmacy*, 54 Fed. Reg. 34623, 34627 (DEA 1989)]. To rebut such a 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.” [*Holiday CVS*, 77 Fed. Reg. at 62, 339 *citing Jeri Hassman, M.D.*, 75 Fed. Reg. at 8,194, 8,236 (DEA 2010)].

Along these lines, in situations where a registrant has had a lengthy history of violations, the U.S. Courts of Appeal have upheld the Agency’s conclusions that past performance is the best predictor of future performance. [*Alra Labs. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995)].

1. Factor One: Recommendation of State Licensing Board

The record contains no recommendations from the State licensing board regarding these Respondents. Further, the record contains no evidence that the Respondents had any adverse State Board action taken against them. Lastly, the record contains no evidence that Ms. Jones had any adverse action taken by the State Board against her.

Recommendations of state licensing boards are relevant, but not dispositive, in determining whether a respondent should be permitted to maintain a registration. [*See Gregory D. Owens, D.D.S.*, 74 Fed. Reg. 36,751, 36,755 (DEA 2009); see also *Martha Hernandez, M.D.*, 62 Fed. Reg. 61,145, 61,147 (DEA 1997)]. According to clear Agency precedent, a “state license is a necessary, but not a sufficient condition for registration.” [*Robert A. Leslie, M.D.*, 68 Fed. Reg. at 15,230; *John H. Kennedy, M.D.*, 71 Fed. Reg. 35,705, 35,708 (DEA 2006)]. 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. 6,580, 6,590 (DEA 2007), *aff’d Chein v. DEA*, 533 F.3d 828 (D.C. Cir. 2008)].

I therefore conclude that the fact that the record does not contain evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether the

⁶⁵ The Administrator has the authority to make such determinations pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2014).

Respondents' continued registration is consistent with the public interest. [*See Top Rx*, 78 Fed. Reg. 26,069, 26,081 (DEA 2013)].

2. Factors Two and Four: Registrant's Experience in Dispensing Controlled Substances, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

Because the Respondents' experience in dispensing controlled substances is related to their compliance with state and federal law, factors two and four will be considered together. [*See, e.g., KK Pharmacy*, 64 Fed. Reg. 49,507, 49,510 (DEA 1999); *Service Pharmacy*, 61 Fed. Reg. 10,791, 10,795 (DEA 1996)].

a. Recordkeeping Violations

Recordkeeping is one of the CSA's essential tenets. For 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. 30,630, 30,644 (DEA 2008), *aff'd* 567 F.3d 215, 224 (6th Cir. 2009)]. Accomplishing this requires "every registrant manufacturing, distributing, or dispensing a controlled substance or substances [to] maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him." [21 U.S.C. § 827(a)(3)].

In this manner, the Agency has consistently "held that the failure to comply with recordkeeping requirements is a basis for revoking a registration. [*Alexander Drug Co.*, 66 FR at 18,299, 18,303 (DEA 2001) *citing Singers-Andreini Pharmacy, Inc.*, 63 FR 4,668 (DEA 1998); *Arthur Sklar*, 54 FR at 34,623; *Summer Grove Pharmacy*, 54 FR 28,522 (DEA 1989); *The Boro Pharmacy and Bell Apothecary*, 53 FR 15,151 (DEA 1988)]. Such lack of accountability is clearly not acceptable for a DEA registrant. [*Alexander Drug*, 66 FR at 18,303–04; *Volkman*, 73 FR at 30,644 (holding that recordkeeping violations alone supported denial of practitioner's application)].

Here, Jones Pharmacy was missing some of its required recordkeeping information. [FOF 84–85]. Specifically, the Respondents violated recordkeeping requirements by failing to record whether Jones Pharmacy's biennial inventory was taken at the opening or close of business, and by failing to indicate the number of tablets per opened commercial container, the number of tablets shipped in each commercial container, and the number of commercial containers that Ms. Jones

had on hand. [FOF 84–85; 21 CFR § 1304.11(e)(3)].⁶⁶ Such lack of accountability violates the DEA's regulations and the requisite closed system of distribution of controlled substances, for without such a complete inventory, the DEA is unable to conduct an accurate accountability audit. Although the inventory was complete in other aspects, Ms. Jones' partial compliance does not obviate her failure to record the required information on the biennial inventory.

