DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–4]

Hills Pharmacy, LLC; Decision and Order

On October 8, 2014, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Hills Pharmacy, LLC (hereinafter, Hills or Respondent), which proposed the revocation of its DEA Certificate of Registration FH0772257, pursuant to which it is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 7730 W. Hillsborough Ave., Tampa, Florida. ALJ Ex. 1, at 1. As grounds for the proposed action (which also includes the denial of any pending applications), the Show Cause Order alleged that Respondent's ''continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.; see also* 21 U.S.C. 824(a)(4).

More specifically, the Show Cause Order alleged that Respondent's ''pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice'' and that its ''pharmacists ignored readily identifiable red flags that [the] controlled substances prescribed were being diverted and dispensed despite unresolved red flags.'' *Id.* (citing 21 CFR 1306.04(a); *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62315, 62319 (2012)). The Show Cause Order further alleged that Respondent's ''pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacist knew or should have known that the controlled substances were abused and/or diverted by the customer.'' *Id.* at 2.

The Show Cause Order listed various red flags which Respondent's pharmacists allegedly failed to resolve before dispensing prescriptions, including: (1) ''multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor''; (2) ''individuals presenting prescriptions for controlled substances known to be highly abused, such as oxycodone and hydromorphone''; (3) ''individuals paying high prices . . . for controlled substances with cash''; and (4) ''individuals residing long distances from the pharmacy.'' *Id.*

The Show Cause Order then alleged that between July 28 and August 4, 2011, Respondent's ''pharmacists dispensed large and substantially similar quantities of'' oxycodone 30 mg tablets ''to at least nine customers, all of whom received their prescriptions from physicians working at the same clinic,'' and that seven of the customers ''resided at least [50] miles from'' Respondent and five of the customers ''resided more than [100] miles from'' it. *Id.* The Government specifically alleged that ''on July 28, 2011, a Hills . . . pharmacist dispensed 210'' tablets of oxycodone 30 mg ''to T.V., who resided in Pensacola, . . . more than [450] miles from'' Respondent. The Order also alleged that ''on August 4, 2011, one or more Hills . . . pharmacists dispensed large quantities of oxycodone pursuant to prescriptions written by the same physician on the same day to two customers with the same last name'' (J.P. and T.P.), both of whom ''resided in St., Augustine, Florida, more than [180] miles from'' it. *Id.*

Next, the Show Cause Order alleged that ''[o]n April 21, 2011, one or more Hills[']. . . pharmacists dispensed large and substantially similar quantities of . . . oxycodone 30 to at least [12] customers, three of whom resided more than [50] miles from [it], and two of whom resided more than [100] miles away.'' *Id.* The Show Cause Order then alleged that ''[a]ll of these prescriptions were written by physicians working at the same clinic and were for amounts ranging from 168 to 240 tablets.'' *Id.*

To similar effect, the Show Cause Order alleged that on January 16, 2012, Hills' pharmacists dispensed three prescriptions for oxycodone 30 mg tablets in quantities which ranged from 168 to 224 tablets to three persons who ''resided more than [50] miles from Hills,'' which were all ''issued by physicians working at the same clinic.'' *Id.* at 3. The Show Cause Order then alleged that on January 19, 2012, a Hills' pharmacist dispensed 120 oxycodone 30 tablets to a person who resided in Panama City, Florida, which is ''located more than [350] miles from'' it. *Id.*

The Show Cause Order also alleged that on December 10, 2012, Hills' pharmacists engaged in a further instance of dispensing prescriptions (for 180 oxycodone 30) to two persons with the same last name on the same date ''at or about the same time.'' *Id.* at 3. With respect to these prescriptions, the Government also alleged that ''both customers were willing to pay as much as [$7.50] per tablet despite evidence that Hills . . . was now charging double for oxycodone than it charged the previous year.'' *Id.* And the Show Cause Order further alleged that on December 10, 2011, a Hills' pharmacist dispensed 224 tablets of oxycodone 30 to a resident of Bradenton, Florida, ''who willingly paid . . . $1232 for the same prescription he purchased just four months earlier for . . . $896,'' and that ''[b]oth of these prescriptions were also facially invalid inasmuch as they contained no patient address.'' *Id.*

Finally, the Show Cause Order alleged that in October 2011, Hills' pharmacists dispensed prescriptions for 196 and 240 tablets of hydromorphone 8 mg to two persons. *Id.* The Show Cause Order alleged that the prescriptions, ''if taken as directed, far exceeded the recommended [daily] dosage of'' the drug. *Id.* The Order also alleged that both ''prescriptions were issued by the same physician and one of them was facially invalid . . . as it contained no patient address.'' *Id.*

Next, the Show Cause Order alleged that Respondent ''failed to create and maintain accurate records in violation of 21 U.S.C. 842(a)(5).'' *Id.* at 4. More specifically, the Order alleged that: (1) Respondent ''failed to complete a biennial inventory as required by 21 CFR 1304.11(c)''; (2) its DEA schedule II order forms did not contain the ''receipt date or quantity received in violation of 21 U.S.C. 827(b) and 21 CFR 1305.13(e)''; (3) it ''failed to retain Copy 3 of'' its schedule II order forms ''as required by 21 U.S.C. 827(b) and 21 CFR 1305.13(a) and 1305.17(a)''; and (4) its schedule II records were not ''readily retrievable . . . at its registered location in violation of 21 CFR 1304.04(a) and (h)(2).'' *Id.*

Finally, the Show Cause Order alleged that a DEA audit of various schedule II drugs found both shortages and overages. The Order alleged that an audit for the period of July 24, 2012 through February 4, 2013 found ''a shortage of 4,135'' tablets of hydromorphone 4 mg and ''an overage of 8,758'' tablets of hydromorphone 8 mg. *Id.* The Order also alleged that an audit for the period of June 27, 2012 through February 4, 2013 found an overage of 1,306 tablets of oxycodone 30 mg, and an audit for the period of June 9, 2012 through February 4, 2013 found overages of 113 tablets of morphine 60 mg and 88 tablets of morphine 30 mg. *Id.*

On October 17, 2014, the Order to Show Cause was served on Respondent

by delivery to an attorney who was representing it in the investigation, and who had emailed a Diversion Investigator the day before that he would ''accept any service of process in that regard for Hills Pharmacy.'' ALJ Ex. 4. On November 14, 2014, Respondent, through its counsel, filed a request for a hearing with the Office of Administrative Law Judges. ALJ Ex. 2. The matter was then assigned to ALJ Gail Randall, who proceeded to conduct pre-hearing proceedings.[1]

On December 2, 2014, the Government filed its Prehearing Statement. ALJ EX. 7. Of note, the Government's Prehearing Statement contained no additional information beyond that provided by the Show Cause Order as to the identities of the patients whose prescriptions were at issue. *Compare* ALJ Ex. 1, at 2–3, *with* ALJ Ex. 7, at 4–5. Thereafter, Respondent moved for an extension, which the Government did not oppose, and on December 16, 2014, the ALJ granted its motion.

On January 9, 2015, Respondent filed its Prehearing Statement. ALJ Ex. 14. Respondent proposed to call as witnesses, ''[a]ny and all patients whose prescriptions were seized by . . . DEA pursuant to the Administrative Inspection Warrant [AIW] executed February 4, 2013 or whose prescriptions for controlled substances were dispensed between January 1, 2011 and February 4, 2013.'' *Id.* at 3. Respondent further attached to its Prehearing Statement a list of 1,461 persons. *Id.* at Exhibit A. Respondent also proposed to call as witnesses all of the physicians who had issued the prescriptions that were seized pursuant to the AIW and the controlled substance prescriptions that it dispensed between January 1, 2011 and February 4, 2013. *Id.* at 3. Respondent attached to its Prehearing Statement a list of more than 130 doctors. *Id.* at Exhibit B. Respondent further estimated that it would require 45 to 60 days to present its case, exclusive of cross-examination and rebuttal.[2] *Id.* at 9.

On January 14, 2015, the ALJ conducted an on-the-record prehearing conference. Noting that the Government had referred to the patients by their initials, the ALJ ascertained that Government intended to request a protective order. Tr. 6 (Jan. 14, 2015). Continuing, the ALJ noted ''the scope of the Respondent's [counsel's] prehearing statement and his inability up to this point to identify the witnesses'' and asked the Government if it was ''willing to exchange the prescriptions which it intend[ed] to utilize . . . so Respondent can ID the actual patients involved?'' *Id.* at 6–7. Government counsel represented that the prescriptions would be sent by Fed Ex that day. *Id.* at 7. Subsequently, the ALJ noted that Respondent's counsel had ''proposed in excess of 1,500 named witnesses and approximately 13,500 pages of documents'' and asked if this was ''still [his] current plan?'' *Id.* at 10. Respondent's counsel replied that if ''the Court limits the scope of the Government's case to just those prescriptions that are provided to us, I may be able to wean that down slightly.'' *Id.*

The ALJ then asked Respondent's counsel to explain the purpose of the patients' testimony. *Id.* Respondent's counsel stated that ''the Government ha[d] not listed in their list of witnesses any of the patients . . . to whom prescriptions were dispensed and ha[d] not identified any of the physicians who issued [the] prescriptions.'' *Id.* at 11. Respondent's counsel then explained that it was his position that the Government's Expert's ''testimony should be excluded because he hasn't had any contact with any of the patients or prescribers to determine whether or not the red flags that he's identified can be resolved.'' *Id.* at 11–12. Respondent's counsel then maintained that if the Government's Expert was allowed to testify on these issues, ''it would be incumbent upon Respondent to demonstrate by the testimony of the patients regarding the inquiry and discussion between the patients and the pharmacists to resolve any of those red flags as identified by [the Expert], and for those prescribers to testify about their basis for issuing the prescriptions for those particular patients.'' *Id.* at 12.

On January 15, the ALJ issued a Preliminary Order Regarding Scope Of Proceedings. ALJ Ex. 19. Therein, the ALJ explained that ''any of those proposed patient and physician witnesses who are not linked to a prescription transaction which the Government asserts created a 'red flag' present[s] the potential for providing no relevant evidence.'' *Id.* at 3. However, the ALJ also held that ''to the extent warranted by the Government's disclosure (and potentially its case-in-chief at the hearing), the Respondent may seek leave to present evidence from prescribing practitioners and/or patient-customers on the narrow issue of rebutting Government evidence that controlled substances were dispensed in the face of 'red flags' of diversion with no attempts made to contact those witnesses to attempt to resolve the 'red flag(s).' '' *Id.* The ALJ thus concluded that ''[a]s the proffer stands now . . . an insufficient basis has been presented for presenting the testimony of all of these 1598 proposed witnesses.'' *Id.* (citing Respondent's Prehearing Statement, at 3 and Exhibits A & B).

Addressing Respondents' proffers of 13,510 pages of documents, the ALJ found ''that many of these documents are not relevant to this proceeding.'' *Id.* at 4. The ALJ thus excluded Respondent from admitting any documents ''not linked to inventory practices, the controlled substance audit, or prescription transactions specified in the Order to Show Cause.'' *Id.* Finally, the ALJ precluded Respondent's Pharmacy Expert from testifying ''regarding applicable legal standards and any aspect of the Respondent's legal obligations as a DEA registrant.'' *Id.* at 5. However, the ALJ held that Respondent's Pharmacy Expert would be permitted to testify as to other areas in accordance with Respondent's proffer. *Id.* at 4.

The same day, the ALJ also issued her Prehearing Ruling. In addition to setting the date of the evidentiary hearing, the Ruling also advised each party that if it chose to amend its witness list to include a new witness, it must file a supplement to its Prehearing Statement and include a summary of the witness's proposed testimony. ALJ Ex. 20, at 3. The Ruling further explained ''that witnesses not properly identified and testimony not summarized in prehearing statements or supplements thereto will be excluded at the hearing,'' and that if either party ''wished to raise any issues of inadequacies or ambiguities regarding the proposed witness' testimony . . . [it] may do so by motion.'' *Id.* Finally, the Ruling specified the date by which all

[1] Respondent raised no objection to the adequacy of service.

[2] Respondent also sought to call the physicians who issued controlled substance prescriptions to the patients listed in Exhibit A after February 4, 2013, as well as the pharmacists who dispensed those prescriptions. ALJ Ex. 14, at 3. It also proposed to call as a witness,''[e]ach and every . . . Diversion Investigator, Special Agent, and/or Task Force Officer who participated in the preparation of the application for the'' AIW or the ''the execution of the'' AIW, and ''[a]ny and all witnesses identified in the Government's Prehearing Statement.'' *Id.* at 4.

Respondent also proposed to call a consultant, who was a former Supervisory Diversion Investigator, who would testify regarding ''his knowledge and experience in the investigation, preparation and execution of'' AIWs, purported errors in the audits, and Respondent's ''procedure for resolving potential 'red flag' issues and compliance with recordkeeping requirements.'' *Id.* at 3, 5–6. Finally, Respondent proposed to call its own expert who would testify as to ''the legal and ethical responsibilities of the pharmacists dispensing prescriptions at'' it, the procedures used by it to resolve red flags, and his review of ''the prescriptions at issue.'' *Id.* at 6.

documentary evidence as well as any affidavits were to be provided to both the tribunal and the opposing party.[3] *Id.*

Thereafter, both of Respondent's counsels moved to withdraw; the ALJ granted the motions. ALJ Exs. 24, 25, 29, 31. Subsequently, new counsel entered an appearance and simultaneously moved for a continuance. ALJ Ex. 27, 30. The ALJ granted the motion and continued the hearing for three weeks, scheduling it for March 10 through March 13, 2015. ALJ Ex. 40. In the meantime, both parties filed supplemental prehearing statements, ALJ Ex. 34 & 37, requests for subpoenas, and additional motions.

On March 10 through 12, 2015, the ALJ conducted an evidentiary hearing in Tampa, Florida. *See* Recommended Decision (hereinafter, cited as R.D.), at 5. At the hearing, both parties elicited testimony from multiple witnesses and submitted various exhibits. Following the hearing, the ALJ left the record open so that the Government could submit an affidavit from a Special Agent who was then out of the country. Tr. 613. On April 16, 2015, the Government submitted the affidavit, and on April 21, 2015, the ALJ admitted the affidavit and closed the record. ALJ 52. Thereafter, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On April 29, 2015, the ALJ issued her Recommended Decision. Therein, the ALJ found that the Government had ''proved its *prima facie* case for revocation through the failing of Respondent's accountability practice and its violation of its corresponding responsibility by dispensing controlled substances without first resolving red flags raised by the prescriptions.'' R.D. 50 (citing 21 CFR 1306.04(a)). The ALJ further held that the testimony of Respondent's pharmacist-in-charge (PIC) on the issue of acceptance of responsibility ''lack[ed] credibility.'' *Id.* at 52. Noting that while its PIC had stated that he had done due diligence in accordance with its protocols prior to dispensing the prescriptions at issue, the ALJ drew an adverse inference based on Respondent's failure to produce evidence to corroborate the PIC's assertion. *Id.* The ALJ thus ''conclude[d] that the Respondent's representatives have not accepted responsibility for the full extent of their actions proven by the Government,'' thus rendering its evidence of remedial measures irrelevant. *Id.* The ALJ then recommended that Respondent's registration be revoked and that any pending applications be denied. *Id.* at 53.

Respondent filed Exceptions to the 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 (which I discuss throughout this decision), I adopt the ALJ's legal conclusions that Respondent violated the corresponding responsibility rule of 21 CFR 1306.04(a) with respect to many of the prescriptions. I also agree with her legal conclusion that Respondent failed to maintain accurate records as required by 21 U.S.C. 827. And I further agree with her legal conclusion that Respondent has failed to accept responsibility for the misconduct which has been proven on the record of the proceeding. Accordingly, I agree with the ALJ's ultimate conclusion that Respondent has committed acts which render its continued registration inconsistent with the public interest and will adopt her recommendation that I revoke Respondent's registration and deny any pending applications. I make the following

Findings of Fact

Respondent is the holder of DEA Certificate of Registration FH0772257, pursuant to which it is authorized to dispense controlled substances in schedules II through V, as a retail pharmacy, at the registered location of 7730 W. Hillsborough Ave., Tampa, Florida 33615. GX 1. This registration does not expire until October 31, 2016. *Id.* According to Respondent's registration, it is owned by Hills Pharmacy, L.L.C.[4] *Id.* No evidence was put forward as to Respondent's current licensure status with the Florida Department of Health.

The Investigation of Respondent

On February 4, 2013, DEA Investigators executed an Administrative Inspection Warrant (AIW) at Respondent. Tr. 233. The lead Investigator presented the AIW to Respondent's PIC (Mr. George), and obtained various records from Respondent including inventory records, receipt records, and prescriptions. *Id.* According to the Investigator, he asked for two years' worth of records.[5] *Id.* The DI further testified that while Respondent provided him with a perpetual inventory of various schedule II drugs, the document ''did have physical inventory dates in there.''[6] *Id.* at 235. According to the Investigator, ''there was not one date [when] every controlled substance was inventoried.'' *Id.* Thus, the beginning dates for the drugs that were audited varied. *Id.* at 236.

The DI further testified that as part of executing the AIW, a closing inventory was taken in which various schedule II drugs were physically counted. *Id.* at 237. According to the DI, the closing counts were taken by Mr. George (Respondent's PIC) and were recorded on a document.[7] *Id.;* GX 7. However, the closing inventory was signed by another Diversion Investigator and witnessed by a DEA Special Agent rather than Mr. George. GXs 7 & 16; Tr. 312.

Using the inventories and the records of Respondent's receipts and prescriptions, the DI conducted an audit of Hills' handling of seven schedule II

[3] There were numerous motions filed during the course of the pre-hearing procedures. My discussion of the motions and rulings is confined to those which limited the scope of the proceeding and the evidence that was admissible.

[4] Notwithstanding its representation in its opening statement that it would ''show that Hills Pharmacy is owned by Hope'' Aladiume and ''her brother is Victor Obi Aladiume,'' Tr. 9, the Government put forward no evidence establishing Hope Aladiume's relationship to Respondent, or whether Victor Obi is her brother. Of note, Victor Obi was the owner of two Tampa pharmacies whose registrations I recently revoked. *Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31310, 31341 (2016). Moreover, Victor Obi served as ''the designated representative of the Respondent'' during this proceeding. Tr. 4.