Thus, the Respondent's lack of attention to detail with its accountability of the controlled substances received and dispensed is adequate grounds for recommending revocation of Jones Pharmacy's registration. [*Alexander Drug Co.*, 66 FR at 18,299, 18,303 (DEA 2001) *citing Singers-Andreini Pharmacy, Inc.*, 63 FR 4,668 (DEA 1998)].

⁶⁶ 21 CFR § 1304.11 lists the controlled substances inventory requirements. As part of the requirements, subsection (a) lists that "[t]he inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory." Further, § 1304.11(e)(3) lists the applicable inventory requirements for controlled substance dispensers. Specifically, the regulation states:

Each person registered or authorized to dispense . . . controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser . . . shall do as follows:

(i) If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or
(ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

§ 1304.11(e)(3).

The applicable portion of § 1304.11(e)(1)(iii) and (iv) states:

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance; (B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); (C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include: (A) The name of the substance; (B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and (C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

§ 1304.11(e)(1)(iii–iv).

b. Red Flags

The term "red flags" does not appear in the Controlled Substances Act, DEA regulations, or the DEA's Pharmacist Manual. [FOF 121]. However, the Government's expert, Dr. Tracy Gordon, indicated that the term "red flags" was generally known to Florida Pharmacists between 2010 and 2012. [FOF 109, 111 & n. 13]. The Respondent's expert, Ms. Donna Horn, indicated that the general pharmacist community was unaware of the "red flags" cited in this case between the 2010 and 2012. [FOF 185–186]. Here, I find Dr. Tracy Gordon's opinion more credible on this point, for Dr. Gordon's experience as a licensed Florida pharmacist who practiced as an Assistant Pharmacy Manager in Florida during the period 2010–2012 infers that she has knowledge of what pharmacists knew during this time. [FOF 106–111 & fn. 13].

The DEA has established a test for determining whether the Respondent's corresponding responsibility has been met in circumstances where the prescriptions raise red flags of potential improper prescribing. This three-part test is articulated as follows:

Because Agency precedent limits the corresponding responsibility to circumstances which are known or should have been known [citations omitted], 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.

[*Holiday CVS, LLC d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 FR 62,321, 62,316 (DEA 2012)]. The "steps necessary to resolve the red flag conclusively will perforce be influenced by the nature of the circumstances giving rise to the red flag." [*Id.* at 62,341].

It is undisputed that Jones Pharmacy dispensed the controlled substances at issue in this proceeding, for the Respondent stipulated to dispensing the aforementioned prescriptions. [FOF 1–61; ALJ Exh. 21]. Further, during the presentation of its case, the Government presented credible evidence that "red flags" were present in the prescriptions at issue in this matter. [FOF 1–61, 122–130, 132–133]. These "red flags" include patients traveling long distances for filling prescriptions (often traveling from out-of-state), prescriptions filled for common cocktail medications, short acting pain medications prescribed without a long acting pain medication,

prescriptions issued by doctors prescribing outside their scope of practice, prescriptions dispensed to patients with the same out-of-state address for the same controlled substances on the same day, and cash payments. [FOF 122–130; 132–133]. This evidence of the existence of “red flags” within Jones Pharmacy’s prescriptions was not rebutted by the Respondent’s expert witness. [FOF 189]. In fact, the Respondent’s expert witness did not opine on any of the prescriptions at issue in this matter. [FOF 190].

This analysis, therefore, centers on the third prong of the *Holiday CVS* test; whether the “red flags” presented in Jones Pharmacy’s prescriptions were conclusively resolved prior to the Pharmacy’s dispensing the controlled substances at issue. [See *Holiday CVS*, 77 FR at 62,316].

In her testimony, Ms. Jones stated that Jones Pharmacy followed the policies and procedures that were in place during 2010–2012 with regard to reviewing prescriptions for issues of concern. [FOF 154]. Those policies and procedures included only two methods of evaluating the legitimacy of a prescription: (1) telephoning the prescribing doctor to ensure that the prescription was authored by the prescribing doctor; and (2) inquiring about the patient’s diagnosis. [FOF 154]. Credible evidence of these procedures was produced at the hearing in the form of Jones Pharmacy’s original prescriptions—the same prescriptions used as the basis for the Government’s allegations herein. [FOF 154, 175]. This evidence, however, is not enough to overcome the Government’s allegations because it falls short of fulfilling a pharmacist’s corresponding responsibility.

When reviewing prescriptions from 2010 to 2012, Jones Pharmacy engaged in a minimal amount of investigation or inspection into the red flags present on the face of the prescriptions. [FOF 154, 175]. Jones Pharmacy’s only methods of evaluating the legitimacy of a prescription included talking with the prescribing doctor to ensure that the prescription was authored by the prescribing doctor, and inquiring about the patient’s diagnosis. [FOF 154]. Jones Pharmacy may have sought to prevent diversion through its practices, but it only looked into these two indicators of possible “red flags” when a prescription was presented with multiple others. [FOF 154].

The Government’s expert, Dr. Tracy Gordon, credibly testified that with regard to the “red flags” presented in the prescriptions stipulated to in this

proceeding, the “red flags” presented were unresolvable. [FOF 120]. Dr. Gordon testified that there are certain situations in which red flags can be resolved, but the prescriptions Jones Pharmacy dispensed contained a multitude of red flags that, when considered together, could not be conclusively resolved. [FOF 121–124, 126–130, 132–133]. For example, patients B.F. and K.W. presented identification from Ohio with addresses on the same street. [FOF 122]. B.F. and K.W. saw the same doctor, and were prescribed common cocktail medications. [FOF 1–6, 122]. Dr. Gordon testified that there was nothing Jones Pharmacy could have done to resolve these red flags when presented together. [FOF 122]. Therefore, I conclude that Jones Pharmacy dispensed controlled substances prescriptions with unresolved red flags.

Similar to this, in *Holiday CVS*, the Administrator rejected the Respondent’s contention that “no case law, no Administrator decision, and no published DEA guidance supports [the Government Expert’s] claims that certain red flags are ‘unresolvable’ on their face.” [77 FR at 62,317]. Instead, the Administrator held that “if the red flags presented by a prescription could not be resolved conclusively so as to permit a lawful dispensing, then the Government satisfied the third element of its prima facie burden.” [*Id.* at 62,322].

Following *Holiday CVS*, I have a duty to view the evidence presented in this matter and determine whether or not Jones Pharmacy conclusively resolved the red flags presented by a prescription prior to dispensing it. [*Holiday CVS*, 77 FR at 62,322]. As stated above, Dr. Gordon testified the red flags presented in Jones Pharmacy’s prescriptions were unresolvable. [FOF 120, 122–124, 126–130, 132–134]. The Respondents did not put on any evidence rebutting specific red flags present in the prescriptions at issue. [FOF 190]. Rather, the Respondents expert only offered opinions regarding what red flags were generally known during 2010–2012. [FOF 184–186].

Thus, the testimony of Dr. Gordon was not contradicted to the extent that it demonstrated Jones Pharmacy filled prescriptions with unresolvable red flags presented from 2010–2012. Due to this, I conclude that Jones Pharmacy did not conclusively resolve the red flags inherent in its prescriptions prior to dispensing. I therefore find that factors two and four weigh in favor of revocation.

c. Additional Indicators of Diversion

Besides the red flags discussed above, the record manifests additional indicators that Jones Pharmacy may have dispensed controlled substances unlawfully. Specifically, the record indicates that Jones Pharmacy’s business, from 2010–2012, was largely comprised of controlled substances sales. [FOF 96, 97 (explaining that 89% of all the controlled substance prescriptions filled by Jones were for cocktail drugs, roughly half of which were dispensed to out of state customers, 99% of the controlled substances were for immediate release pain medications, and 93% of the prescriptions dispensed were for cash paying customers)]. These statistics are unusually high compared to national averages. [FOF 70–72, 117; see also *East Main Street Pharmacy*, 75 FR 66,149, 66,153 (DEA 2010) (noting that the Administrator has considered percentages of a pharmacy’s dispensing practices as compared to national averages as an indicator of unlawful conduct)].