[5] According to the DI, ''not all of the required records were onsite.'' Tr. 252. The DI specifically identified the offsite records as including prescriptions from February 4, 2011 through April 2011, inventories from February 4, 2011 through the end of 2011, and receiving records from February 4, 2011 through the end of 2011. *Id.* at 253. The DI further testified that Respondent's attorney had stated that the records were offsite and that the office manager had the key and was not available that day. *Id.*

Respondent, however, disputed that the records were offsite. Its PIC testified that the records were onsite in a locked storage room, but that he had left the storeroom key at home that day, and that when Respondent's owner arrived with the duplicate key ''two hours later,'' ''the officers [had] left'' so he provided the records to its lawyer. *Id.* at 536.

[6] According to the transcript, the Government asked the DI: ''Did you inquire whether Hills had a bi-annual inventory?'' Tr. 234. After he explained that he was provided with the above-mentioned perpetual inventory, the Government asked the DI: ''So that's how you conclude there was no bi-annual inventory?'' *Id.* at 235. The DI answered ''correct.'' *Id.*

Federal law requires, however, that a registrant take biennial and not biannual inventories. 21 U.S.C. 827(a). Moreover, the transcript was not corrected. Thus, I take the transcript as it is.

[7] However, other testimony was to the effect that the closing inventory counts were done by the PIC, another DI, and the Special Agent who signed the inventory as a witness. Tr. 287, 312. Moreover, Mr. George testified that he did not participate in the counting of the drugs on hand. Tr. 535. And he further testified that the Investigators did not tell him that they were ''doing the actual count.'' *Id.* Be that as it may, I find no reason to reject the closing count.

controlled substances. According to the DI, he conducted the audit by adding Respondent's purchases to the initial inventory figures to calculate the quantity of each drug that Respondent was accountable for. Tr. 237. The DI then explained that the ''total accounted for'' was calculated by using the closing inventory (*i.e.,* the inventory taken on the date of the inspection) and adding the amounts distributed or transferred of each drug. *Id.* According to the DI, the latter was ''basically . . . what they filled at the pharmacy'' as the Investigators did not ''come across'' any ''sales . . . to other pharmacies.'' *Id.* He further testified that in calculating Respondent's purchases, ''the only numbers that [he] used was stuff that we actually had a physical 222 [form] or [a] CSOS representation'' and that he did not count product which was recorded in the perpetual inventory if there was no 222 form for it. *Id.* at 273.

Comparing the ''total accountable for'' with the ''total accounted for'' for the seven drugs, the DI found that Respondent had overages in six of the drugs, the most significant being 1,306 dosage units (du) of oxycodone 30 mg and 8,758 du of hydromorphone 8 mg.[8] GX 4. Moreover, Respondent had a shortage of 4,135 du of hydromorphone 4 mg. *Id.*

Respondent disputed the accuracy of the audits. Specifically, its PIC testified that there were controlled substances in the will-call bins. Tr. 536–37. Respondent's PIC then explained that these drugs would be prescriptions that were finished in ''vials with the label'' and ''waiting for the patient to come and collect it.'' *Id.* at 537. Moreover, a DI testified that the audit team did not count the prescriptions in the will-call bins. *Id.* at 290. He also did not recall if drugs that were quarantined for disposal were counted. *Id.*

Respondent, however, put forward no evidence that there were any drugs quarantined for disposal on the date that the AIW was executed, let alone that any of those drugs were those being audited. Subsequently, the DI testified that ''[w]e asked where the controlled substances were,'' and counted the drugs in the safe because ''that's where we were shown.'' *Id.* at 291.

Respondent's PIC also testified that there were some medications that were returned to the pharmacy's stock when they were not picked up by the customer. Tr. 525. He further identified a document (RX 6, at 3) which lists six instances (by date, RX number, patient name, and quantity) in which a patient apparently did not pick up a prescription for hydromorphone 8 and the drugs were returned to stock. Tr. 525. The PIC testified that he did not know if DEA counted the pills that were returned to stock if they were still on hand. *Id.*

Respondent did, however, introduce into evidence various documents for each of the audited drugs, including a list of the prescriptions that were dispensed, its perpetual inventory for the drug, the invoices and scheduled II order forms for its receipts, and, as explained above, in some instances, a document listing ''returns to stock'' from patients. As discussed later in this decision, with respect to the overages alleged by the Government as to oxycodone 30 mg and hydromorphone 8 mg, the records show that Respondent placed additional orders that were not counted by the Government and establish that the overages in these two drugs were substantially less than the quantities alleged by the Government. Respondent's records do not, however, call into question the conclusion that it had a large shortage in hydromorphone 4 mg and actually support the conclusion that the shortage was even larger than that alleged by the Government.

The same DI also testified as to other alleged violations. More specifically, the DI testified that several DEA Order Forms for Schedule II drugs (Form 222) were not properly completed, because ''[w]hen they don't receive a drug, they need to write a zero if they didn't receive anything.'' Tr. 255. While the DI did identify an instance in which Respondent had notated the receipt of six packages of methadone 10 mg, he noted that Respondent had failed to include the date that the packages were received. *Id.; see also* GX 10, at 9. He then testified regarding a further order form, on which three of the four line items had been filled in with both the quantity received and the date received, explaining with respect to an entry that was not completed, that the forms ''are missing [the] number of packages received, [the] date received.'' Tr. 255. However, when asked by the ALJ whether the pharmacist would ''put the date that he entered the zero'' for a similar entry which was left blank (GX 10, at 1, line 2), the DI testified; ''I'm not sure about that, but we need the number zero at least.'' Tr. 256.

The DI also testified that there were some instances in which Respondent provided him with a photocopy of the purchaser's copy of the 222 form, rather than the original which it is required to maintain for a period of two years. *Id.* at 257 (discussing GX 11, at 2). The DI also testified that Respondent did not have any inventory document other than the perpetual inventory documents that its PIC provided. *Id.* at 270. Re-emphasizing the point, the DI subsequently testified that ''that's all we had, so we had to use it.'' *Id.* at 278.

The Allegations of Dispensing Violations

Following the execution of the warrant, another DI provided a CD which contained copies of the schedule II prescriptions[9] that were seized to Robert Parrado, R.Ph., who reviewed them and testified as an Expert for the Government. The DI testified that the Investigators did not obtain the patient profiles (which apparently could have been extracted from the computer which was imaged by the inspection team) and thus did not provide them to Mr. Parrado. Tr. 300.

Mr. Parrado testified that he obtained his B.S. in Pharmacy in 1970 from the University of Florida College of Pharmacy and that he has held a Florida pharmacist's license since 1971. Tr. 14; GX 2, at 1. Mr. Parrado testified that he has practiced as a pharmacist at both community pharmacies as well as hospital pharmacies; he also testified that he had been the pharmacy department manager at multiple pharmacies, including two pharmacies that he owned for approximately 19 years. Tr. 15–16; GX 2, at 1–2.

Mr. Parrado was a member of the Florida Board of Pharmacy from January 2001 through February 2009, and served as both Vice Chairman and Chairman of the Board. Tr. 17; GX 2, at 3. He is a member of the Florida Pharmacy Association, having served as both its President and then Chairman of the Board. GX 2, at 3. He is also a member of the Hillsborough County Alcohol & Drug Abuse Task Force, the National Community Pharmacists Association, and the American Society for Pharmacy Law. *Id.* Finally, he has made numerous presentations on the dispensing of controlled substances by pharmacists, *id.* at 3–7, and has testified as an expert witness for both the prosecution and defense in criminal and administrative matters. Tr. 18.

On *voir dire,* Mr. Parrado explained that he reviewed only the front and back of the prescriptions in forming his opinions, and that while he had also recently been provided with and looked at ''some Respondent exhibits [that]

[8] According to the Government, Respondent had overages of 5 du in methadone 10 mg, 82 or 88 du in morphine sulfate 30 mg, 113 du in morphine sulfate 60 mg, and 2 du in morphine sulfate 100 mg. GX 4, at 1.

[9] According to the DI, the Investigator did not seize ''any noncontrolled prescriptions'' and ''just took [the] [s]chedule [II] scrips.'' Tr. 299.

looked like partial . . . medical records . . . for about 25 patients,'' he had already formed his opinion before he reviewed those documents. Tr. 29–30, 32. Mr. Parrado also testified that he did not interview any patients, doctors or pharmacists, and that he was not provided with any information regarding interviews conducted by DEA personnel of the patients, doctors, or pharmacists. *Id.* at 39. Mr. Parrado testified that he did a limited amount of research on his own, which included doing Google map searches to determine how far the patients lived from Tampa, looking to see whether the doctors had a valid license, looking up the pharmacy on the Board of Pharmacy's Web site to determine its ownership and prescription department manager, and looking to see whether the pharmacists had valid licenses and a disciplinary history. *Id.* at 40–42. After an extensive *voir dire* by Respondent's counsel, Respondent objected to Mr. Parrado's being recognized as an expert in community pharmacy practice. *Id.* at 50. The ALJ properly overruled the objection, finding that Mr. Parrado was qualified to testify as an expert in retail pharmacy practice based on ''his knowledge, skill, experience, training, and education.'' *Id.* at 52.

On resumption of direct examination, the Government asked Mr. Parrado if there is ''a specific protocol'' that a pharmacist must follow ''before dispensing a controlled substance?'' *Id.* at 53–54. Mr. Parrado explained that a pharmacist ''has to ensure that the prescription is valid,'' and that under both the Florida Statutes and federal regulations, ''a pharmacist has to ensure the prescription is valid by making sure that it was written by a doctor in the course of his professional practice and that it was for a legitimate medical purpose.'' *Id.* at 54. Asked what a pharmacist is ''required to look for on the actual prescription,'' Mr. Parrado testified:

> Well, there are certain requirements that have to be on a prescription. What creates a red flag is anything that causes a pharmacist concern about that prescription. . . . [T]here is a thing a pharmacist has to do before he fills a prescription that is called prospective drug review. He has to go over that prescription. He has to evaluate the prescription for appropriateness of therapy, for seeing if there is any therapeutic duplications of medications. Are there any drug/drug interactions? Are there any drug/disease interactions? Is the prescription for—does it show signs of clinical abuse or misuse? You know, that's just a basic thing a pharmacist does before he fills a prescription.
>
> And then, knowing all the requirement of a prescription, what must be on that prescription as far as the patient name and address, the physician's name and address, the DEA number, the name of the medication, the strength, the directions, all those things, the quantity, have to be on that prescription.

Id. at 54–55.

Asked by the Government to explain what a ''red flag'' is and to give examples, Mr. Parrado testified that ''a red flag . . . is anything that would cause a pharmacist concern,'' and that ''[t]here are lots of things that lead to red flags'' when a pharmacist is ''trying to determine'' if a prescription was issued ''for a legitimate medical purpose.'' *Id.* at 55–56. Mr. Parrado then identified multiple red flags, including, what he termed the ''first red flag,'' that being ''the drug itself,'' as there are ''known drugs of abuse'' that are being ''commonly'' abused. *Id.* at 56. Mr. Parrado then identified additional red flags to include: the ''the dosing''; ''[a] person travelling a long distance to acquire that drug''; ''a person willing to pay a lot, a lot of money in cash to obtain that drug''; and ''a person getting . . . certain cocktails of drugs.'' *Id.* As to the latter, Mr. Parrado explained that:

> A cocktail is multiple drugs . . . that are known to be abused on the street, and the most common . . . has a name, it's called the Holy Trinity, which would be oxycodone, which is an opioid, a benzodiazepine, which would be a tranquilizer such as Xanax, and a muscle relaxer like Soma. Those three together are well known combinations or cocktails that are abused on the street.

Id.

Next, the Government asked whether ''a pharmacist look[s] at the actual amounts that are prescribed when determining whether there's a red flag on that prescription?'' *Id.* Mr. Parrado answered that a pharmacist is ''required by law . . . to make sure that the dosing is not excessive or inappropriate'' and ''[t]hat's one of our things that we are trained in.'' *Id.* at 57. Continuing, Mr. Parrado explained that:

> One of the things that a pharmacist knows or should know is that oxycodone . . . that 80 milligrams a day has been listed in the literature as a lethal dose for an opioid naïve patient. So, when being presented with a prescription for a dose that would exceed 80 milligrams in one day, that pharmacist would need to stop and take a look and verify that the patient is not opioid naïve and has been on a regiment [sic] that has led him to develop a tolerance to that dose.

Id.

Mr. Parrado further identified as a red flag the simultaneous prescribing of two immediate release opioids, which he stated ''would be inappropriate therapy.'' *Id.* at 58. He also identified as a red flag ''pattern prescribing,'' which he defined as ''when I see the same medications, the same groups of medications, same combinations of medications in very similar quantities and very similar doses coming out of one . . . clinic.'' *Id.* Continuing, Mr. Parrado testified:

> When I see multiple people presenting with a very similar group or combination of prescriptions coming from one particular clinic, that is very much a red flag. That's not what happens in the average course of a day in a pharmacy. You don't see groups of people coming in from the same clinic, all getting the same drugs in large quantities and all willing to pay cash.

Id. at 59.

Mr. Parrado identified a further red flag as ''multiple people living in one household all receiving the same medications.'' *Id.* Mr. Parrado then testified: ''[i]s it possible? It could be, but it's just not—it doesn't happen on an everyday basis'' and that he ''would have to resolve [this red flag] before [he] could fill'' the prescriptions. *Id.*

Mr. Parrado testified that ''the basic way of resolving a red flag is . . . to verify [the prescription] with the prescriber,'' and that ''you consult with the prescriber'' and not his staff or nurse, ''over your concerns.'' *Id.* at 60. According to Mr. Parrado, the pharmacist must then ''use [his/her] professional judgment'' and ask ''[d]id I believe what I just heard? . . . [Are] there any red flags in the conversation I just had?'' *Id.* Mr. Parrado added that ''I've had many, many instances where after a conversation with the physician I said absolutely I'm not going to fill that prescription.'' *Id.*

Mr. Parrado further testified that some red flags are unresolvable. *Id.* As an example of unresolvable red flags that would lead him to refuse to fill a prescription, he identified ''a group of multiple people travelling a long distance, all getting the exact same or very similar prescriptions from one physician and all coming in with very, very large quantities of cash.'' *Id.* at 60–61. Mr. Parrado then testified that ''if you do see a red flag and you can resolve it, you document it on the prescription and then you fill it.'' *Id.* at 61. Mr. Parrado reiterated that the resolution is written ''[o]n the prescription itself.'' *Id.*

To counter Mr. Parrado's testimony as to the procedures a pharmacist must follow in dispensing controlled substances, Respondent called Dr. Sam Badawi. Dr. Badawi obtained his Doctor of Pharmacy degree from Samford University in 2002, and he is licensed to practice pharmacy in both Alabama and Florida, becoming licensed in the latter State in 2010. Tr. 346. He also

holds Juris Doctor degrees from both the Birmingham School of Law (2008) and Stetson University (2014), as well as an L.L.M. (2011) from Stetson in international intellectual property. *Id.*

Mr. Badawi testified that he had worked as a full-time retail pharmacist in Alabama until sometime in 2004 or 2005, when he ''transitioned into clinical pharmacy and IV infusion,'' which involved working ''with hospice patients who required intravenous pain prescriptions'' and ''morphine pumps.'' Tr. 348. While Mr. Badawi asserted that he continued to work on a part-time basis in retail pharmacy, he subsequently went to work for Amgen, a biotechnology company where his duties involved clinical trial design. *Id.* at 366.

On *voir dire,* Mr. Badawi testified that while he had worked in retail pharmacy for about ten years, four of those years were as an intern. And while he then asserted that he had worked in retail pharmacy ''from 02 all the way up to 08, when [he] moved to Florida,'' *id.* 372, his testimony was that for much of this time he worked only on a ''floating'' or ''part-time basis.'' *Id.* at 374. Mr. Badawi also acknowledged that when he worked at Amgen, as well as when he worked as a clinical pharmacy director, he did not interact directly with patients. *Id.* at 374–76. He further acknowledged that he had never taught pharmacy or published any articles; he also testified that his experience managing a pharmacy was limited to doing so on an interim basis ''for a couple of months.'' *Id.* at 376.

Mr. Badawi further acknowledged that he is not currently practicing pharmacy. *Id.* at 377. As for his experience testifying as an expert witness, Mr. Badawi testified that it is limited to a single criminal case in which he was listed as a witness but did not testify. *Id.* at 381. While the Government objected to Mr. Badawi's being qualified as an expert witness on the standard of pharmacy practice as it affects the dispensing of controlled substances, the ALJ overruled the objection and deemed him qualified ''as an expert in the standard of [pharmacy] practice as to the effective dispensing of controlled substances.'' *Id.* at 390.

On direct examination, Mr. Badawi testified that when a controlled substance prescription presents a red flag, ''[a] reasonable, prudent pharmacist will follow the DEA [Pharmacist's] Manual,'' which was published in 2010 and which at ''page 67'' lists criteria that ''may be an indication . . . that [the] prescription was not issued for a legitimate medical purpose.'' *Id.* at 391. Continuing, Mr. Badawi testified that ''[a]nd you have six options. And then it tells you what to do.'' *Id.* at 391–92. Mr. Badawi then referenced a Florida Board of Pharmacy Rule (Fla. Admin. Code r.64B16–27.831), which states that ''a prescription that is not issued for a legitimate medical purpose is not a valid prescription,'' and ''gives you five different scenarios'' before adding that ''in a retail setting, I would follow first the DEA Manual.'' *Id.* at 392.

Mr. Badawi then testified as to the prevention techniques listed in the Manual, which include ''[k]now[ing] your patient . . . what's the story behind that patient,'' ''know[ing] your drug, and know[ing] the prescriber and the DEA.'' *Id.* at 393. Mr. Badawi asserted that this is what a reasonably prudent pharmacist would do, ignoring that the Manual then states that ''[w]hen there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification.'' Pharmacist's Manual, at 67.

Mr. Badawi then testified that ''[a] red flag is a caution sign for the pharmacist,'' but ''on its face alone does not mean the prescription is invalid.'' *Id.* at 394. Continuing, Mr. Badawi testified that the Manual says that:

> if any of these criterias [sic] are found . . . the prescription may not be issued for [a] legitimate medical purpose. So actually it's a caution sign. You stop and you look, meaning that you default back on your training, your knowledge, state laws, federal laws, common sense as a professional, and you exercise that professional judgment, meaning a discretion.
>
> So after you stop with that red flag, and then you proceed with caution, and you exercise your discretion. So, if a pharmacist chooses to exercise that discretion favorably by resolving the red flag, then you dispense it. If not, then you don't dispense it.

Id. at 395.

Respondent's counsel then questioned Mr. Badawi about the specific red flags identified by the Government's Expert and how a pharmacist should resolve the red flag. *Id.* at 395–96. As to how a pharmacist should resolve the circumstance where prescriptions are presented ''from multiple individuals for the same or similar types of drugs [narcotics] in similar quantities,'' Mr. Badawi acknowledged that this is a red flag. *Id.* Mr. Badawi then testified that a pharmacist should ''fall back to the DEA Manual rules'' and ''[k]now the patient. So I have two patients with the same address from the same prescriber, so I would actually inquire into the circumstance of these two patients.'' *Id.* at 396. Continuing, Mr. Badawi added that ''then you want to know the doctor'' and whether he is ''a pain management'' or ''an ortho surgeon'' and ''[w]hat's the origination of that prescription?'' *Id.* According to Mr. Badawi, if the pharmacist still had doubts despite knowing this:

> you pick up the phone and ask to speak to the prescriber to find out more of the story because sometimes your patients are not going to tell you everything. So I don't want to miss the whole picture. So I would call the prescriber and verify. And if I still have doubts, I would not dispense that prescription. So that goes all under professional judgment, not just looking at the piece of paper and making a decision.

Id. at 396–97. Mr. Badawi maintained, however, that this red flag could be resolved and the prescription could be dispensed. *Id.* at 397.

Respondent's counsel then asked Mr. Badawi whether the fact the drug alone was for oxycodone 30 mg was a red flag of the prescription's potential illegitimacy. *Id.* at 397–98. While Mr. Badawi initially answered that ''[t]he drug by itself, no,'' he then testified that a Board of Pharmacy Regulation ''says that if the patient, all he or she is getting [is a] controlled substance, the oxycodone by itself could be under Florida law a red flag because it meets that criteria.'' *Id.* at 399. Then asked what a pharmacist should do to meet the standard of practice where a patient presents only a prescription for oxycodone 30 mg, Mr. Badawi answered: ''Know your patient. So I would actually look into the patient profile history of that patient'' to see ''if there are any notes being documented in the computer from prior pharmacists that actually dispense [sic] for this individual.'' *Id.* Mr. Badawi then explained that one of the reasons for reviewing the patient profile is that ''there are certain drugs'' that you ''want to steer away from opioid-naïve patients'' and that a pharmacist ''want[s to] make sure that the patient is able to tolerate the drug because it's a CNS-depressant.'' *Id.* at 400. Mr. Badawi also explained that the pharmacist must review the patient profile to determine whether there are any ''drug-drug interactions.'' *Id.* at 401.

Mr. Badawi acknowledged his agreement with Mr. Parrado's testimony that a prescription that calls for the dispensing of a ''very large or larger than normal amounts of a narcotic'' raises a red flag which requires that the pharmacist make an inquiry. *Id.* at 402–03. He also acknowledged that a narcotic prescription which provides for dosing that is ''larger-than-normal,'' or ''larger-than the manufacturer's recommended dosage'' also creates a red flag which requires the pharmacist to

look at the patient profile and determine if the patient has developed tolerance. *Id.* at 403–04. Mr. Badawi then explained that the doses of patients being treated with narcotics ''typically increase[ ] over time to achieve the pharmacological effect and also with respect to tolerance,'' and it ''very common'' for a patient to be prescribed both an extended release drug and immediate release drug ''for breakthrough pain.'' *Id.* at 404.

As for the circumstance of a patient presenting prescriptions for two short acting narcotics, Mr. Badawi testified that he ''would consider it as a red flag, and I would investigate further, and I would exercise my professional judgment.'' *Id.* at 418–19. When later asked on cross-examination, what possible explanation there could be for a patient to be prescribed two short-acting opiates together, Mr. Badawi suggested that a patient with kidney failure who is undergoing dialysis three times a week may require a combination because ''the drug is being excreted by the kidneys.'' *Id.* at 435–36.

Mr. Badawi further testified that it is ''common for physicians to issue prescriptions for [schedule II] drugs without the address being on the face of the prescription.'' *Id.* at 406. However, he testified that DEA had issued guidance that a pharmacist is to look at his/her State's rule'' to determine whether the patient's address could be added to the prescription. *Id.* at 406–07.

As for how a pharmacist would address the circumstance in which a patient lives ''a significant distance . . . from the pharmacy,'' Mr. Badawi testified that ''you want to know the patient, the reason why they're 100 miles way.'' *Id.* at 407–08. Mr. Badawi then suggested that the patient could be ''on a special assignment to MacDill Air Force Base,'' which is located in South Tampa; that the patient could be a snowbird and that Florida has ''a lot of snowbirds''; the patient could be on a three-month job assignment in Tampa or ''moving in with his fiancée.'' *Id.* at 408. Mr. Badawi then testified that he was ''not discounting that'' this ''is a red flag,'' and that a pharmacist should ''investigate more.'' *Id.* He then maintained that ''there is a professional judgment for the pharmacist to exercise, and based on the fact, you act accordingly.'' *Id.* And he further asserted that the proximity of the prescribing doctor to the pharmacy could explain why the patient who had travelled a long distance was filling the prescription at the pharmacy. *Id.* at 409.

Later, in response to a question by the ALJ, Mr. Badawi maintained that even if the patient was travelling a long distance, if the patient was a regular patron, ''that would actually resolve the distance.'' *Id.* at 437–38. However, after again testifying that the pharmacist should know his patient, the prescriber and the medical condition, Mr. Badawi explained that the pharmacist ''may want to inquire more about the patient [sic] reasons for being in hypothetically Tampa.'' *Id.* at 438.

Asked what types of prescriptions a reasonable pharmacist would ''expect to see'' when ''there is a pain management facility that is seeing a large number of patients for chronic pain,'' Mr. Badawi testified that a pharmacist would expect the prescriptions to be for ''primarily opioids.'' *Id.* at 416. Then asked what a pharmacist should do ''to adhere to the standard of practice . . . and address that issue,'' Mr. Badawi testified that ''when I was there, most of the patients . . . were regulars, and they were getting it actually on set intervals.'' *Id.* at 416. As for ''a new patient, you would go through ID verification [and] [y]ou would actually have them fill out more of a history, diagnosis.'' *Id.* at 417. Mr. Badawi then agreed with Respondent's counsel's suggestion that knowing that the clinic administered random drugs screens would ''assist a reasonable pharmacist.'' *Id.* Asked what other information a pharmacist would want to know about the practices of a pain management clinic, Mr. Badawi testified that a pharmacist would want know that the practitioners ''hold a valid DEA license'' and that the clinic has ''an active state license to conduct business.'' *Id.* at 418. Continuing, Mr. Badawi explained that ''you utilize the [Prescription Drug Monitoring Program] and the patient profile. So it's the totality of the circumstances, not just one angle, like a tunnel vision, when you actually want to verify these red flags.'' *Id.*

Mr. Badawi then testified that standing alone, none of the red flags identified by the Government's Expert render a prescription invalid. *Id.* at 419. He then explained that ''[r]ed flags are meant for the pharmacist to stop and inquire. So, now, if you have a combination thereof, not just one flag, maybe the weight of the inquiry is probably more than just one red flag.'' *Id.* at 419–20. He then testified that none of the red flags or combinations thereof identified by the Government's Expert required that the pharmacist reject the prescription. *Id.*

Mr. Badawi then testified that with the exception of a Board rule which requires a pharmacist to make a photocopy of a patient's identification, or if a copier is not available, to document descriptive information on the back of a prescription, there is no requirement that a pharmacist document his resolution of a red flag on the prescription. *Id.* at 421. Asked whether it is the standard practice for a pharmacist to document how he/she resolved every red flag, Mr. Badawi answered:

> . . . I don't know if you could document every single thing. I mean, you pick your battles. You want to document the major issues, and documentation nowadays, especially with these computer systems that would make you approve a prescription via a thumbprint scan, you don't even have to put a code on the computer anymore. These electronic records are kept.
>
> I would rather, as a reasonable, prudent pharmacist, and to benefit my other colleagues who are working after my shift, to have access to this documentation is to have it on the computer under the patient notes so they can see what I've done versus the paper trail.

Id. at 422. However, when asked on cross-examination if it is ''within the standard of practice . . . to not document how a red flag is resolved,'' Mr. Badawi answered: ''No, it is not in the standard of practice to make a blanket statement and not to document any red flags that are being resolved.'' *Id.* at 436–37.

Mr. Badawi also testified that he had attended a presentation by Mr. Parrado two years earlier on dispensing controlled substances, during which Mr. Parrado ''said there is a lot of gray area, it's not black or white, and to always use your professional judgment.'' *Id.* at 425. According to Mr. Badawi, during the presentation Mr. Parrado did not mention that the distance a patient travels is a red flag and that Mr. Parrado also told the attendees that ''there is no ceiling on'' the quantity of narcotics that a patient can be prescribed. *Id.* at 426. Mr. Badawi also testified that Mr. Parrado did not identify as a red flag the circumstance of a prescription missing a patient's address. *Id.* at 426–27. He also asserted that Mr. Parrado did not identify as a red flag the circumstance of patients residing at the same address. *Id.* at 427. While the Government objected to Mr. Badawi's testimony regarding the presentation on the ground that it had not been disclosed in advance of the hearing, to which Respondent's counsel asserted that this testimony was offered to impeach Mr. Parrado, *id.* at 424–25, 427; the ALJ overruled the objection. *Id.* at 427.

On cross-examination, Mr. Badawi acknowledged that he had not looked at any of the prescriptions. *Id.* at 430. Nor did he look at any of the patient profiles. *Id.* Asked if ''traveling hundreds of miles to see a physician is

a potential red flag,'' Mr. Badawi testified: ''It's not a potential red flag. It is a red flag.'' *Id.* When then asked if travelling hundreds of miles to see a physician whose clinic was affiliated with the pharmacy was a red flag, *id.,* Mr. Badawi testified that the affiliation raised a separate issue regarding possible ''kickbacks and Stark laws,'' but that ''has nothing to do with the controlled substance dispensing.'' *Id.* at 431. However, after again agreeing that distance ''is a red flag,'' Mr. Badawi stated that ''[i]f they're sending patients in the back door and the pharmacists suspect that's a red flag, that's a separate issue on its own.'' *Id.*

On questioning by the ALJ, Mr. Badawi acknowledged that there are some red flags that are not resolvable such as a prescription for some astronomical number of a drug such as morphine. *Id.* at 439. As an example, he testified: ''a 12-year old with [a] high doses of opioids, maybe in the hundred, for a broken bone. That seems excessive. So I would actually consult with the physician.'' *Id.* Mr. Badawi did not, however, explain what action he would take if the physician asserted that the prescription was legitimate.

As another example of an unresolvable prescription, Mr. Badawi offered where ''there is any drug-drug interactions that would deem that the prescription is not in the best interests of the patient.'' *Id.* However, in Mr. Badawi's view, this involved a ''medical issue'' and ''therapeutic appropriateness'' and ''not necessarily the validity of the prescription.'' *Id.* As an example, he then identified a patient being prescribed opioids when she was pregnant because even though the prescriptions may have been valid ''medically speaking,'' the fetus could be born addicted. *Id.* at 440. Mr. Badawi did not, however, address whether the simultaneous prescribing of drugs such as oxycodone 30, alprazolam, and carisoprodol also raises an issue of drug-drug interactions.

As between Mr. Parrado's and Mr. Badawi's testimony, there was substantial agreement on a number of issues. Where, however, there are areas of disagreement, I generally find that Mr. Parrado's testimony was more credible based on his years of service on the Florida Board of Pharmacy and because his experience in retail pharmacy is far lengthier and more current than that of Mr. Badawi.

The Prescription Evidence

At the hearing, the Government introduced into evidence copies of the front and back of 83 prescriptions for schedule II controlled substances which it alleged were dispensed by Respondent's pharmacists in violation of 21 CFR 1306.04(a) because they presented red flags which were not resolved. *See* GXs 3, 13, 14, and 15. Nearly all of the prescriptions were issued by physicians at the 24th Century Medical Center,[10] which was located at 7747 W. Hillsborough Ave. in Tampa, *id.,* a short walk from Respondent. According to a DEA Intelligence Research Specialist (IRS) who reviewed data that came from Respondent's dispensing software, 1,460 patients filled a total of 4,287 schedule II prescriptions at Respondent between January 3, 2011 and February 2, 2013. GX 12, at 2; Tr. 219. The IRS further determined that 3,867 of these prescriptions—more than 90 percent—were written by six doctors who worked for Victor Obi. Tr. 219, 223; GX 12, at 2. These doctors include S. A.-H., P.C., R.R., H.D., V.S., and J.E., who worked at the 24th Century clinic. According to the online records of the Florida Department of Health, 24th Century is a pain management clinic which has been owned by Mr. Obi since January 4, 2010.[11]

For example, the Government introduced a prescription issued by Dr. P.C. of the 24th Century Medical Center on July 28, 2011 to T.V. for 210 oxycodone 30 mg, which Respondent filled the same day. GX 3, at 1. While T.V.'s address was not written on the prescription, the prescription bears an address label listing T.V.'s address as being in Pensacola, Florida, a distance of 472 miles from Respondent. R.D. at 6.

Mr. Parrado testified that the prescription presented several red flags, including the lack of the patient's address; that it was for oxycodone 30 mg, a known drug of abuse; and that it was for a minimum of 180 milligrams a day, which is ''well above the 80 milligrams threshold'' and ''a very high dose'' and large quantity. Tr. 63. Mr. Parrado then noted that the patient's address was in Pensacola, 472 miles from Respondent. *Id.* at 64; R.D. at 6.

Mr. Parrado testified there was no indication on the prescription that ''anything was done . . . except that it was filled.'' *Id.* Asked whether it was possible to resolve the various red flags, Mr. Parrado replied that it was possible, ''but it would have taken a lot of investigation'' and that he ''would have had to have a good reason why that patient had to travel all the way to this clinic to get a prescription filled.'' *Id.* at 64–65. Continuing, Mr. Parrado stated that he could ''see if a patient is driving that far because they're . . . see[ing] a specific physician that has a specialty that's not available anywhere else.'' *Id.* at 65. Mr. Parrado subsequently testified that he was not aware that the physician has any specific specialty. *Id.* at 68. After the ALJ properly overruled Respondent's counsel's objection that Mr. Parrado was testifying beyond the scope of his expertise, the ALJ asked ''what would indicate on a prescription to you as a pharmacist of what you're looking for in this physician?'' *Id.* at 69. Mr. Parrado answered:

> . . . When I look at a prescription, I look and see where it came from. . . . You know a pharmacist has to exert his professional judgment on all prescriptions before he fills them. So I would be looking to see . . . I'm looking at a high dose of a very strong opioid narcotic. Where is that coming from . . . ? Is that coming from a cancer center, from an orthopedic office, somebody just had a big surgery? . . . I look for things like that, and I didn't see anything like that on here or I didn't see anything on this prescription that would indicate that a pharmacist had called to verify any of those things.

Id. at 69–70.

Next, on August 4, 2011, Dr. S.A.-H., also of the 24th Century Medical Center, issued a prescription to J.P. for 196 oxycodone 30 mg; Respondent filled the prescription the same day. GX 3, at 2. Here too, J.P.'s address was not written on the prescription; rather a label was attached which listed J.P.'s address as being in St. Augustine, Florida, a distance of 196 miles from Respondent. *Id.;* R.D. at 6.

Asked if the prescription presented any red flags, Mr. Parrado identified the lack of the patient's address; that is was written for oxycodone 30, ''a known drug of abuse''; that ''it's a very high quantity''; that the patient lived ''a rather good distance'' from Tampa; that it came from the 24th Century clinic; and that ''[t]he patient paid $784 in cash.'' *Id.* at 70–71. As to the cost of the prescription, Mr. Parrado testified that:

> You don't see people paying $784 in cash. You tell a person they have a $50 co-pay and

[10] Throughout this decision, the 24th Century Medical Center is also referred to as the 24th Century clinic and 24th Century.

[11] I take official notice of the online records of the Florida Department of Health which establish that Victor Obi-Anadiume is the owner of 24th Century Medical Center and has been since January 4, 2010. Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding-even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulation, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). Respondent may dispute my finding by filing a properly supported motion within fifteen calendar days of this Order which shall commence on the date this Order is mailed.

they go ballistic on you. And for a person to willingly pay $784 and not have any documentation as to why they did that and to see that over and over every day is a concern to me. . . . That's a red flag that I couldn't resolve.

Id. at 71. Mr. Parrado then explained that ''there were multiple red flags on here'' and that ''[a]ny attempt to have . . . done anything with them to resolve them would have been documented on the prescription.'' *Id.* at 71–72. However, Mr. Parrado ''did not see any documentation on this prescription that led me to believe anything was done.'' *Id.*

Also on August 4, 2011, Dr. P.C. of the 24th Century Medical Center issued a prescription to T.P.—who has the same last name as J.P.—for 224 oxycodone 30 mg; Respondent filled the prescription the same day. GX 3, at 3. Here too, T.P.'s address was not written on the prescription; rather a label was attached which listed her address as also being in St. Augustine, Florida. *Id.;* R.D. at 6. Moreover, Respondent's dispensing software assigned the number 2037897 to J.P.'s prescription and the number 2037898 to T.P.'s prescription. GX 3, at 2–3.

Asked if T.P.'s prescription presented any red flags, Mr. Parrado testified that ''[h]ere we have two people with the same last name traveling from St. Augustine . . . to get very similar prescriptions.'' Tr. 72. After noting the quantity of each prescription, Mr. Parrado testified that there were ''the same red flags as before. No address, the known drug of abuse, the high quantity, traveling the long distances'' and that T.P. ''paid $896 in cash.'' *Id.* According to Mr. Parrado, T.P.'s prescription ''was the very next prescription entered'' in the dispensing software after J.P.'s. *Id.* at 74.

Also on August 4, 2011, Dr. P.C. issued a prescription for 240 oxycodone 30 to W.J.; Respondent filled the prescription the same day. GX 3, at 4–5. Here too, W.J.'s address was not written on the prescription and had been added by a label which listed his address as being in San Antonio, Florida, a distance of 36 miles from Respondent. *Id.;* R.D. 6.