The record also indicates that the pricing of Jones’ controlled substances was extremely high, and 93% of controlled substance prescriptions were paid for in cash. [FOF 93, 97]. It is true that a pharmacy’s level of controlled substances sales is not in and of itself a red flag for diversion or abuse. And it is also true that a pharmacy can charge the prices it wishes with regard to its controlled substances. But high prices and copious dispensing of controlled substances can be an indicator of possible diversion because it elucidates a customer base willing to pay exorbitant prices for a drug the customer could otherwise purchase at a nearby pharmacy for much less.⁶⁷ [FOF 132]. This is especially true when a prescription is sold at over 1,000 times

⁶⁷ In its brief the Government cites federal court precedent that supports the proposition that high prices are an indicator of unlawful controlled substance dispensing. [Gov’t Br. 51 (citing *U.S. v. Fuchs*, 467 F.3d 889, 905 (5th Cir 2006) (noting that evidence that the pharmacy “charged much higher prices than other pharmacies” supported the conclusion that the pharmacist was part of a criminal conspiracy); *U.S. v. Tanner*, 61 F.3d 231, 237 (4th Cir. 1995) (finding evidence that pharmacist “charged extremely high prices . . . indicate that [he] was fully cognizant that his acts were illegal, and that these sales were not mere accidents”); *U.S. v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979) (finding evidence including “the prices charged by Hayes support the jury’s conclusion that Hayes also knew that the prescriptions were not issued for a legitimate medical purpose”); *U.S. v. Lovin*, 2009 WL 3634194, *7 (S.D. Cal. 2009) (finding “evidence from which the jury could infer the defendants knew the substances were distributed for an other than legitimate medical purpose” included “the nature of the drugs sold and the exorbitant prices charged”)].

the wholesale cost of the product. [FOF 97].

Finally, the record shows that Jones Pharmacy's profits from 2010–2012 were almost entirely derived from controlled substances sales. [FOF 137–139]. Specifically, Jones Pharmacy's annual profits from dispensing controlled substances in 2010 was \$530,483, as opposed to the profits for non-controlled substances of \$10,189. [FOF 137]. Jones Pharmacy's annual profits from dispensing controlled substances in 2011 was \$439,990, as opposed to the profits for non-controlled substances of \$38,241. [FOF 138]. Jones Pharmacy's annual profits from dispensing controlled substances in 2012 was \$316,942, as opposed to the profits for non-controlled substances of \$58,123. [FOF 139]. The total amount of gross profits Jones Pharmacy made from the sales of schedule II narcotics during this three year period, 2010–2012, was in excess of \$1.2 million. [FOF 72]. While I note the downward trend in profits derived from controlled substances for the years 2010, 2011, and 2012, Jones Pharmacy's amount of profits from controlled substance sales as compared to non-controlled substances is exorbitantly high. [FOF 117]. These statistics, coupled with the fact that 93% of controlled substances sales were paid for in cash, [FOF 97], indicate that Jones Pharmacy was dispensing controlled substances in the face of red flags for the sake of reaping lucrative cash profits. [FOF 70, 72].

d. Jones Pharmacy's Knowledge of Red Flags

As an attempt to defend its dispensing actions and profit margins, the Respondents put on evidence purporting to show that Ms. Jones, along with the general pharmacy community, was unaware of the term or concept of “red flags” from 2010–2012. [FOF 173, 186; *see also Holiday CVS*, 77 FR at 62,316 (holding that “Agency precedent limits [a registrant's] corresponding responsibility to circumstances which are known or should have been known.” (internal citations omitted))]. As support, the Respondents argue that Ms. Jones was simply naïve; she did not know or have reason to know that the prescriptions at Jones Pharmacy were not written for a legitimate medical purpose because the term or concept “red flags” was not generally known in the Florida pharmacy community from 2010–2012.⁶⁸ [FOF 185, 198]. For the

⁶⁸ While Ms. Horn testified that the first time she heard of the term “red flags” was in 2014, the term or concept “red flags” has long been recognized as a reflection of the norms of the pharmacy

reasons listed below, I find that this defense fails, and Ms. Horn's expert testimony as it relates to Florida pharmacists' knowledge of the term or concept of “red flags” from 2010–2012 is not persuasive.