Mr. Parrado testified that the prescription presented red flags which included the lack of the patient's address; that the drug was for oxycodone 30, a known drug abuse; that the quantity was very high; that the patient was travelling from a town which is ''40 miles from Tampa''; that the patient paid $960; that the prescription was written by a doctor from the same clinic; and that the prescription number (2037895) preceded the numbers on the prescriptions presented to J.P. and T.P. Tr. 75. Mr. Parrado explained that ''[t]hese were all filled on the same day, so you have multiple prescriptions coming in from people travelling a long way, from the same clinic, for very similar drugs, and paying in cash, very large quantities of cash.'' *Id.* at 75–76. Mr. Parrado then testified that there was no evidence on the prescription that the red flags were resolved. *Id.* at 76.

On July 29, 2011, Dr. S.A.-H. issued a prescription for 140 oxycodone 30 to W.D.; Respondent filled the prescription the same day. GX 3, at 6–7. Here again, the prescriber had not written W.D.'s address on the prescription and his address was added by label which listed it as being in St. Cloud, Florida, a distance of 92 miles from Respondent. *Id.; see also* R.D. at 6. Mr. Parrado testified that the prescription presented ''the exact same red flags as . . . the previous prescriptions,'' and that there was no documentation that the red flags were resolved. Tr. 76–77.

Mr. Parrado provided testimony to the effect that other prescriptions in GX 3 presented the same red flags as he had previously identified. These included two prescriptions written on July 29, 2011 by Dr. P.C. for 168 oxycodone 30 to C.D. and 224 oxycodone 30 to D.M., as well as two prescriptions written by Dr. S.A.-H. the same day for 168 oxycodone 30 to B.P. and 224 oxycodone 30 to C.C. GX 3, at 8–15. Respondent dispensed the prescriptions the same day. GX 3, at 8–15. As written, none of the prescriptions contained the patient's address. *See id.* at 8, 10, 12, and 14. However, the prescriptions bear labels which show that C.D. and B.P. lived in Gainesville, 134 miles from Respondent; D.M. lived in Hudson, 36 miles from Respondent; and C.C. lived in Spring Hill, 42 miles from Respondent. *See id.; see also* R.D. at 6.

Mr. Parrado testified that these prescriptions raised an additional red flag, in that he was ''starting to see a pattern . . . coming from this one clinic of the same prescriptions'' and that ''[t]here is no individualization of therapy, which is important.'' Tr. 80. He also testified that he did not see any evidence that the red flags were resolved. *Id.* at 82.

On April 21, 2011, Dr. P.C. issued a prescription for 196 oxycodone 30 to C.B., which Respondent filled the same day. GX 3, at 16. Again, Dr. P.C. did not write C.B.'s address on the prescription. *Id.* According to the address label, C.B. lived in Big Pine Key, which is near Key West and a distance of 400 miles from Respondent. *Id.;* R.D. at 6. Mr. Parrado testified that he did not see any evidence that the red flags were resolved. *Id.* at 82.

Also on April 21, 2011, Dr. R.R. issued a prescription for 224 oxycodone 30 to S.S., which Respondent filled the same day. GX 3, at 17. Dr. R.R. did not write S.S.'s address on the prescription. *See id.* According to the address label, S.S. lived in Lakeland, a distance of 44 miles from Respondent. *Id.; see also* R.D. at 7.

After testifying that the prescription raised the same red flags as the previous prescriptions, Mr. Parrado explained that there was documentation on the prescription that the pharmacist had dispensed two different brands. Tr. 82–83; *see also* GX 3, at 17. However, Mr. Parrado did not see any evidence that the red flags were resolved. *Id.* at 83.

Pages 18 through 25 of Government Exhibit 3 contain copies of eight prescriptions which were also written on April 21, 2011 by physicians from the 24th Century clinic for oxycodone 30 (in quantities that range from 140 to 240 tablets) and filled the same day. As with the previous prescriptions, none of the prescribers wrote the patient's address on the prescription; instead, the prescriptions bear a label with the address. *See* GX 3, at 18–25. Asked whether these prescriptions presented any additional red flags, Mr. Parrado testified that:

> It's just another day of doing the same thing. Yeah, could something like this happen once occasionally a person travels a long way and pays cash? Of course. Does it happen consistently day after day after day? No. That's what would be a nonresolvable red flag.

Tr. 84.

The Government then asked Mr. Parrado if he knew where Hudson is in relation to Tampa.[12] Tr. 85. Mr. Parrado answered that it is 30 to 40 miles on the way to New Port Richie (which was the town or residence of one of these patients). *Id.* The Government then asked why it would ''be a red flag if it's just 30 miles?'' *Id.* Mr. Parrado explained:

> It's not so much just the red flag, it's the rapidity of people coming from other cities. You know, there's a lot of physicians' office, a lot of pharmacies between Hudson and Tampa. Why did they choose this pharmacy? That would have been the red flag I would have wanted resolved.

Id. Mr. Parrado then testified that he did not see any documentation that the red

[12] None of the patients whose prescriptions are reproduced at pages 18 through 25 resided in Hudson. *See* GX 3, at 18–25. Rather, the patients were from Tampa, Wildwood (79 miles), Dunedin (14 miles), Palm Harbor (14 miles), New Port Richey (25 miles), Port Richey (26 miles), Gainesville (134 miles) and Lutz (18 miles). R.D., at 6–7.

flags presented by the April 21, 2011 prescriptions had been resolved. *Id.*

Next, the Government asked Mr. Parrado about the price of a prescription written by Dr. H.V.D. (also of 24th Century) on January 16, 2012 for 224 tablets of oxycodone 30, which Respondent filled the same day.[13] Tr. 86. The price of the prescription was $1,232. *Id.; see also* GX 3, at 28. The Government then asked Mr. Parrado if he had ''any independent knowledge of what oxycodone normally sold for at that time?'' Tr. 86. Respondent objected to the question on the basis that there was no foundation as to Mr. Parrado's knowledge. *Id.* While the ALJ sustained the objection she allowed the Government to establish a foundation. *Id.* at 87. The Government then asked Mr. Parrado if, in his ''view as an experienced pharmacist,'' the price was ''a red flag.'' *Id.* Mr. Parrado answered ''yes,'' and explained:

> It's a very high price. I do know that about this time, in this timeframe, 2012, average wholesale price of oxycodone ran anywhere between $33 100 to maybe, depending on what wholesaler you went to, it could run as high as $150, $200 100. But that would still—this price would still be far exceeding anything that I would have ever, ever considered charging.

Id. at 87–88. Mr. Parrado subsequently testified that ''I cannot say in my 40 plus years as a pharmacist I have ever sold a prescription for $1,232 cash. That's just not something I've ever seen in my practice.'' *Id.* at 89. Mr. Parrado then testified that he was practicing pharmacy ''[i]n 2012.'' *Id.* Asked to look at the prescriptions reproduced at pages 29 and 30, both of which were written by doctors with 24th Century, Mr. Parrado testified that they presented the same red flags.[14] *Id.*

Next, the Government asked Mr. Parrado about two Dilaudid (hydromorphone[15]) prescriptions which were written by Dr. R.R. of 24th Century on October 10 and 13, 2011, which Respondent filled. GX 3, at 31–32. The first prescription authorized the dispensing of 240 tablets of Dilaudid 8 mg to D.K.; the second authorized the dispensing of 196 tablets of Dilaudid 8 mg. to G.C.[16] *See id.* The labels for both prescriptions included the initials ''KG,'' thus indicating that they were dispensed by Kasey George, Respondent's PIC.

Asked whether these prescriptions presented any other red flags, Mr. Parrado testified:

> Yeah. For starters, the drug. Dilaudid 8 milligram, extremely, extremely potent opioid. From my education, experience, and training, the average daily dose of Dilaudid would be probably between 12 and 24 milligrams a day. It would be a dose that would be a high dose because mostly people don't take Dilaudid 8 milligrams unless they're in a terminal stage of cancer. . . . [T]hat's just a drug that's very rarely dispensed anymore because of the potency, especially in that quantity. And to see a patient come in and get 200 plus of these tablets would be a . . . concern. To see multiple prescriptions for 200 tablets would be almost a nonresolvable red flag to me.

Tr. 90. Mr. Parrado further clarified that his opinion regarding the quantity applied to both prescriptions. *Id.* at 91. He then testified that he saw no evidence that the red flags had been resolved and added that the dose ''is almost double the recommended upper daily dose.'' *Id.*

On January 19, 2012, Dr. R.R. of 24th Century issued a prescription for 120 oxycodone 30 to S.D. GX 3, at 33. According to the address label (Dr. R.R. again not having written the patient's address on the prescription), S.D. lived in Panama City, Florida. GX 3, at 33. Mr. Parrado testified that Panama City is in the western panhandle of Florida, and the parties stipulated that it is 331 miles from Respondent. Tr. 92; R.D. at 7. Mr. Parrado again found no evidence that the red flags had been resolved. Tr. 93.

Continuing, the Government questioned Mr. Parrado about prescription labels found at pages 34 and 35 of its Exhibit 3 which showed the prices Respondent was charging for oxycodone 30 in late April 2011 and in early December 2011. Specifically, the evidence showed that in late April 2011, Respondent was charging $3.75 for a tablet of oxycodone 30, but that in early December 2012, it was charging $7.50 a tablet. GX 3, at 34–35. Mr. Parrado explained that he determined the price per tablet because he knew ''in that time frame that the wholesale costs had not doubled.'' Tr. 96. Mr. Parrado then testified that the price Respondent charged raised a red flag. *Id.* at 96–97. However, after recognizing that ''we don't have the prescription,'' the Government did not ask whether there was any evidence that the red flags had been resolved. *Id.*

The last page of Government Exhibit 3 contains the front and back of a prescription (dated April 25, 2011) which was written by a doctor from Tampa who was not affiliated with 24th Century. GX 3, at 36. The prescription authorized the dispensing of 120 tablets of methadone 10 mg for pain to B.V. but did not list B.V.'s address. *Id.* Of note, the front of the prescription contains the notation: ''verified by Dave'' with the date and time. *Id.* The back of the prescription contains a photo copy of a state-issued identification card and the prescription label which list B.V.'s address as Riverside, Florida. *Id.* According to the stipulation, Riverside is 200 miles from Respondent. R.D. at 7.

After noting that the prescription ''had some documentation that somebody verified something,'' Mr. Parrado testified to the effect that it was unclear what the pharmacist verified. Tr. 97; *see also id.* (''What does this mean? What did they verify? Who is this somebody? Was that the prescriber? You know, what were they verifying?''). Then asked what red flags were presented by the prescription, Mr. Parrado testified:

> Methadone . . . it is a drug that . . . it's being abused on the street. There's a lot of concern. I have a lot of concern about the use of . . . methadone because of the pharmacokinetics of the drug and the way it acts on patients. And . . . taking two tablets every 12 hours would probably be okay. I would want to verify with the doctor if the patient had developed a tolerance to this. I've seen people that have overdosed and died on methadone on the third dose of methadone because of the kinetics of that drug.

Id. at 97–98. Subsequently, Mr. Parrado reiterated his testimony that he did not know what the pharmacist had verified with respect to the prescription and that he did not see any evidence that ''red flag of distance'' had been resolved. *Id.* at 102.

Thereafter, the Government showed its Exhibit Number 13 to Mr. Parrado. This exhibit includes 20 prescriptions for schedule II narcotics including oxycodone 30, MS Contin 30 (morphine sulfate continuous release), and Dilaudid in both eight and four milligrams per dosage unit. *See generally* GX 13. Each of the prescriptions was issued by a physician with 24th Century between April 14 and 20, 2011, and on each of the

[13] Here too, the patient's address was added by a label and had not been written by the physician; the label shows that the patient lived in Floral City, Florida, 63 miles from Respondent. GX 3, at 28.

[14] The first of these prescriptions was written by Dr. R.R. on January 18, 2012 for 224 oxycodone 30. GX 3, at 29. The patient's address was added by a label and showed that he lived in Dunnellon, Florida, 88 miles from Respondent. *Id.; see also* R.D. at 7. The patient paid $1232 for the prescription. GX 3, at 29.

The second prescription was written by Dr. P.C. on January 19, 2012 for 168 oxycodone 30. GX 3, at 30. The patient's address was added by a label and showed he lived in Inglis, Florida, 80 miles from Respondent. *Id.; see also* R.D. at 7. The patient paid $966 for the prescription. GX 3, at 30.

[15] Mr. Parrado testified that ''[h]ydromorphone is the generic name of Dilaudid.'' Tr. 92.

[16] As before, Dr. R.R. did not write either patient's address on the prescription. GX 3, at 31–32. Labels attached to the prescriptions show that D.K. lived in Clearwater, a distance of 19 miles from Respondent, and that G.C. lived in Largo, a distance of 21 miles from Respondent. *See id.;* R.D. 7.

prescriptions, the patient's address had not been written on the prescription but had been added by a label. *Id.*

Also, each prescription presented the issue of the distance travelled by the patient, with the closest any patient resided being in Tarpon Springs, a distance of 18 miles to Respondent. *See* GX 13, at 23; R.D., at 7. The other patients lived in Brooksville (46 miles), Gainesville (134 miles), Newberry (145 miles), Ocala (100 miles), High Springs (158 miles), Spring Hill (42 miles), Sarasota (58 miles), Weeki Wachee (48 miles), Silver Springs (107 miles), Dunnellon (88 miles), and Lecanto (70 miles). *See generally* GX 13; R.D. at 6–7.

Asked by the Government whether the GX 13 prescriptions raised the same or additional red flags, Mr. Parrado answered: ''[i]t's all the same.'' Tr. 105. After noting that one of the prescriptions was for a patient from Dunnellon, Mr. Parrado then testified that he did not see any indication that the red flags had been resolved. *Id.* at 105–06.

Next, the Government asked Mr. Parrado about two prescriptions issued on January 8, 2013, by Dr. P.C. to B.W. and filled by Respondent the same day. Tr. 107–8; GX 14, at 1–5. The prescriptions were for 100 Dilaudid 8 mg and 60 methadone 10 mg. GX 14, at 1–4. While Dr. P.C. was not affiliated with 24th Century, he also failed to include B.W.'s address on the prescriptions; however, both prescriptions bear an address label which lists B.W.'s address as Tallevast, Florida, which is 54 miles from Respondent. *Id.,* at 2, 4; R.D. 7. The evidence also showed that B.W. presented a Florida Identification Card. GX 14, at 5.

Asked if these prescriptions presented any red flags, Mr. Parrado testified that the dosing instruction on the Dilaudid prescription called for taking one tablet every four hours, which would result in a daily dosage of 48 milligrams, ''double the upper recommended dose.'' Tr. 107. Mr. Parrado then noted that the prescriptions raised an additional and serious concern because both Dilaudid and methadone were being prescribed and both drugs ''are immediate release opioids . . . which could contribute to respiratory depression.'' *Id.* Mr. Parrado subsequently testified that B.W.'s address and presentation of an identification card raised additional issues that ''a reasonable pharmacist [would] want to investigate.'' *Id.* at 110.

The record includes prescriptions for 75 Dilaudid 8 mg and 90 methadone 10 mg issued on January 21, 2013, by Dr. E.G.-R. (who was not affiliated with 24th Century) to T.F. of Brooksville; Respondent filled the prescriptions the same day. GX 14, at 7–8. While the back of each prescription includes a handwritten notation dated ''1/21/13,'' *id.* at 8, Mr. Parrado testified that he did not ''know what that is'' and the notation ''doesn't tell me anything.'' Tr. 110. After testifying that the distance in miles between Brooksville and Tampa is ''maybe 30, 40 miles,'' Mr. Parrado testified that it is ''not so much the distance'' but that ''it's not an easy drive'' as there are ''a lot of stop lights and a lot of traffic to get'' to the doctor's clinic, which was located ''several miles'' from Respondent. *Id.* at 111. Mr. Parrado then explained that he would want to know why the patient had ''come there,'' that he ''would have had concern'' as to the methadone dose, and that he ''would have wanted to verify'' why the doctor had prescribed ''two immediate release medications.'' *Id.* However, Mr. Parrado did not see any evidence that the red flags were resolved. *Id.*

Mr. Parrado testified that while a prescription (GX 14, at 11–12), which was written by Dr. S.A.-H. of 24th Century, was for ''only 90 tablets'' of oxycodone 30 mg, the patient's address was in Middleburg, Florida, which is ''a good ways from Tampa.'' Tr. 111. According to the stipulation, Middleburg is 175 miles from Tampa. R.D. at 7. Mr. Parrado also testified that the price of the prescription, ''$675 for just 90 tablets[,] seems like a very high price.'' Tr. 112.

Aside from the first four prescriptions in GX 14, each of the remaining 16 prescriptions was written by a doctor with the 24th Century clinic. *See* GX 14, at 11–42. Asked if the red flags of ''the distance where the patient lived'' and ''the fact that they came from the same clinic'' were ''inherent in all'' of the 16 prescriptions, Mr. Parrado answered ''yes,'' and that he did not ''see any evidence of any kind of documentation'' that the red flags were resolved. Tr. 112–13.

While the back of each of the prescriptions issued by the 24th Century physicians also contains checkmarks or scribble, Mr. Parrado testified that ''that just looks like they're verifying the quantity and possibly the directions, but . . . not addressing the red flag.'' *Id.* at 113. Mr. Parrado then explained that ''[i]t's common for pharmacists when they're verifying a prescription . . . before a prescription can be dispensed, the pharmacist has to look at [it] to make sure the right drug is being dispensed, the right quantity, directions are correct on the label. That looks like that's what was being checked off there.'' *Id.*

Government Exhibit 15 contains an additional 13 prescriptions. GX 15. The first two prescriptions were written by Dr. V.S. on January 28, 2013 to J.A. and were for 56 Adderall 30 mg and 84 Dilaudid 8 mg. *Id.* at 1, 3. While the prescriptions list Dr. V.S.'s affiliation as the MD Plus Clinic in Lakeland, Florida, *id.,* Dr. V.S. was also listed as one of the prescribers affiliated with 24th Century. GX 3, at 33; GX 13, at 1. *Id.* On neither prescription did Dr. V.S. write J.A.'s address; according to the labels attached to the back of each prescription, J.A. resided in Winter Haven, which is 60 miles from Respondent. GX 15, at 2, 4; R.D., at 7.

Mr. Parrado testified that Adderall is a stimulant and that the patient was ''getting an upper and downer together.'' Tr. 114. Asked if this was a red flag, Mr. Parrado testified that ''I would have wanted to know why they were giving an upper and a downer together. Maybe the patient was having some kind of narcolepsy . . . from one drug to cause him to need a stimulant from the other side, but I would have expected to see some documentation on that.'' *Id.* Mr. Parrado then testified that Winter Haven is ''a very long way from Tampa,'' although he erroneously stated that the distance was ''a hundred plus miles.'' *Id.* He then testified that he did not see any evidence that the red flags were resolved. *Id.* at 115.