First, the Respondents aver that “Ms. Jones complied with her corresponding responsibility as she understood it at the time by taking the actions that she took to check the validity of the prescriptions.” [Resp. Br. 32; FOF 135]. At the hearing, Ms. Jones testified that she was naïve, and did not know about “red flags” for abuse or diversion until May 2014. Specifically, Ms. Jones stated that “we may have made mistakes that people may call dumb, naïve, stupid, but it was not our intent to put stuff in the hand[s] of other people.” [FOF 135].

In its brief, the Government challenges the sincerity of the anti-diversion ethos Ms. Jones declared at the hearing by pointing out inconsistencies in Ms. Jones's testimony and the Respondents' documentary evidence. The Government first points to high prices Ms. Jones charged and the cash profits Ms. Jones made to show that she “was fully cognizant that [her] acts were illegal” and “not mere accidents.” [Gov't Br. 53]. Next, the Government notes a gaping inconsistency in Ms. Jones testimony which I find particularly persuasive in assessing Ms. Jones credibility. [Gov't Br. 55–56].

In defending an assertion made by Florida Department of Health Inspector Crane—that a person could notice from Jones Pharmacy's parking lot that the pharmacy catered to pill seekers because of its “loitering” clientele—Ms. Jones stated:

The people [Ms. Crane] considered loitering were people that lived in the area. They were usually older gentlemen that sat outside of some of the businesses. There was a barber shop . . . There was a Haitian restaurant. There was a Hatian market. There was also a tax office . . . I don't think loitering was an appropriate term. They were actually people, I considered the pharmacy to be a part of the community, because they were people who made sure if I was walking in by myself, they would say are you okay? Good Morning. How are you? I felt like they

profession. [*Holiday CVS*, 77 FR at 62,319 (noting that the “red flag” standard is what pharmacists are “taught in schools”); *East Main Street*, 75 FR 66,149, 66,157 (DEA 2010) (“a pharmacist is ‘absolutely’ taught to question the legality of a prescription” such as “a combination of a narcotic, a benzodiazepine, a muscle relaxant, and a sleeping pill” with similar doses for everybody, [with] no individualization of therapy”); Gov't Br. 61]. Thus Ms. Jones' personal knowledge of the term “red flags” is not the focus here. The focus here is Ms. Jones' professional judgement when dispensing prescriptions that presented suspicious indicators such as the “red flags” discussed herein. [FOF 67].

looked out for me, so I don't feel like they were loitering.

[Tr. 415]. But in her letters to her congressional representatives urging action on behalf of the DEA to change her pharmacy's address, Ms. Jones stated that she was “‘lucky’ to move her business to a ‘better environment’ where she could ‘go in the parking lot and not worry about smelling urine or seeing people hanging out on the sidewalk.’” [FOF 146]. This inconsistency, while seemingly trivial, calls into question the credibility of Ms. Jones' assertion that it was never Jones Pharmacy's intent to divert controlled substances because this statement purports that Ms. Jones was cognizant of the loitering, (possibly pill seeking) clientele outside her store. [FOF 69, 146].

Second, the testimony of Respondent's Expert, Ms. Donna Horn, is not credible as it relates to the general knowledge of Florida pharmacists from 2010–2012. Ms. Horn has a multitude of experience in the prevention of prescription filling errors. [FOF 181]. When Ms. Horn was the President of the National Association of Board of Pharmacies, she prioritized a “platform” of “reducing medication errors.” [FOF 181]. In contrast to her vast prevention of filling error experience, however, Ms. Horn indicated that she has not conducted any research on a pharmacist's corresponding responsibility. [FOF 190]. Ms. Horn also indicated that she has not published any research on corresponding responsibility issues. [FOF 190]. Further, Ms. Horn stated that she last practiced pharmacy as a pharmacist filling prescriptions fifteen years ago, and has never practiced as a pharmacist filling prescriptions in Florida, for she is only licensed as a pharmacist in Massachusetts [FOF 181].

When asked about the basis for her knowledge with regard to pharmacists' general knowledge of “red flags,” Ms. Horn indicated that she looked at some of the administrative opinions on the DEA's website in forming her opinions. [FOF 185]. But as counsel for the Government rightly pointed out, Ms. Horn's opinions about what was “generally known among pharmacists based on DEA publications—contradicts the only source she claimed to consult.” [Gov't Br. 63].