As for the rest of the prescriptions in GX 15, the patients lived in Citra (117 miles from Respondent), Brooksville (46 miles), Gainesville (134 miles), Tarpon Springs (18 miles), Ocala (100 miles), Nokomis (79 miles), and Newberry (145 miles). GX 15, at 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, and 26. Mr. Parrado testified that the distances travelled by the patients raised red flags and that he did not see any evidence on the prescriptions that there was any attempt to resolve the red flags. Tr. 116.

Asked by the Government whether Respondent's pharmacists ''exercise[d] the appropriate standard of care in the State of Florida,'' *id.* at 119–20, Mr. Parrado testified:

> No. In my opinion, there are multiple things that a pharmacist has to do before he dispenses a prescription. He has to establish the appropriateness of the therapy. He has to discuss the . . . excessive and inappropriate quantities. He has to assess the therapeutic duplication of the two immediate release medications, all of which are in the laws and rules of the practice of pharmacy.
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> * * *
>
> There are probably four or five other notations in the Florida law that things the pharmacist would have had to have done to verify the prescription and make sure it was

appropriate and everything was correct before he dispensed it, and I didn't see where any of that was done. Therefore, I didn't think he reached the standard of care.

Id. at 120. After a series of objections to the Government's questions were sustained by the ALJ, Mr. Parrado subsequently testified that he ''would not have dispensed these [prescriptions] without having resolved any of the red flags.'' *Id.*

On cross-examination, Mr. Parrado acknowledged that every red flag he had ''talked about . . . could potentially be resolved.'' *Id.* at 127. He further acknowledged that there are millions of people who do not have insurance and must pay for their prescriptions with cash. *Id.* at 131. However, when asked whether he had ever filled a controlled substance prescription for someone who did not have ''insurance to cover their [sic] prescription,'' Mr. Parrado answered that he was not going to give ''a yes or no answer because . . . a person who . . . can't afford insurance . . . is not going to pay 1,200 or 1,300 dollars for a prescription.'' *Id.* at 132. Mr. Parrado further testified that whether the prescription was paid for with cash, credit card, or check, it's ''all the same to me.'' *Id.* at 133.

After Mr. Parrado reiterated his earlier testimony that he ''didn't see where anything [as to the resolution of red flags] was documented,'' Respondent's counsel asked if it is ''true that Florida does not require a pharmacist to document the resolution of red flags on the face of the prescription?'' *Id.* at 134. Mr. Parrado answered: ''I would never document it on the face, I'd write it on the back.'' *Id.* at 135. Mr. Parrado then acknowledged that ''there's no regulation that says you have to, but that's just the standard of practice and has been for decades.'' *Id.* When then asked whether a pharmacist could document the resolution of a red flag ''somewhere other than the back of the prescriptions,'' Mr. Parrado replied: ''I've never seen it documented anywhere other than that.'' *Id.*

However, Mr. Parrado subsequently acknowledged that resolution of a red flag could be documented other than on the back of a prescription. *Id.* at 136. And he later agreed with Respondent's counsel that if a patient had been a regular and long standing patient of the pharmacy, it would not be ''necessary to do the full-blown documentation that you would do on the first prescription once you've resolved the red flag.'' *Id.* at 177. However, he maintained that some notation should still be made on the prescription so that if the prescription was questioned by a regulatory agency, there would be some evidence to defend the dispensing decision. *Id.; see also id.* at 190. Mr. Parrado also acknowledged that ''some pharmacists document [the] resolution of red flags so that it is . . . available to help their colleagues who [are] filling in for them.'' *Id.* at 191.

Mr. Parrado rejected, however, the suggestion of Respondent's counsel that documentation need not be placed on the prescription because ''there's no way for the floater pharmacist . . . who takes over to actually go through [the prescription file] and know where those [notes] are because they're all written on the back of prescriptions.'' *Id.* at 192. As Mr. Parrado explained, the pharmacist would see the prescription number when he looked up the patient's profile on the computer, and ''it would be very easy to go pull that prescription out of the file.'' *Id.* Then asked how a pharmacist would know which prescription to pull if the patient had been filling the prescription every month for ten years, Mr. Parrado testified: ''That's why you would have documented this as a regular patient. You would have done something on that scrip[t].'' *Id.* at 192. However, he then acknowledged that notes generally can be made in the pharmacy's dispensing software. *Id.* at 193.

Mr. Parrado acknowledged that a patient who has been on opiates for a significant time and who has developed tolerance may need to exceed the manufacturer's daily recommended dosage. *Id.* at 137. He acknowledged that the dosing depends on ''the specifics'' of the patient's condition. *Id.* He also agreed that having a patient on a narcotic contract so that the patient only obtains narcotics from a single clinic could be helpful in resolving red flags. *Id.* at 137–38. He further agreed that if the narcotic contract ''called for routine urine screens to ensure that the patient was actually taking the drug,'' that would ''be helpful'' in ''prevent[ing] diversion.'' *Id.* at 138.

Asked if he had reviewed PMP data to determine the drug history of any of the patient, Mr. Parrado said that he had not and that the law did not allow him to. *Id.* While he testified that he looked at thousands of prescriptions from Respondent which covered more than two years, DEA did not give him noncontrolled prescriptions and he looked only at the schedule II prescriptions. *Id.* Given this, Respondent's counsel later asked Mr. Parrado if he had ''no way of knowing what . . . adjunct drug therapies . . . any of these patients were taking?'' *Id.* at 160. Mr. Parrado answered:

Well, only because of what I saw in the Respondent's exhibits where there were some partial medical records that did have all the drugs the patient was taking on a very few cases, and on those it was the same on every one of them, the same group, same combination.

Id.

Mr. Parrado acknowledged that Florida law (Fla. Stat. § 893.04(2)(a)) states that a pharmacist may dispense a controlled substance in the exercise of his professional judgment when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patients' agent. Tr. 139. After Respondent's counsel pointed that this provision does not require that the pharmacist alone talk to the physician alone and allows a pharmacist to talk to the patient or the patient's agent, Mr. Parrado testified that ''it says in [Fla. Admin. Code r.] 64B16–27.831 that when you have a concern you shall contact the prescriber.'' *Id.* at 139–40.

Turning to J.A., the patient who had received prescriptions for Adderall and Dilaudid, Mr. Parrado conceded that while opiates ''have a respiratory depressant effect,'' they are not categorized as depressants under the Controlled Substances Act. *Id.* at 141–42. He also acknowledged that when a drug has a shortage and its wholesale price rises, the retail price would also rise. *Id.* When then asked whether it is standard practice to input the average wholesale price of a drug into a pharmacy's dispensing software and that the software has algorithms that actually generate the retail price, Mr. Parrado explained that ''[t]here are different ways to fix that algorithm'' and that he had sometimes overridden the price set by the software. *Id.* at 143. While Mr. Parrado acknowledged that, in 2008 and 2009, two major oxycodone manufacturers had recalled their products resulting in shortages and that wholesalers would take advantage of this and charge higher prices, he disagreed with the suggestion that ''those shortages continued and had ripple effects throughout Florida well into 2010 and 2011.'' *Id.* at 144. Rather, he testified that the shortages did not have ''that much'' of an effect and ''[o]nce it became available again the prices were not that far skewed'' [17] *Id.*

While Mr. Parrado acknowledged that he did not go to the pharmacy closest to his home because he knows the pharmacist at the pharmacy he goes to, he explained that ''[m]ost people go to

[17] By contrast, Mr. George testified that from 2010 through 2012, the wholesale ''price sometimes went three times to 10 times more.'' Tr. 538–39.

a pharmacy for . . . some sort of a convenience, or a reason, and he [the patient] had to have a reason to go to that pharmacy. That's what I would want to know. That's what I would want to document.'' *Id.* at 146. Asked if he documented on the back of every controlled substance prescription the reason a patient had driven 10 or 15 miles on roads with stop lights to get to his pharmacy, Mr. Parrado answered: ''No, of course not.'' *Id.* at 148. However, he then adhered to his position that ''[s]tandard practice is if you have the red flag to document it.'' *Id.* As for whether it would be a red flag if the patient ''lives 20 or 30 miles away and [has] seen a doctor who's in close proximity to the pharmacy'' and ''[t]hat red flag then is resolved?''; Mr. Parrado testified that ''I'd still want to know the address. There's going to be multiple red flags here.'' *Id.* at 148–49. On a further question regarding ''the red flag of someone driving 10 or 15 miles'' and ''[i]f the physician happens to be in close proximity to the pharmacy, that resolves the red flag, doesn't it?''; Mr. Parrado testified: ''Not necessarily'' and explained that: ''[i]t's not just one thing. It's multiple things. That's the combination of red flags.'' *Id.* at 149.

Mr. Parrado testified that the drugs themselves (hydromorphone and oxycodone 30) raised a red flag as they are known drugs of abuse. *Id.* at 149–50. While Mr. Parrado acknowledged that he had filled prescriptions for oxycodone 30, he could not ''remember ever filling a prescription for hydromorphone.'' *Id.* at 150. However, when asked what he would document on a prescription when he was practicing and was presented with a prescription for oxycodone 30 but there were no other red flags, Mr. Parrado testified: ''[n]othing because it wasn't a red flag.'' *Id.* at 151; *see also id.* at 166.

Asked the same question with respect to hydromorphone, Mr. Parrado answered: ''Well, you know, there again, looking at the dose, I would have to look at the patient profile, see if the patient has developed a tolerance to that drug, and at that point the red flag—there's nothing to write down because there isn't a red flag.'' *Id.*at 151. Later, on cross-examination, Mr. Parrado acknowledged that his review of the prescriptions did not include any information that would have allowed him to determine whether the patients had been on narcotics for a significant period and developed tolerance as he reviewed only what DEA gave him. *Id.* at 161–62. He also acknowledged that neither the prescription nor the prescription label ''tells you anything about the patient [sic] history.'' *Id.* at 177.

Turning to the red flag of pattern prescribing, Mr. Parrado acknowledged that if a physician prescribed different narcotics for different patients, sometimes wrote for extended release drugs and other times immediate release drugs, and varied the strength of the drugs, this would not be pattern prescribing. Tr. 153. Mr. Parrado then agreed that the same would hold true for the clinic itself. *Id.* And he subsequently acknowledged that pain management is a legitimate medical practice, which often times requires the prescribing of opioids in significant quantities as patients develop tolerance. *Id.* at 154.

As for the red flag of therapeutic duplication, Mr. Parrado agreed that extended release drugs ''were expensive'' even though ''[t]here were some generics available'' during the time period at issue and that a patient who lacked insurance ''would have difficulty paying for an extended release oxycodone product.'' *Id.* at 155–56. Mr. Parrado then acknowledged that if a patient required oxycodone 30 for his ''normal pain,'' the physician would not be acting illegally if he prescribed a lower strength drug for the patient's ''breakthrough pain.'' *Id.* at 156.

Turning to the methadone prescription which Respondent filled for B.W. (GX 14, at 3) (on the same day it also filled a Dilaudid prescription for him), Mr. Parrado conceded that he did not have any evidence that B.W. had overdosed, abused the drug, or sold it on the street. Tr. 158–59. Mr. Parrado then acknowledged that he had no evidence that any of the prescriptions were abused or sold on the street. *Id.* at 159.

Asked whether his concern about methadone-related overdoses was a general concern or a specific concern related to B.W., Mr. Parrado testified:

> That was a concern that I would have wanted to have seen a red flag resolved. Why is he on hydromorphone and methadone both, which are both immediate release . . . you know, you don't use two immediate release opioids for breakthrough pain. You use a long acting as a base and then the immediate release for breakthrough.

Id. Later, on cross examination, Mr. Parrado explained that the problem with using methadone for pain management ''is that the pain relief you get . . . probably peaks at about three to four hours and tapers off rather quickly after that, but the respiratory depressant part . . . continues to grow even after the pain relief has gone down, so people are apt to take another pill,'' thus increasing the respiratory depressant effect. *Id.* at 174. However, Mr. Parrado acknowledged that methadone may be appropriate for certain patients. *Id.*

Mr. Parrado then agreed with Respondent's counsel that ''it's not common, but it's not completely unheard of for individuals who may not have insurance or may have allergies or other reasons why certain long-acting drugs do not work'' [18] *Id.* at 159–60. And he also agreed with Respondent's counsel that because of genetic differences, some persons may metabolize certain opiates in a more effective manner than others. *Id.*

Mr. Parrado further acknowledged that the DEA Pharmacist's Manual does not use the term red flag and does not specifically tell pharmacists how to identify red flags. *Id.* at 163. However, he then testified that the ''[M]anual gives you a lot of information that you have to use your professional judgment . . . . It's not going to list line by line, but that's why you have pharmacists exercising professional judgment.'' *Id.* Mr. Parrado further testified that a pharmacist ''should be able to defend that professional judgment.'' *Id.*

After acknowledging that neither the CSA nor DEA regulations use the term ''red flags,'' as well as that the CSA and DEA regulations do not ''talk about distances from patients,'' Mr. Parrado agreed that ''there is no bright line that . . . if it's beyond a certain distance, it's always wrong.'' *Id.* at 164. However, Mr. Parrado subsequently testified that if patient lived more than 40 miles from the doctor's office, that would be ''one of the red flags for diversion.'' *Id.* at 208.

As for whether family members seeing the same doctor ''makes the doctor's prescriptions for those family members invalid,'' Mr. Parrado testified that ''[i]t raises a question. It may not make it invalid.'' *Id.* at 164. Mr. Parrado then explained that ''I have to validate—I have to verify the validity of that script.'' *Id.* at 165. While Mr. Parrado acknowledged that a pharmacist could ''possibly'' resolve the red flags created by the circumstances of two people in the same household ''need[ing] the exact same drug and pay[ing] those large quantities of money,'' he rejected the suggestion of Respondent's counsel that this could legitimately occur where ''family members . . . live together, didn't have insurance'' and had to ''pay out of pocket.'' *Id.* Mr. Parrado then testified: ''You can buy a lot of insurance for $2,700'' and that the costs

[18] Mr. Parrado subsequently acknowledged that extended release opioids could be problematic for patients who have had bariatric surgery. Tr. 175. Also, on questioning by the ALJ, he testified that if a patient was allergic to a medication, ''you wouldn't be filling'' that prescription. *Id.* at 213.

of the prescriptions would be a red flag that he ''could not have resolved.'' *Id.*

Mr. Parrado further acknowledged that in evaluating whether a pharmacist had complied with the standards of practice in dispensing a prescription, ''it would be helpful'' to know various information. *Id.* at 177. These include ''what the pharmacist knew'' about: (1) The patient, including his/her medical condition, history, diagnosis, cause of the pain and drug utilization; (2) the prescribing physician, including his/her specialty, board certifications, practice location, and reputation; and (3) the drug being prescribed . *Id.* at 178; *see also id.* at 202–03.

Asked if he was aware that one of the physicians who issued the prescriptions he had testified about ''is a noted anesthesiologist,'' Mr. Parrado testified that ''if it doesn't say it on the prescriptions itself, I wouldn't know it.'' *Id.* at 183–84. Then asked by Respondent if he knew ''that that particular noted anesthesiologist was a physician at a major regional hospital before being involved in the practice of pain management care,'' Mr. Parrado answered: ''[n]o, I would not have known that.'' *Id.* at 184. Mr. Parrado also testified to the effect that the fact that the physicians (with the exception of one who had since died) who practiced at 24th Century have had their registrations renewed would not change his opinion. *Id.* at 186.

Mr. Parrado further acknowledged that the issue of prescribers not placing the patient's address on prescriptions has become ''very common,'' but that the pharmacist has to verify the patient's address. *Id.* at 193. He also testified that in 2008, DEA sent a letter to pharmacists which stated that the pharmacist ''could add in'' the patient's address. *Id.* at 194. Mr. Parrado then agreed that if the prescription was only missing the patient's address, this does not raise ''a concern about diversion.'' *Id.* at 195. Subsequently, the Government identified several prescriptions where the patient's address had not been placed on the front of the prescription. *Id.* at 206 (discussing GX 13, at 3, 5, 21, 27, and 29). However, in each instance, the patient's address was on the dispensing label which was affixed to the back of the prescription.[19] *See id.* at 4, 6, 22, 28, and 30.

While Mr. Parrado continued practicing through 2012, he could not remember the pharmacies he worked at having ever filled prescriptions written by a doctor at the 24th Century clinic. *Id.* at 195–96. While Mr. Parrado acknowledged filling prescriptions that came from the Kenaday Clinic (*see* GX 14, at 7–10), he testified that ''[o]n the ones I filled, I called and checked them very carefully.'' Tr. 196–97. Asked what he did to resolve the red flags, Mr. Parrado testified that there was an issue of dosing and whether ''the patient had developed a tolerance for that dose,'' and that he called the doctor.[20] *Id.* Mr. Parrado added that he had spoken to the doctor twice, after which he ''wouldn't fill anymore.'' *Id.* at 199.

Asked whether there were other concerns besides the dosing with the prescriptions written by the Kenaday doctor, Mr. Parrado testified that another prescription presented a distance concern and he did not fill the prescription and gave it back to the patient. *Id.* Subsequently, Mr. Parrado then acknowledged that the prescription that presented the dosing issue may also have presented another issue, that being that the doctor had prescribed ''a combination of hydrocodone, Xanax, [and] Soma.'' *Id.*at 200. Mr. Parrado testified that after talking to the physician and believing that the prescriptions had a legitimate medical purpose, ''after that I didn't feel comfortable anymore and after speaking with the doctor a couple more times I decided I could not take his word for the validity and I wouldn't fill them anymore.'' *Id.* at 201. As Mr. Parrado further testified, ''[o]nce I saw the pattern of prescribing coming from that clinic is when I stopped.'' *Id.* at 202.

Finally, Mr. Parrado acknowledged that a doctor can issue a prescription for a legitimate medical purpose and the patient may nonetheless misuse it or sell it on the street, but that this does not make the prescription invalid. *Id.* at 204. Nor does a patient's misuse or selling of the drug to another make a pharmacist's decision to dispense the prescription wrong unless the pharmacist knew or should have known that the patient was going to misuse or sell the drug. *Id.* at 205.