For example, Ms. Horn testified that in 2010, a combination of a benzodiazepine, a narcotic, and a carisoprodol was not a sign of drug abuse. Yet in one of the 2010 decisions that Ms. Horn claimed to review, *East Main Street Pharmacy*, the Administrator held that “the

combination of a benzodiazepine, a narcotic and carisoprodol is ‘well known in the pharmacy profession’ as being used ‘by patients abusing prescription drugs.’” [75 FR at 66,149]]. Likewise, the Government lists five such examples in its brief where Ms. Horn’s opinion—concerning what was generally known in the pharmacy community about a pharmacist’s corresponding responsibility—stands in stark contrast to the administrative decision she purportedly used to form the basis of that very opinion. [Gov’t Br. 63]. As such, I am not persuaded by Ms. Horn’s testimony regarding what was generally known of “red flags” in the Pharmacy community from 2010–2012.

I therefore conclude that the concept of red flags has long been recognized as a reflection of the norms of the pharmacy profession, and Jones Pharmacy’s purported ignorance is not a credible defense. [*Holiday CVS*, 77 FR at 62, 319 (noting that DEA has held that the “red flag” standard is what pharmacists are “taught in schools” (*Holiday CVS*, 77 FR at 62,319), and that “a pharmacist is ‘absolutely’ taught to question the legality of a prescription” such as “a combination of a narcotic, a benzodiazepine, a muscle relaxant, and a sleeping pill” with similar doses for everybody, [with] no individualization of therapy.” *East Main Street*, 75 FR at 66,149)]. The Government, therefore, has met its burden of proof in this matter.

e. Mitigating Evidence

Thus, because the Government has established its *prima facie* case, the burden of production now shifts to the Respondents to demonstrate that they take full responsibility for their unlawful conduct and they have put in place remedial measures so that such violations will not happen in the future. [*Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (DEA 2008) (quoting *Samuel S. Jackson*, 72 FR 23,848, 23,853 (DEA 2007)) (holding that a registrant must “present sufficient mitigating evidence to assure the Administrator that [it] can be entrusted with the responsibility carried by such a registration”); *Leo R. Miller*, 53 FR 21,931, 21,932 (DEA 1988)]. And because “past performance is the best predictor of future performance,” [*ALRA Labs., Inc., v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995)], “this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must both accept responsibility for its actions and demonstrate that it will not engage in future misconduct.” [*Holiday CVS*, 77 FR at 62,323 citing *Medicine Shoppe-*

Jonesborough, 73 FR at 387; see also *Jackson*, 72 FR at 23,853; *John H. Kennedy*, 71 FR 35,705, 35,709 (DEA 2006); *Prince George Daniels*, 60 FR 62,884, 62,887 (DEA 1995)]. Once a respondent has accepted responsibility for her actions, she may “demonstrate what corrective measures she has undertaken to prevent the re-occurrence of similar acts.” [*Hassman*, 75 FR at 8194 citing *Jayam Krishna-Iyer*, 74 FR 459, 464 & n.8 (2009)].

As stated above, a registrant’s acceptance of responsibility must be unequivocal. In her testimony, Ms. Jones repeatedly stated that she “could have done more” when ensuring a prescription was issued for a legitimate medical purpose. [FOF 136 & fn. 21]. But as the Government rightly states in its brief, “[a] registrant cannot accept responsibility for past misconduct without first understanding those responsibilities.” [Gov’t Br 72].

Ms. Jones testified that the procedures she followed in 2010 were procedures she learned from her experience at other pharmacies. [FOF 152–154]. With regard to the prescriptions at issue in this proceeding, and Jones Pharmacy’s prescribing practices in 2010–2012, Ms. Jones stated repeatedly that she should have done things differently; that she could have, and should have, done things much different.⁶⁹ [FOF 125, 131, 135, 136 and n.19]. Then when asked on cross-examination about her responsibilities to ensure prescriptions were issued for a legitimate medical purpose, Ms. Jones said she thought she was exercising her responsibility because she was dispensing in accordance with her prior experience. [FOF 136 & fn. 19].⁷⁰

⁶⁹ In *MacKay v. DEA*, 664 F.3d 808, 820 (10th Cir. 2011) the U.S. Court of Appeals for the Tenth Circuit addressed the Administrator’s consideration of a practitioner’s purported acceptance of responsibility. The Court held:

[t]he DEA may properly consider whether a physician admits fault in determining if the physician’s registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether the continued registration is in the public interest. . . . [T]he . . . Administrator had no evidence that Dr. MacKay recognized the extent of his misconduct and was prepared to remedy his prescribing practices.