Respondent's PIC's Testimony

As noted above, Respondent's Expert Mr. Badawi did not address any of the prescriptions which the Government submitted into evidence. Kasey George, Respondent's PIC, did offer testimony as to why some of the prescriptions were dispensed.

Mr. George testified that he has been a pharmacist for 21 years, that he has 12 to 13 years of experience in retail pharmacy, and that he has been Respondent's PIC for seven years. Tr. 445–46. Mr. George holds an active pharmacist's license in Florida and holds inactive licenses in three other States. *Id.* at 446. He testified that he does not have either a criminal history or a disciplinary history on his pharmacy license. *Id.* at 445. He also testified that he had obtained his pharmacy degree from Temple University in 1994, that he had taken continuing education classes, and that he had attended a class on dispensing controlled substances in 2013 at which Mr. Parrado had spoken. *Id.* at 447–48.

Mr. George testified that he is the only full-time pharmacist at Respondent, which is open six days a week, and that if he has a day off, he schedules a temporary pharmacist to work that day. *Id.* at 448. Respondent's counsel then asked what controlled substance dispensing protocols were in place at Respondent from 2011 through February 2013, when the Administrative Inspection Warrant was served. *Id.* at 448–49. According to Mr. George, the protocol:

> involves many things, including first we have check [sic] that the doctor's office is located within 20 miles from the pharmacy. Then we check the patient's ID, Florida ID, and make sure that the patient has a Florida ID. The next step we do is we check the prescribing physician's address and their phone number, and we check in the publicly listed Web site to see that it matches what's printed on the prescription. Then we check that the doctor has a valid DEA license active and also an active NPI number.
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> * * * * *
>
> . . . And we check the—call the doctor's office and get the diagnosis for the condition treated. And also we ask for the diagnosis studies they have done and make sure that the studies are consistent with the medical condition that is being treated and also the prescription. . . . And we ask for all the records to be sent to the pharmacy, and we check that they have the narcotic contract with the patient. . . . And also we ask for the urine drug test result and those records. Then we are not done with that.
>
> And we have to check the patient's ID, which is present with the DMV Web site to

[19] Asked by Respondent's counsel if ''Florida law says there shall appear on the face of the prescription or written record thereof'' and thus allows for the patient's address to be placed on the back, Mr. Parrado testified: ''[t]hat law was changed. At the time these prescriptions were written, that law did not say on the prescription record thereof. . . . It just said it had to be on the face of the prescription.'' Tr. 209. According to the 2011 Florida statutes, Section 893.04(c) stated that ''[t]here shall appear on the face of the prescription or written record thereof for the controlled substance . . . [t]he full name and address of the person for whom . . . the controlled substance is prescribed.'' Fla Stat. Ann. § 893.04(c) (2011). Contrary to Mr. Parrado's testimony, the statute had the same wording throughout the relevant time period.

[20] At this point the Government objected that the question was ''beyond the scope of direct examination.'' Tr. 197. Respondent's counsel replied that the question went to Mr. Parrado's credibility, and the ALJ overruled the objection. *Id.* at 198.

see that address is correct. Then . . . end of 2011, PDMP came. From that day onwards, we check for every new patient, and every time they come we have to check the PDMP to see any doctor shopping or any early filling and check also . . . the patient's credibility because if their [sic] address is available there. And after that, all that pharmacist's professional judgment also comes into that protocol.

Id. at 449–51.

Mr. George testified that he reviewed the prescriptions submitted by the Government and he acknowledged that he was the dispensing pharmacist on ''the vast majority of'' them. *Id.* at 451. He testified that he had used the above protocol in dispensing the prescriptions. *Id.* He then denied that he was required to fill prescriptions that originated at certain clinics or that were presented by certain patients. *Id.*

Mr. George testified that he was ''required to document every conversation with a patient or physician if the conversation was about concern related to'' a controlled substance prescription. *Id.* at 451–52. Asked by Respondent's counsel ''where was that documented?''; Mr. George testified: ''[w]e have a two-page pharmacist's due diligence checklist separately filed in a binder in an A to Z format according to patient's last name, and all the documents pertaining to that patient's prescription is [sic] attached to that in the file.'' *Id.* at 452. Mr. George further testified that he had used the due diligence forms for the patients whose prescriptions were at issue in this case. *Id.* Mr. George then testified that when DEA executed the AIW, they did not ask him to provide the due diligence forms and did not take them. *Id.* Nor did they ask him to provide documentation showing that he had made inquiries and resolved red flags. *Id.* at 452–53.

Asked by Respondent's counsel where he would ''document the resolution of questions about'' a controlled substance prescription, Mr. George answered:

> It used to be if it is one or two items you used to document on the face of the prescription. Since the information needed to prevent the abuse and misuse and diversion, a lot of documents [sic] involved, if I decided to go extra step to get all the available documents filed in a separate sheet and document a pharmacist's checklist so I can do beyond the required, more than the required and go and fill in in vast places.

Id. at 455–56. Noting his testimony that he had formerly documented the resolution of such questions on the back of the prescription, Respondent's counsel asked Mr. George when he changed to using checklists and obtaining the records he described. *Id.* at 456. Mr. George testified that it was ''[f]rom 2010 onwards.'' *Id.* at 457.

Mr. George then explained that his protocol also included interviewing the patients to ''ask them their conditions and why they're being [sic] taken [sic] these prescriptions.'' *Id.* Mr. George further asserted that ''in that interview, I can find out what is the real need and also if they have any intention to abuse or misuse or any diversion involved in that scheme.'' *Id.* at 458.

Mr. George testified that ''we verify . . . the credibility of the doctors through the paperwork and the documents.'' *Id.* He further stated that ''I visit the doctor's office and the clinic occasionally and get to know the doctors,'' and ''I talk personally to the doctors and also make sure that they have a protocol in place, which I also make sure that that is inconsistent of our protocol.'' *Id.* Continuing, Mr. George testified that ''I make sure that all that paper which I mentioned, narcotic contract and opiate contract, all are in place.'' *Id.*

Mr. George acknowledged that he was familiar with the physicians who wrote the prescriptions at issue, and that most of them worked for 24th Century, which ''is a pain management clinic.'' *Id.* at 459. Asked by Respondent's counsel what he knows about the specialties and certifications of 24th Century's doctors, Mr. George answered:

> One doctor, he is no more. He's [sic] passed away three or four years ago. He was the director of this clinic, and he was the chief anesthesiologist in [sic] Tampa General Hospital. He was a famous doctor, and his expertise was a big asset at clinic, and many patients liked him.

Id. Subsequently, Mr. George testified that the name of this doctor was Cornelius Ruperto. *Id.* at 466.

Notably, Dr. Ruperto did not write any of the prescriptions at issue in this matter. *See generally* GXs 3, 13, 14, and 15. Moreover, his name is not listed on any of the prescription forms. *See generally* GXs 3, 13, 14, and 15. This is for good reason, as according to Dr. Ruperto's online obituary of which I take official notice,[21] Dr. Ruperto died on December 8, 2008, more than two years before the earliest prescription in evidence. And of further note, Mr. George offered no testimony regarding the specialties or board certifications of the doctors who actually wrote the prescriptions at issue in this matter.

Asked by Respondent's counsel how he resolved the red flag of multiple patients presenting similar narcotic prescriptions which were written by the same doctor, Mr. George acknowledged that ''[i]f I see that a doctor is writing a certain medication and the same quantity and same way to every patient, then it is a red flag to me.'' *Id.* at 467. Continuing, Mr. George explained: ''[b]ut . . . when I see that doctor write the medications, but in different doses and different quantity . . . it's different, and they write different medication along with it, and their treatment plan is different, then after my due diligence is being done, I feel comfortable filling that prescription.'' *Id.* Mr. George subsequently testified that the 24th Century doctors prescribed oxycodone in both 15 and 30 mg dosages, methadone in 5 and 10 mg dosages, morphine in 30, 60 and 100 mg dosages, hydromorphone in 4 and 8 mg dosages, and sometimes Opana. *Id.* at 475–76.

Next, Respondent's counsel asked Mr. George about the oxycodone 30 prescriptions whose labels bear sequential RX Numbers and which were dispensed on August 4, 2011 to J.P. and T.P., who have the same last name and had travelled from Saint Augustine (196 miles). GX 3, at 2–3. Mr. George asserted that ''I remember that case in detail'' and that J.P. and T.P. were husband and wife and that T.P. had a bulged disc from a 1998 accident and ''was our patient from 2009.'' Tr. 468. He also asserted that J.P. had ''a motor vehicle accident'' and ''had problems with his neck and . . . back.'' *Id.* at 468–69. Mr. George did not explain when J.P.'s accident had occurred or how long he had been Respondent's patient. *See id.* While Mr. George asserted that he filled the prescriptions, because ''after doing all the due diligence and following the protocols, talking to the doctors, I was comfortable within my professional judgment to fill that prescription,'' *id.,* Respondent produced no evidence to corroborate his testimony, not even the two-page due diligence checklists. Of consequence, the ALJ did not find Mr. George's testimony credible as to the actions he took to resolve the red flags presented by J.P.'s and T.P.'s prescriptions.[22] R.D. 48.

[21] *See www.legacy.com/obituaries/tbo/obituary.aspx?n=cornelio-aquino-ruperto&pid=121231660.* Respondent may dispute my finding by filing a properly supported motion no later than 15 calendar days from the date this Order is mailed.

[22] Mr. George further testified that in 2012, ''J.P. was filling the prescription in the pharmacy, and when I called the doctor's office, I found that J.P. had an admission'' to a hospital in St. Augustine. *Id.* at 469–70. According to Mr. George, the doctor then requested the records from the hospital in St. Augustine; the records showed that J.P. ''was positive for his oxycodone and Valium he was on,'' as well as cocaine. *Id.* at 470. According to Mr. George, J.P. was then discharged from the clinic for breaching his contract and he decided to stop filling prescriptions for him. *Id.* Mr. George did not explain, however, why J.P. had the prescription he was attempting to fill if he had been discharged from 24th Century.

Mr. George also acknowledged that a prescription that exceeds the manufacturer's recommended daily dosage presents a red flag. Tr. 470. Mr. George testified that the prescription ''does not say the whole story'' and when the patient's dose is above the manufacturer's recommended dose, the pharmacist ''ha[s] to go and look at the patient's profile and profile history to make sure why this patient is taking higher doses.'' *Id.* at 471. Mr. George further testified that ''everybody know [sic] that tolerance plays a big role in the doses prescribed'' and that ''there is no ceiling doses for opiates.'' *Id.* Mr. George then testified that when a prescription is for a higher dose than the recommended dose, ''the pharmacist's duty is to call the physician and check with them . . . and go through [the] profile and see how long [the patient's] been on that medication and . . . learn how much the tolerance is.'' *Id.* Mr. George then maintained that when he filled prescriptions that exceeded the maximum recommended dosage, he did all of these steps ''and I write my notes on my due diligence checklist why I did it.'' *Id.* at 472.

Addressing the prescriptions that were missing patient addresses, Mr. George testified that the former head of the Office of Diversion Control had published a memo which ''says that if the pharmacist has to make any changes in C2 prescriptions, they have to follow state laws and guidelines.'' Tr. 472. Mr. George then noted that Florida law ''clearly says that [the address] shall be on the face of the prescription or the written record thereof,'' and added that he would ''verify the patient's address though the DMV Web site[] [a]nd also check the PDMP'' and use the prescription label to provide the address. *Id.* at 472–73.

As for the instances in which patients presented prescriptions for two short-acting opiates, Mr. George testified that ''there are many reasons'' that ''doctors write two prescriptions,'' including that ''the patient is allergic to certain medications,'' ''has intolerance for the drug,'' may have had ''gastric bypass surgery,'' or be a ''dialysis patient.'' *Id.* at 474. However, Mr. George testified that ''[n]ormally doctors write the long-acting medication along with the short-acting.'' *Id.*

As for how he resolved the red flag, Mr. George testified that ''you . . . study the situations [sic] and what is the condition of the patient through talking to the doctors and talking to the patients and checking their profiles [and] history.'' *Id.* Asked by Respondent's counsel if those are ''actual examples of things that occurred where you got information like that from patients who filled prescriptions,'' Mr. George answered: ''Yeah. We will get information. That's the case.'' *Id.* at 474–75. Mr. George did not, however, offer any testimony identifying the specific conditions of those patients who presented two prescriptions for short-acting narcotics which were filled by Respondent.

Mr. George further testified that he obtained medical records from the 24th Century clinic. *Id.* at 477. Respondent's counsel then asked Mr. George if he had ''seen Respondent's Exhibit 3 before today?'' *Id.* at 479. Mr. George answered ''yeah,'' and added that ''it is actually from one of the copies which I get from the clinic''; he then testified that these records ''were maintained at'' Respondent and that the records were present when DEA executed the AIW. *Id.* Mr. George also testified that the Exhibit contained an accurate representation of the records Respondent maintained on three of its patients, K.D. (pages 1 through 17); S.D. (pages 18 through 33); and H.C., Jr. (pages 34 through 51). Tr. 480, 482. Notably, the records contained such items as driver's license verifications, radiology reports, progress notes, and opioid contracts. *See generally* RX 3.

On *voir dire,* the Government asked Mr. George how he received the records from the clinic. Tr. 490–91. Mr. George answered: ''sometimes it is in a block of a—I send my technician to get it because patients are waiting in my—I go and ask them to get the copy and get it to me so I can verify it before filling it.'' *Id.* at 491. Mr. George subsequently testified that Respondent's Exhibit 3 was ''a representative sample of the type of record [he] got for hundreds of patients [of his] pharmacy.'' *Id.* at 498.

Asked by Respondent's counsel ''what, if any information on pages 20 through 29 . . . was important to [him] at the time'' he was deciding to fill controlled substance prescriptions for S.D., Mr. George testified that the records told him ''what the diagnosis is, why this patient [is] being treated for the medication they [sic] are [sic] prescribed.'' *Id.* at 480–81. He further asserted that he looked at the progress notes (RX 3, at 29) to ''see any changes in there,'' as well as page 30, which told him that ''the patient has [an] opiate contract there.'' *Id.* at 481.

Mr. George then testified that he looked at these records as ''an extra step to prevent the abuse and misuse of the controlled substances.'' *Id.* Asked whether his training as a pharmacist gives him ''the ability to understand certain things within the medical record as far as the diagnosis and the condition of the patient,'' Mr. George testified that ''[t]hrough experience, I learned to look through these forms and understand it [sic].'' *Id.* Mr. George then testified that the records included indications of conditions that would cause pain. *Id.* at 481–82.

Asked whether there was information on page 44 (a December 6, 2012 Visit Note for H.C., Jr.) that would allow a layperson and pharmacist ''to determine what condition the patient was being treated for,'' Mr. George answered ''yes.'' *Id.* at 482. Asked if ''the information contained in these medical records [is] consistent with the patient having pain and needing a controlled substance prescription from a pharmacist's perspective?'', Mr. George again answered ''yes.'' *Id.* at 482–83.

Next, Mr. George was asked about the prescription (GX 3, at 1) Respondent dispensed on July 28, 2011 to T.V., who lived in Pensacola—472 miles from Respondent—for 210 tablets of oxycodone 30. Tr. 493. Mr. George testified that she had been his patient ''since 2009,'' and that in deciding to fill her prescription, he had had done ''all my due diligence, checked with the doctors, checked all the medical records [he] could'' and ''interviewed the patient.'' *Id.* at 494. Mr. George further testified that ''when this patient came in the counseling and when I was talking . . . [the] patient knew that distance is a very fact that pharmacist may not fill it.'' *Id.* According to Mr. George, T.V. said she had gone ''through four back surgeries'' and had tried ''interventional pain injections'' which ''failed.'' *Id.* Mr. George then testified that T.V. ''lifted her shirt and said, look at my back, and I looked that there were four scars'' and T.V. ''mentioned that there were rods and plates placed here.'' *Id.* at 495. Mr. George thus maintained that ''even though the distance was far, through my experience and the need of the patients [sic], it made me come to a conclusion that this patient, I will fill the prescriptions.'' *Id.*

While on cross-examination, Mr. George testified that another pharmacist had filled this specific prescription, *id.* at 578–79, he reiterated his earlier testimony that T.V. had ''been coming from 2009 onwards.'' *Id.* at 579. He then added that ''I know this patient very well, and I have a very well written record on this patient.'' *Id.*

After again stating that he did not fill the prescription, Mr. George testified that ''every pharmacist who worked in that Hills Pharmacy have [sic] that file. That's the reason the due diligence paper is filed separately.'' *Id.* at 579–80. Mr. George then testified that ''[w]hen this patient comes again, that

pharmacist has the opportunity to go and look at why this patient's prescription was filled last month'' and ask ''[i]s there any reason, or should I reject this?'' *Id.* at 580. Continuing, Mr. George testified: ''[w]hen they [sic] see other pharmacist, especially my notes, saying that all the due diligence were [sic] done and all the red flags were resolved, that pharmacist will be comfortable looking at. And they will probably call the doctors, I don't know [sic] he called or not. But that is his duty to call the doctor and verify.'' *Id.* Mr. George again reiterated that this documentation was written down ''[i]n my due diligence sheet'' which is ''in the pharmacy.'' *Id.; see also id.* at 551 (Mr. George's testimony that the due diligence forms are in a binder which is ''[s]till in the pharmacy.'').

Subsequently, the ALJ asked Mr. George if he recalled why T.V. ''travelled from Pensacola to Hills Pharmacy?'' *Id.* at 588. After answering ''yes,'' Mr. George testified:

> This patient had multiple surgeries done in Tampa General Hospital and that time the doctor, the chief anesthesiologist was Dr. Cornelio Ruperto, and he become [sic] the director of the clinic where this prescription was written. So she used to come *and see that doctor always.* And while I was interviewing that patient she said she likes the doctor and she wanted to continue seeing that doctor. That's why she was coming from that 450 miles.

Id. (emphasis added).

Respondent's counsel then asked Mr. George about the back side of two prescriptions for 180 oxycodone 30 (GX 3, at 35) which cost $1350 each and were written for H.C., Sr., and H.C., Jr.; the latter is the same person whose records are found at pages 34 through 51 of Respondent's Exhibit 3. Tr. 495–96. Asked to explain what inquiry he made to learn about him and his condition, Mr. George testified:

> [W]hen I got this prescription, I did all my due diligence and followed my protocols. Then I looked—he has a bulging disc, and I filled this prescription. He is coming in my pharmacy from 2009 onwards. And when he came to pharmacy with all these conditions, he'd been filling for [sic] insurance—he had insurance coverage that time. Then that time he was paying $35, was the copay. So he'd been paying that from 2009 'till end . . . of 2010.
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> Then he left the pharmacy. Then two years he did not come to the pharmacy. Then in 2012, he came back to the pharmacy with a prescription, and he did not have insurance, which Hills Pharmacy always ask when he was in where is your insurance, and he said he lost the insurance. He didn't have any insurance coverage.
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> Then he said that I need this medication, I'm on this medication. And he brought a profile also where he was. And I don't remember that it is a—and he showed me he was taking this medication. So he said he's willing to pay whatever the cash price at that time. And I filled this prescription for cash.

Id. at 496–97. Mr. George then testified that H.C., Jr.'s drug therapy had not changed from when he had insurance. *Id.* at 497. Mr. George did not, however, offer any testimony regarding his decision to also dispense oxycodone 30 to H.C., Sr.

Mr. George subsequently testified that he had no knowledge that any of the patients who received the prescriptions at issue abused or diverted the drugs he dispensed to them. *Id.* at 498. Respondent's counsel then asked him ''how do you respond to the allegations . . . that you filled prescriptions that had red flags on them?'' *Id.* at 498–99. Mr. George testified:

> From 2013 onwards, I modified my protocol and changed it to print out patients' residence to less than 15 miles, and also in our protocol changes that we only fill the doses consistent with the manufacturer's recommended doses, and also we will not fill for patient for the controlled substances who reside in the same addresses. So after making that [sic] changes, if it—today I will—that red flag will be considered in a different way and say that this is not according to my protocol, so I will not be comfortable.
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> That doesn't mean that what I did before that was not written for legitimate medical purpose, but at this point, because my protocol is more stringent and more strong, in my effort to prevent the misuse and abuse and diversion, I will check one more time.

Id. at 499–500.[23] Mr. George then testified that as of February 19, 2015 (three weeks before the hearing), Respondent ''completely stopped'' filling controlled substance prescriptions ''issued from any pain management clinic.'' *Id.* at 500. Asked why he had made this change, Mr. George testified that ''I know we all have a part to do to prevent the abuse and misuse and diversion of the controlled substances. As a professional provider, and the Government—DEA is trying to prevent that. And as a professional provider, I also have a responsibility for that.'' *Id.* at 500–01. He then added that part of the reason he had changed his policies was because ''always there are bad apples everywhere'' and ''I know that I'm less than the perfect.'' *Id.* at 501. Mr. George then testified that he had ''never'' filled a controlled substance prescription having ''knowledge that it was not issued for a legitimate medical purpose.'' *Id.* at 502.

Next, Mr. George testified regarding a chart he had created which shows from January 1, 2011 through November 30, 2014, the total prescriptions dispensed by Respondent during each year (except for 2014), the total non-controlled and schedule II prescriptions dispensed, and the total schedule III through V prescriptions dispensed. RX 2, at 1. Notably, the chart does not provide any data for the schedule II prescriptions alone, and instead adds them to the non-controlled prescriptions. *See id.* The chart also purports to show the percentage of Respondent's total dispensings comprised by schedule III through V drugs, the ''percentage change from previous year'' and the ''percentage change from 2011.'' *Id.* While five of the six entries in the latter two columns show percentage reductions, the chart does not state whether the percentage change is in the total schedule III through Vs dispensings or in the percentage of total dispensings comprised by schedule III through V drugs. Moreover, the 2014 figures do not include data for the month of December.

Another chart shows data for Schedule II through V for the years 2011 through 2013 and for 2014 through November 30. RX 2, at 3. The chart reflects a decrease in the total number of controlled substance prescriptions dispensed and a decrease in the percentage of total dispensings comprised by schedule II through V dispensings. *See id.*

Subsequently, Mr. George answered ''yes'' when asked by Respondent's counsel: ''[d]o you accept responsibility for the fact that you filled prescriptions for controlled substances that had red flags on them?'' Tr. 507. However, when then asked if he had ''ever knowingly ignored your duties as a pharmacist to exercise your professional judgment?'', Mr. George answered: ''No, I never did.'' *Id.* at 507–08. Mr. George further testified that ''even though I did my best, our best to control that and prevent the abuse and misuse, that is not perfect. It is always less than perfect. Human beings are not perfect. I accept that responsibility.'' *Id.* at 539–40.

On cross-examination, Mr. George acknowledged that a prescription which calls for the dispensing of ''a high quantity'' of a controlled substance presents a red flag as do ''patients coming from long distance.'' *Id.* at 552. However, he then maintained that he

[23] On cross-examination, however, Mr. George was asked if a patient's address being 63 miles from Tampa presented a red flag. Tr. 570. Mr. George testified:

> Sixty-three miles, this time, yes, I will not fill that 63 miles, above 50 miles because my protocol has changed after the administrative warrant then to less than 50 miles. But at that time then when I filled it, it was a red flag, but I did my due diligence and followed the protocol, so that time it was okay in that I resolved that red flag.

Id. at 570–71.

had resolved all the red flags and had documented this on the due diligence checklists which were in the binder ''in the pharmacy.'' *Id.* He further testified that he would consult the medical records he obtained before dispensing controlled substances. *Id.* at 553. Asked by the Government if he ''understand[s] medical records,'' Mr. George testified:

> I don't understand it the way the doctors are trained to understand. By experience, I look whether this prescription was issued for a legitimate medical reason. This is not my duty as a pharmacist. I would do something above and beyond in order to support the effort to prevent abuse and misuse. It is not part of my duty to read the medical report. I am doing an extra step for myself and to serve the community.

Id. at 554–55.

The Government then asked Mr. George about Respondent's dispensing of 240 oxycodone 30 tablets to K.D., on April 21, 2011, pursuant to a prescription issued by Dr. S.A.-H. of the 24th Century Clinic (GX 3, at 20); K.D. is one of the patients whose partial records were submitted into evidence. *See* RX 3, at 1–17. Asked whether he ''consult[ed] the medical record that is accompanying this prescription before dispensing that prescription,'' Mr. George answered: ''I didn't say that. I said my medical records are filed in the pharmacy, not with this prescription.'' Tr. 557. Then asked whether he had dispensed the prescription, Mr. George testified that he did not dispense ''[t]hat particular prescription'' and that ''another pharmacist'' had filled the prescription. *Id.* When asked ''who would that person be,'' Mr. George testified that the copy was ''very faint'' and that could not see ''the signature on that page, because the copy is faded.'' *Id.* I find, however, that the prescription label is readable and bears Mr. George's initials.

The Government then asked Mr. George if he had dispensed the prescription found in the patient file for S.D., who resided in Panama City, Florida. *Id.* at 560. This prescription, which was written on January 19, 2012 by Dr. R.R. of 24th Century clinic, authorized the dispensing of 120 tablets of oxycodone 30. RX 3, at 33. Mr. George acknowledged that he had dispensed the prescription. Tr. 560. He also acknowledged that he had reviewed the partial medical file before dispensing the prescription. *Id.* at 560–61. However, when then asked if he could ''tell from this medical record what other controlled substances were dispensed on that particular day,'' Mr. George testified:

> No. I look only for my prescription which is received in my hand. That is only my concern on that time. Where other places or where the patient got the medication, if I have the PDMP, that will support me on that cause. If I get the medical record, I have no way of saying and understanding where the patient had a different prescription unless I talk to the patient or doctors if he write any other prescriptions. I cannot guess where the prescription was filled for that patient.
>
> And . . . I have one more thing to add on that question. This, as I said, these documents I am looking at, looking [sic] all these documents, above and beyond what the duty required of me because to help. It is not my pharmacist job to read, that is doctor's job. DEA give [sic] license to the doctors and they are well trained in writing these prescriptions, and they have the capacity to look at the patient's record and they are the one who is writing this prescription. I call them—give me a second. I call them, verify them, why they did it, what is the treatment plan, and I look above and beyond what are required of pharmacist. I go all the papers and I make my professional judgment whether this patient can be—this prescription can be dispensed.

Id. at 561–62.

Asked whether he saw a treatment plan in S.D.'s medical record, Mr. George testified:

> In this, all records when you go through the records, there is a medical, the copy of the MRIs and the report from the radiologist and why they are treating it and the notes from the doctor's office, and it say what medication they are writing there, and the doctors notes, the visitation notes there.

Id. at 562.

Then asked whether he looked at S.D.'s MRI, Mr. George testified: ''I don't look at MRI. I look at what is the diagnosis in that, whether patient, if it says that a patient has a bulging disc. A couple of the reasons why this medication being prescribed. That's my scope there.'' Tr. 563. Mr. George then testified that he did look at the MRI report before dispensing the prescription. *Id.*

Mr. George then denied that he was familiar with the term drug cocktail. *Id.* at 563–64. Significantly, the note for S.D.'s January 19, 2012 visit lists multiple drugs that were prescribed by the doctor, including 120 oxycodone 30, MS Contin, Soma (carisoprodol), Xanax, and also included the note of ''add Dilaudid 8 mg #120.'' RX 3, at 29.

S.D.'s patient file also includes a visit note dated June 13, 2012. RX 3, at 24–27. This note states that ''Pt. has not taken meds in 5 months'' and lists S.D.'s current medications as including five drugs: (1) Carisoprodol 350 mg, one tablet twice daily; (2) Dilaudid 8 mg [24]; (3) MS Contin CR 30 mg, one tablet daily; (4) oxycodone 30 mg, one tablet ''every 4–6 hours''; and (5) Xanax 1 mg., one tablet ''twice daily.'' *Id.* at 25. According to the visit note, a drug screen was conducted and S.D. tested negative for opiates. *Id.* at 26. Finally, the visit note lists the prescriptions issued by the physician at this visit; with the exception of Dilaudid, which was discontinued, the prescriptions for carisoprodol, MS Contin, oxycodone 30, and Xanax were re-issued with the previous dosing instructions. *Id.* at 27. However, none of the prescriptions issued to S.D. at this visit are in the record.

Subsequently, the Government asked Mr. George if he had filled the prescription (GX 3, at 16) issued by Dr. P.C. (24th Century) to C.B. of Big Pine Key, which authorized the dispensing of 196 oxycodone 30. Tr. 568–69. Mr. George acknowledged that he had filled the prescription. *Id.* at 569. Asked if he knew where Big Pine Key is, Mr. George stated that he knew that it was in Florida. *Id.* Then asked if he knew how far it was from Respondent, Mr. George testified: ''I don't know. It is written in my due diligence list.'' *Id.* When later asked if he recalled investigating why C.B. had travelled from Big Pine Key to get the prescription, Mr. George answered:

> On this particular patient I don't remember, but I know that when it is more than this distance, definitely I did counsel the patient and record it in the due diligence sheet why they travel. In many cases, I don't remember particularly this patient again. Many cases the reasons are their [sic] spouse are [sic] living in Tampa, they're [sic] in job assignment, or their [sic] doctor is here and they like the doctor. So there are many reasons, but I don't particularly remember. This is from 2011.

Id. at 573.[25]

[24] No dosing instruction was listed.

[25] To similar effect, the Government asked Mr. George if he knew where Floral City is. Tr. 569. Mr. George answered: ''Again, I don't know where the city [sic] located in, but I know it is in Florida.'' *Id.* After acknowledging that the distance from Floral City to Tampa (63 miles) was a red flag, Mr. George maintained that ''I resolved the red flag looking at all the, doing the due diligence and checking with the doctors whether the patient need [sic] the medications and now all the treatment.'' *Id.* at 571. And asked whether he ever determined why the patient had travelled 63 miles to get the prescription, Mr. George stated that ''[o]n most of the patients when I talk to them and interview them and counsel them why they are traveling, and the reasons I get I will put in my due diligence sheet.'' *Id.* Then asked by the Government ''[s]o you don't know the reason right now,'' Mr. George answered: ''right now, because if you said yesterday I would have looked at it.'' *Id.*

On re-direct, Respondent's counsel, having noted the Government's questions ''about remembering specifics about certain patients,'' asked Mr. George how many patients he had ''dispensed controlled substances for in the last five years?'' *Id.* at 586. Mr. George testified that ''I cannot remember because daily three, four patients comes [sic], in five years,

Continued

The Government's Rebuttal Case

Subsequently, the Government recalled Mr. Parrado to question him about Mr. George's testimony with respect to the medical records in Respondent's Exhibit 3. Tr. 598–99. Mr. Parrado testified that he had ''never had medical records in any pharmacy I've ever worked in or managed.'' *Id.* at 599.

With respect to the medical record for S.D., which, as found above, showed that he had received prescriptions for oxycodone 30, MS Contin, carisoprodol and Xanax, even though he had not been on medications for five months and had tested negative for opiates, Mr. Parrado explained that ''[t]here were some notations in his chart that caused me concern.'' *Id.* at 601. Mr. Parrado specifically noted the notation that SD ''had not taken his medication in five months'' and that his drug screen was negative for opiates ''but yet he was prescribed a lethal dose of oxycodone that day.'' *Id.*

Asked on cross-examination that ''you know that there's no ceiling on narcotics, don't you,'' Mr. Parrado answered: ''[W]ell, but there is. On an opioid naïve patient there is.'' *Id.* at 601–02. Asked ''[d]o you know whether S.D. was opioid naïve,'' Mr. Parrado testified: ''[F]rom seeing the record, yes. He had not taken the medication in five months per his own dosing.'' *Id.* at 602. Mr. Parrado then added that the S.D.'s visit note stated that he had tested negative for opioids. *Id.* Asked if he knew from Respondent's Exhibit that ''S.D. had been taking opioids for years?[26]'', Mr. Parrado answered: ''[y]es, but he had not taken them in five months per his own.'' *Id.* at 603. While Mr. Parrado acknowledged that he had no personal knowledge that S.D. had not taken the drugs for five months, Mr. Parrado explained: ''[W]hat I'm talking about, if I as a pharmacist was looking at that chart and seeing that, I could not have dispensed that. My professional judgment would have prevented me from dispensing that prescription.'' *Id.* And after Respondent's counsel asked whether he knew if the notation meant ''that the patient didn't get medication from the clinic for five months or whether . . . the patient was not seen at all anywhere for five months?'', *id.* at 604, Mr. Parrado testified:

> The notations said, and if I'm going to be looking at a chart as a pharmacist to determine if there was something, if this dose is appropriate to begin with, the fact the patient said he had not taken the medication, I'm seeing in the medical record that the drug screen says opiate negative. That's telling me I now have an opioid naïve patient. I have a concern.

Id. at 605.

On further questioning by Respondent's counsel, Mr. Parrado reiterated that the patient's statement that he had not taken medication in five months ''was in that chart that I looked at.'' *Id.* However, notwithstanding that Respondent obtained the visit note, which lists multiple controlled substance prescriptions that were issued to S.D. at his June 13, 2012 visit, the Government did not submit any prescriptions (and their labels) showing that Respondent actually dispensed any of the prescriptions listed in the visit note.

Discussion

Under the CSA, ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In the case of a retail pharmacy, which is deemed to be a practitioner, *see id.* § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

Id.

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether'' to suspend or revoke an existing registration. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[27]

Under the Agency's regulation, ''[a]t any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to . . . 21 U.S.C. [§]824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to factors two and four.[28] I find

how I calculate it, it's not possible. And it is very hard to remember that. And I am a human being doing other business too, so I cannot remember everything, keep everything.'' *Id.* at 586–87.

While that may be, Respondent certainly knew what prescriptions were at issue well in advance of the hearing, and if it was true that Respondent was maintaining the due diligence checklists, Mr. George could have reviewed those checklists with respect to the patients who filled the prescriptions.

[26] Notwithstanding the question, there is nothing in the 16 pages of S.D.'s records that establish that he had been taking opioids for years. To be sure, there is a 2009 MRI report; a document indicating that a driver license check was performed on June 24, 2010, and another document indicating that S.D. made visits on monthly basis from August 12, 2011 through January 19, 2012, before reappearing five months later on June 13, 2012. However, the only evidence as to the prescriptions he had received prior to the June 2012 visit is the January 19, 2012 Progress Note and the prescription of the same date. In any event, Mr. Badawi was ''still present in the hearing room'' when Mr. Parrado was called in rebuttal and the ALJ explained that ''if there's some expert conflict over this testimony, there's an opportunity for counsel to explore that.'' Tr. 597. Respondent did not call Mr. Badawi to challenge Mr. Parrado's testimony that S.D. was opioid naïve at the time he presented the June 2012 prescription.

[27] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459,462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[28] As to factor one, there is no evidence that the Florida Department of Health has either made a recommendation to the Agency with respect to Respondent, or taken any disciplinary action against Respondent. *See* 21 U.S.C. 823(f)(1). However, even assuming that Respondent currently possesses authority to dispense controlled substances under Florida law and thus meets a prerequisite for maintaining its registration, this finding is not dispositive of the public interest inquiry. *See Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.''). Accordingly, this factor is not dispositive either for, or against, the revocation of Respondent's registration. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that Respondent, its owner, its manager, or any of its pharmacists, has been convicted of an

that the record taken as a whole provides substantial evidence that Respondent's pharmacists violated their corresponding responsibility when they dispensed many of the prescriptions at issue. I also find that the Government has established by substantial evidence that Respondent has failed to maintain accurate records, as well as other violations. Accordingly, I conclude that the Government has established that Respondent has committed numerous acts which render its continued ''registration inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Because I further agree with the ALJ's finding that Respondent has not accepted responsibility for its misconduct, I also agree with the ALJ that it has not rebutted the Government's *prima facie* showing. Because I find that Respondent's misconduct is egregious, I will order that Respondent's registration be revoked and that any pending application be denied.

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

The Dispensing Allegations

''Except as authorized by'' the CSA, it is ''unlawful for any person [to] knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.'' 21 U.S.C. 841(a)(1). Under the Act, a pharmacy's registration authorizes it ''to dispense,'' *id.* § 823(f), which ''means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.'' *Id.* § 802(10).

The CSA's implementing regulations set forth the standard for a lawful controlled substance prescription. 21 CFR 1306.04(a). Under the regulation, ''[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.'' *Id.* Continuing, the regulation provides that:

> [T]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, *but a corresponding responsibility rests with the pharmacist who fills the prescription.* An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person *knowingly filling* such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[29]

Id. (emphasis added).