Id. See also *Chein v. DEA*, 533 F.3d 828, 837 (D.C. Cir. 2007) (upholding revocation order, noting in part that the physician had not “accepted responsibility for his misconduct”); *Hoxie*, 419 F.3d at 483 (DEA properly considers admission of fault in determining whether a registration should be revoked).

⁷⁰ Ms. Jones carefully avoided any admission that she failed to exercise her corresponding responsibility.

I agree with the Government that the issue with these statements is that they “place [Ms. Jones] in the role of a third party bystander to wrongdoing.” [Gov’t Br. 72]. Ms. Jones asserts that the practices and procedures she employed were those she utilized at other pharmacies. [FOF 154]. These statements do not act to “unequivocally” accept responsibility for Ms. Jones’ actions. To the contrary, these statements shift the blame to prior pharmacies that Ms. Jones worked for.

Next, the Government rightly notes that Ms. Jones places culpability of her actions on the “professed confusion about legal responsibilities.” [Gov’t Br. 72]. And Ms. Jones’ wavering responses on cross examination undoubtedly show her lack of understanding of a pharmacist’s corresponding responsibility. For example, when asked whether or not there are circumstances that would cause Ms. Jones to reject a prescription because she believed it was not issued for a legitimate medical purpose, Ms. Jones stated “there are circumstances that would cause me to reject a prescription. I don’t think I can make the determination whether it’s for a legitimate medical purposes because I would have to say that I’m in that person’s body and I know how they feel if we’re speaking just about pain medications.” [FOF 135]. Then when asked whether she knew one way or another if she had a corresponding responsibility, Ms. Jones stated “I did not know that the law said that I had to make sure that prescriptions said it was legitimate, medically legitimate.” [FOF 135].

In *Sigrid Sanchez, M.D.*, the Administrator considered a similar situation where a practitioner averred—in the face of wrongful prescribing allegations—that it “‘was the first time in [her] professional career that [she] had been a dispensing practitioner,’ and that she ‘was completely unaware that [she] had run afoul of the laws

Q: When you filled those prescriptions on April 19 and 20 of 2010, were you exercising your responsibility to insure they were issued for legitimate medical purposes?

A: I think I was at the time, yes.

Q: It’s fair to say you fulfilled the responsibilities as you understood them at the time, correct?

A: Correct.

Q: And you understand those responsibilities differently today, correct?

A: Differently today—differently in the sense of I can do more; differently, no, in the sense if the prescription is written by the prescriber, I don’t think it makes it an illegitimate, not a legitimate prescription for medical purposes. I think I can do more digging to make sure that the patient is going to use it appropriately and not make it so that somebody else has access to it . . . But I still do rely on the prescriber to write prescriptions for legitimate medical purposes. [Tr. 599–600].

governing dispensing practitioners.” 78 FR 39, 331, 39,333 (DEA 2013). Assessing these claims, the Administrator stated “[o]ne must wonder why [the practitioner] did not make a similar effort to familiarize herself with the various requirements applicable to the dispensing of controlled substances under both the CSA and state laws.” [Id.]. Considering this, the Administrator held that the practitioner’s purported “ignorance of law is no excuse.” [Id.].

The matter at hand is very much the same. Ms. Jones claimed that she was following her corresponding responsibility as she understood it from 2010–2012 when over a hundred prescriptions that were presented with multiple unresolved red flags were dispensed at Jones Pharmacy. Ms. Jones purported to accept responsibility for Jones Pharmacy’s dispensing practices by repeatedly asserting that she did what she knew at the time, but now she knows she could have done more. [FOF 136 & fn. 19]. But then Ms. Jones demonstrated by her statements that she does not fully understand her corresponding responsibility even yet today. [FOF 135]. Thus, there remains no excuse for the Respondents’ past dispensing conduct and continued lack of knowledge of Jones Pharmacy’s corresponding responsibility to ensure that controlled substances dispensed reach only patients with legitimate medical needs. [See 21 CFR § 1306.04(a)].

I agree with the Government that as such, the Respondents’ “[c]laims of reliance on others [and] professed confusions about legal responsibilities demonstrate precisely the opposite of acceptance of responsibility.” [Gov’t Br. 72]. For these reasons, I conclude that Ms. Jones has not accepted responsibility for the unlawful dispensing that occurred at Jones Pharmacy from 2010–2012.

Because I find that Ms. Jones has not unequivocally accepted responsibility for the dispensing of prescriptions with red flags present from 2010–2012, I will not consider the remedial efforts that the Respondents put forth in their case

in chief. [See *Holiday CVS, LLC*, 77 FR at 62,346 (explaining that a registrant’s acceptance of responsibility and showing of remedial measures are independent “essential requirements for rebutting the Government’s prima facie showing that continuing an existing registration would be ‘consistent with the public interest.’” 21 U.S.C. 823(f); see also *Hassman*, 75 FR at 8194 citing *Jayam Krishna-Iyer*, 74 FR at 464 & n.8. and *The Medicine Shoppe*, 79 FR 59,504, 59,510 (DEA 2014) (holding that there is no need to address a Respondent’s remedial measures when the respondent has not accepted responsibility for its misconduct).

3. Basis for Denial of SND Healthcare LLC’s Application for a DEA Registration

Even though Jones Pharmacy and SND Healthcare are separate entities, they are treated as one integrated enterprise for purposes of this proceeding. In *MB Wholesale, Inc.*, 72 FR 71,956, 71,958 (DEA 2007), the Deputy Administrator denied an application by one business entity for a DEA Certificate of Registration as being inconsistent with the public interest, 21 U.S.C. 823(f), based on a separate, related business entity’s dispensing conduct where the two were “nominally separate business entities.” [Id.]. The Deputy Administrator clarified that the Agency will treat two separately organized business entities as one integrated enterprise under the Controlled Substances Act where it is appropriate to do so based on the overlap of ownership, management, and operations of the two entities.” [72 FR at 71,958].

In this instance, there is no dispute that SND Healthcare and Jones Pharmacy are one integrated enterprise. Ms. Jones is the owner and operator of both Jones Pharmacy, and SND Healthcare. Jones Total Health Pharmacy, LLC, and SND Healthcare LLC, are both incorporated in the state of Delaware. [FOF 144]. The corporate documents produced in this proceeding show that Ms. Jones is the owner for both business entities. [FOF 144]. The

corporate documents also reveal that Ms. Jones is the Registered Agent, the Florida Community Pharmacy Permit applicant, managing member, and authorized representative who submitted the Applications By Foreign Limited Liability Company For Authorization To Transact Business in Florida for both business entities. [FOF 144]. In light of this, I find that it is proper to consider Jones Total Healthcare, LLC, and SND Healthcare, LLC, as one integrated enterprise under the Controlled Substances Act because the ownership, management, and operations of each entity are sufficiently similar.

By virtue of this finding, and because Agency has held that past performance is the best predictor of future performance, [*Alra Labs. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995)], I conclude that the unlawful dispensing practices at Jones Total Health Pharmacy, LLC, are an appropriate basis to deny the pending application for SND Healthcare, LLC’s DEA Certificate of Registration.

VI. Conclusions and Recommendation

Given the egregious dispensing practices that took place at Jones Pharmacy from 2010–2012, I recommend that the Respondents’ Certificate of Registration for Jones Pharmacy be revoked, and any applications for modification or renewal be denied. Further, for the same reasons described herein, I recommend that the pending Certificate of Registration application for SND Healthcare be denied.⁷¹

Dated: April 29, 2015

Gail A. Randall,

Administrative Law Judge.

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⁷¹ There is no evidence in this record under Factors Three and Five that would mitigate the conduct that is inconsistent with the public interest under Factors Two and Four. I therefore conclude that the absence of such evidence “militates neither for nor against the revocation sought by the Government.” *Top Rx Pharmacy*, 78 FR 26,069, 26,081 (2013).