As the Agency has made clear, to prove a violation of the corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28667, 28669 (2015). Thus, the Government can prove a violation by showing either that: (1) The pharmacist filled a prescription notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose; or (2) the pharmacist was willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose. *See id.* at 28671–72. As to establishing that a pharmacist acted with ''willful blindness, proof is required that: '(1) The defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.' '' *Id.* at 28672 (quoting *Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 563 U.S. 754, 769 (2011)).

Here, the Government makes no claim that any of Respondents' pharmacists dispensed the prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, relying primarily on *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62341 (2012), the Government argues that a pharmacist violates the corresponding responsibility rule when he/she dispenses a controlled substance prescription ''in the face of a red flag (*i.e.*[,] a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he . . . takes steps to resolve the red flag and ensure that the prescription is valid.'' Gov. Post-Hrng. Br. 21.

The Government argues that Respondent's pharmacists violated this regulation by filling prescriptions for such drugs such oxycodone, hydromorphone, and MS Contin (morphine sulfate) which presented various ''red flags'' which were never resolved. Gov. Post-Hrng. Br. 22–24. It contends that its expert, Mr. Parrado, gave ''unrefuted testimony'' that ''Respondent repeatedly distributed controlled substances pursuant to prescriptions that contained one or more unresolved red flags for diversion.'' *Id.* at 22. And after listing six different circumstances which Mr. Parrado identified as presenting red flags, it argues that he ''testified that no evidence could be found to show the red flags had been resolved prior to dispensing.'' *Id.* As evidence that the red flags were not resolved, it relies on Mr. Parrado's testimony that it is the standard of pharmacy practice that the resolution of a red flag is documented on the prescription itself and that none of the prescriptions entered into evidence contain any such documentation.[30] *Id.* at 23.

However, with the exception of a provision of Florida law which requires that a pharmacist document that he has checked a patient's identification (or made a photocopy of the identification and attached it to the prescription), no provision of the CSA, DEA regulations, Florida law, or the Board of Pharmacy's rules requires that a pharmacist document the resolution of a red flag or flags on the prescription itself. While it may be the custom of the pharmacy profession to document the resolution of a red flag or flags on the prescription, that does not make it improper to document the resolution someplace else.

Recently, I rejected allegations that a registrant's pharmacists had failed to resolve red flags when the only evidence the Government offered to prove that fact was the absence of

offense under either federal or Florida law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

While the Government did not allege in the Show Cause Order any misconduct with respect to factor five, following the hearing, the Government argued that Mr. George provided incredible testimony. Because I consider his testimony in evaluating the evidence as to the dispensing allegations, as well as whether Respondent has credibly accepted responsibility for its misconduct, I deem it unnecessary to separately address Mr. George's testimony under factor five.

[29] As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)).

[30] In fact, the record includes several prescriptions which contain notations on the back of the prescriptions suggesting a phone call was made to someone about the prescriptions. GX 14, at 7–10. These prescriptions were issued by a doctor at a clinic other than 24th Century. *See id.* at 7, 9. However, the Government did not ask Mr. George to explain the notations even though his initials are on the dispensing labels as the dispensing pharmacist.

documentation on the prescriptions themselves. *See Superior Pharmacy I and II,* 81 FR 31310 (2016). In *Superior,* I noted that ''while evidence of a custom certainly has probative value, it is not conclusive proof.'' *Id.* at 31335 n. 55 (citing *Sorrels* v. *NCL (Bahamas) Ltd.,* 796 F.3d 1275, 1282 (11th Cir. 2015) (''[E]vidence of custom within a particular industry, group, or organization is admissible as bearing on the standard of care in determining negligence. Compliance or noncompliance with such custom, though *not conclusive* on the issue of negligence is one of the factors the trier of fact may consider in applying the standard of care.'') (emphasis added) (quoting *Muncie Aviation Corp.* v. *Party Doll Fleet, Inc.,* 519 F.2d 1178, 1180–81 (5th Cir. 1975))). *See also* II Wigmore, Evidence, § 379, at 403 (Tillers rev. ed. 1983) (explaining that with respect to evidence of custom or usage of trade, ''the question is not whether the offered instances fully prove the custom alleged, but merely whether they are receivable as having probative value''). Thus, while the absence of documentation on the prescriptions is clearly probative evidence that Respondent's pharmacists failed to resolve the strong suspicion presented by many of the prescriptions—indeed, Mr. George testified that he previously documented the resolution of red flags on the prescriptions until 2010 when he started using the due diligence checklists, Tr. 455–57,—the absence of documentation on the prescriptions is not conclusive proof that Respondent's pharmacists failed to do so.

Moreover, while there is no requirement that a pharmacist document the resolution of a red flag on a prescription, a regulation of the Florida Board of Pharmacy (then in effect) specifically required that ''[a] patient record system . . . be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed'' and that the ''system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing.'' Fla. Admin. Code r. 64B–16–27.800. This rule also required that the pharmacy maintain ''[a] list of all new and refill prescriptions obtained by the patient at the pharmacy . . . during the two years immediately preceding the most recent entry'' and include the ''prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber.[31]'' *Id.*

The rule further required that the record include the ''[p]harmacist['s] comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* And the rule also required that the pharmacist make ''a reasonable effort . . . to obtain from the patient . . . and record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs . . . being used by the patient which may relate to prospective drug review.'' *Id.* Finally, the rule required that ''[t]he pharmacist . . . record any related information indicated by a licensed health care practitioner.'' *Id.*

Of further note, the Board of Pharmacy's rules require that a pharmacist ''review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness.'' Fla Admin Code r. 64B16–27.810. This rule specifically requires that a pharmacist identify such issues as: ''[o]ver-utilization,'' ''[t]herapeutic duplication,'' ''[d]rug-drug interactions,'' ''[i]ncorrect drug dosage,'' and ''[c]linical abuse/misuse.'' *Id.*

Notwithstanding that the Board's rule specifically requires that a pharmacist document in the patient record his/her comments relevant to the patient's drug therapy and ''other information peculiar to the patient'' or drug, as well as ''any related information'' provided by the patient's physician, and thus, would seem to provide relevant evidence in assessing whether a pharmacist resolved the suspicion created by the prescriptions, the Government did not introduce any of the patient profiles. Nor did it provide any of the patient profiles to Mr. Parrado, Tr. 300, even though on cross-examination, he acknowledged that a pharmacist would generally need to see the patient profile to determine whether a patient had developed tolerance.[32] *Id.* at 151.

In *Superior Pharmacy I and II,* I found the Government's evidence, which was limited to the prescriptions (which contained no documentation that the red flags were resolved) and its Expert's testimony, insufficient to establish that the pharmacists violated their corresponding responsibility. Here, however, there is additional evidence, which establishes by a preponderance of the evidence, that Respondent's pharmacists acted knowingly or with willful blindness when they dispensed at least some of the prescriptions, which lacked a legitimate medical purpose. More specifically, both Mr. George's testimony and the partial medical records support this finding with respect to some of the prescriptions.

At the outset, the evidence shows that more than 90 percent of the schedule II prescriptions Respondent filled between January 3, 2011 and February 4, 2013 were written by doctors employed by Victor Obi, the brother of Respondent's owner. GX 12, at 2. *See also, e.g., United States* v. *Leal,* 75 F.3d 219, 223 (6th Cir. 1996) (holding that where ''more than 90% of the prescriptions'' a pharmacist filled were written by one doctor was probative evidence that pharmacist knew of illegitimate prescribing practice). Mr. George clearly knew that the overwhelming majority of the schedule II prescriptions Respondent filled were issued by Mr. Obi's employees.

As found above, on July 28, 2011, Respondent dispensed 210 tablets of oxycodone 30 to T.V., who had travelled 472 miles from Pensacola to obtain a prescription from Dr. P.C., one of the doctors at 24th Century. GX 3, at 1. I find that the distance T.V. travelled to obtain the prescription, as well as the drug—a known drug of abuse—and dosing, were sufficient to establish a subjective belief on the part of the pharmacist who filled the prescription that there was a high probability that the prescription lacked a legitimate medical purpose.[33] Indeed, Mr. George

[31] This rule remains in effect today; however, the rule now requires that the information be maintained for a period of four years preceding the most recent entry.

[32] It is not that the patient profiles were unobtainable, as the evidence shows that Respondent's computer was digitally imaged by the AIW team, Tr. 217, 301; and thus, the profiles could have been extracted.

[33] Respondent argues that the Government cannot establish that a pharmacist has violated his corresponding responsibility unless it first establishes that the prescription lacked a legitimate medical purpose and that the issuing physician acted outside of the usual course of professional practice. Resp.'s Exceptions, at 9. It argues that ''neither the fact of this corresponding responsibility nor the pharmacist's performance of his corresponding responsibility affects whether the prescription was, in the first place, issued to the patient for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' *Id.* And it further argues that ''the test for the proper dispensing of a controlled substances remains at its foundation a medical question'' and that ''the Government provided not one scintilla of evidence to prove that the prescriptions at issue were issued for other than a legitimate medical purpose.'' *Id.* at 9–10.

Respondent is mistaken. While it is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose, Respondent ignores that the invalidity of a prescription can be proved by circumstantial evidence. *See, e.g., United States* v. *Leal,* 75 F.3d

acknowledged that the distance T.V. was travelling was a red flag. Tr. 494.

Regarding T.V., Mr. George testified that she had been a patient since 2009, that she had shown him scars from back surgeries, and that ''even though the distance was far,'' his experience and ''the need of the patients'' [sic] led him to fill the prescription. *Id.* at 494–95. Mr. George further justified dispensing T.V.'s prescriptions,[34] explaining that she had multiple surgeries at Tampa General Hospital when Dr. Ruperto was its Chief Anesthesiologist, and that he had become the director of the 24th Century clinic. *Id.* at 588. Mr. George then explained T.V. ''used to come *and see that doctor always.* And while I was interviewing that patient she said she likes the doctor and she wanted to continue seeing that doctor. That's why she was coming from that 450 miles.'' *Id.* (emphasis added).

Dr. Ruperto did not, however, issue the July 28, 2011 prescription. Indeed, his name does not appear among the lists of physicians on any of the 24th Century prescriptions. And while Mr. George testified that T.V. saw Dr. Ruperto ''always'' because she liked the doctor and that she had been coming to Respondent ''from 2009 onwards,'' Dr. Ruperto had died in December 2008, before T.V. had even started patronizing Respondent. I thus find that Mr. George's testimony as to why Respondent filled the prescription disingenuous. And I further conclude that Respondent's pharmacist knowingly filled an unlawful prescription.

On January 19, 2012, Respondent dispensed 120 tablets of oxycodone 30 to S.D., who had travelled 331 miles from Panama City to obtain the prescription from Dr. R.R. of the 24th Century Clinic. GX 3, at 33. In addition to the strong suspicion created by the distance S.D. had travelled, the partial medical records—which Mr. George testified he would obtain and review before dispensing—show that Dr. R.R. prescribed five different controlled substances to S.D. at this visit including oxycodone, MS Contin, Soma (carisoprodol), Xanax and Dilaudid, the latter being added at this visit. RX 3, at 29; *see also id.* at 27.

Thus, S.D.'s partial medical record created additional strong grounds for Mr. George (whose initials are on the prescription label as the dispensing pharmacist) to subjectively believe that there was a high probability that the prescriptions lacked a legitimate medical purpose. First, the record showed that Dr. R.R. had prescribed a drug cocktail of CNS depressants of opiates (oxycodone), benzodiazepines, and carisoprodol, which as Mr. Parrado explained, is known as the Holy Trinity and to be highly abused on the street. Notably, Mr. Badawi offered no testimony refuting Mr. Parrado on this issue. And while Mr. George denied being familiar with drug cocktails, Tr. 563–64, DEA had identified this combination of drugs in several final decisions as being highly abused prior to the events at issue here. *See Paul Volkman,* 73 FR 30630, 30637 (2008); *see also East Main Street Pharmacy,* 75 FR 66149, 66157–58 (2010).

Mr. Parrado also testified that the maximum recommended dose of Dilaudid (hydromorphone) was 24 mg per day and that patients usually do not take the eight milligram dosage unless they have terminal cancer; he also testified that prescribing two short acting opiates is inappropriate therapy and raises a red flag. *Id.* at 57–58. As to Mr. Parrado's testimony regarding the maximum recommended dosing of Dilaudid, Mr. Badawi offered no testimony in refutation and he also agreed that prescribing a quantity ''larger than the manufacturer's recommended dosage'' creates a red flag. *Id.* at 402–03. Nor did Mr. Badawi offer any testimony refuting Mr. Parrado's testimony that the eight milligram dose was not usually prescribed unless the patient had terminal cancer. *See generally id.* at 402–40. Of note, neither of the progress notes in S.D.'s partial medical file indicates that he had been diagnosed with cancer of any stage, let alone terminal. RX 3, at 28–29 (Jan. 19, 2012 visit); *id.* at 26 (June 13, 2012).

Mr. Badawi also agreed with Mr. Parrado that the prescribing of two short-acting opiates together is a red flag that would require further investigation. Tr. 419. He then testified that a patient with kidney failure who undergoes dialysis could legitimately require two short-acting opiates. There is, however, no documentation on either progress note that S.D. had kidney failure. RX 3, at 25–29. And while Mr. Parrado acknowledged that prescribing an extended release drug would be problematic for a patient who had undergone bariatric surgery, S.D. was prescribed MS Contin, which is an extended-release drug.[35]

Of further note, Mr. George testified that he had reviewed S.D.'s partial file before dispensing the prescription. Tr. 560–61. However, Mr. George offered no testimony other than his generalized assertion that he always did his due diligence, which neither the ALJ nor I find credible, to explain how he resolved the suspicion created by S.D.'s prescriptions. Thus, given the sum total

219, 223 (6th Cir. 1996); *United States* v. *Veal,* 23 F.3d 985, 988 (6th Cir. 1994) (per curiam); *United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979). I find that to be the case here. For similar reason, I reject Respondent's contention that the Government failed to meet its burden because Mr. Parrado is a pharmacist with ''no medical training or experience that would have allowed him to evaluate the legitimacy of a physician's prescribing.'' Resp. Exceptions, at 20.

In its Exceptions, Respondent also argues that ''[i]n *Holiday CVS,* there was evidence that two prescribers lacked a valid DEA registration'' and that ''[t]here was also evidence that the red flags were irresolvable.'' Exceptions, at 10. Respondent then argues that the decision's ''three-factor test is therefore founded upon evidence that prescriptions were, in fact, issued outside the usual course of professional practice (*e.g.,* by a prescriber without a valid DEA registration)[,]'' and that [h]aving established the threshold question, the three-factor test was applied to determine if all of the red flags that a reasonably prudent pharmacist would have identified were conclusively resolved prior to dispensing.'' *Id.*

Here too, Respondent is mistaken. To be sure, in *Holiday CVS,* the Agency relied in part on the prescriptions the two pharmacies filled that had been written by two physicians who were no longer registered (one had allowed his registration to expire, the other's registration had been revoked). 77 FR at 62316. With respect to these prescriptions, the Agency did so because the evidence showed that the pharmacies subscribed to a database which compiles information as to physicians' registration status, and thus, the pharmacists should have known that the physicians were no longer registered; the order also noted that in the case of the doctor whose registration had been revoked, that order was published in the **Federal Register** and yet one the pharmacies was still filling his prescriptions more than six months later. *Id.* These prescriptions were not merely suspicious, they were flat out illegal, and as such, there was nothing for the pharmacists to resolve, as under no circumstance could they be lawfully filled. *See* 21 CFR 1306.03(a).

This, however, was only one part—and a small part—of the case, and the three-part test was discussed in the context of the pharmacies' decisions to dispense prescriptions for oxycodone 30 and alprazolam 2, which were written by doctors in South Florida for patients, many of whom had travelled from out-of-state (*e.g.,* Kentucky and Tennessee) to the pharmacies which were located in Sanford, Florida, 200 miles or more from the physicians. *Id.* at 62318. Of further note, in *Holiday CVS,* while the Government sponsored the testimony of an expert in pharmacy practice, it did not offer any testimony from a physician as to the medical propriety of the prescriptions. *See generally id.* at 62325–34 (recommended decision's discussion of Government' evidence). Here too, the Government relied on the circumstantial evidence that the prescriptions lacked a legitimate medical purpose. Accordingly, I reject Respondent's contention that ''the Government provided not one scintilla of evidence to prove that the prescriptions . . . were issued for other than a legitimate medical purpose.'' Resp. Exceptions, at 10.

[34] While there is only one prescription for T.V. in the record, Mr. George's testimony suggests that there were other prescriptions that Respondent had filled for her.

[35] While Mr. George asserted that a patient could have allergies and thus need to be prescribed two short-acting medications, here too, there is no evidence in either progress note that S.D. had such an allergy.

of the information Mr. George had available to him when he dispensed oxycodone to S.D., I find that Mr. George was willfully blind to the fact that the prescription he dispensed lacked a legitimate medical purpose.

Likewise, the partial medical record for H.C., Jr., shows that on December 6, 2012, he, too, received the cocktail known as the Holy Trinity from Dr. R.R. of the 24th Century Clinic. RX 3, at 47. More specifically, he received a prescription for 180 oxycodone 30 mg, along with prescriptions for 112 tablets of OxyContin 40 mg, 84 tablets of carisoprodol 350 mg, and 84 tablets of Xanax (alprazolam) 1 mg. *Id.* The evidence further showed that he paid $1350 just to fill the oxycodone 30 prescription. GX 3, at 35.

Mr. George offered a lengthy explanation as to why he had filled H.C., Jr.'s, prescription. More specifically, Mr. George explained that H.C., Jr., had been a patient who previously had insurance, that for two years he did not come to the pharmacy, and that when he returned he had lost his insurance but said he needed the medication and brought Mr. George a profile showing he had been on the medication and was ''willing to pay whatever the cash price at that time.'' Tr. 496–97. While Mr. George asserted that when he got the oxycodone 30 prescription, he did his due diligence and followed his protocols and determined that H.C., Jr. had a bulging disc, *id.*at 496, he offered no testimony specifically explaining what steps he took to resolve the high degree of suspicion which arose from H.C., Jr.'s being prescribed this highly abused combination of drugs by Dr. R.R. or any other physician who had previously prescribed this combination of drugs to H.C., Jr. I thus find that Mr. George subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose and that he deliberately avoided learning of this fact. And Mr. George offered no testimony as to why he also filled an oxycodone 30 prescription of the same quantity for H.C., Sr.

The evidence also shows that on the same day, J.P. and T.P. who, according to Mr. George, were husband and wife, travelled 196 miles from St. Augustine to 24th Century, where they obtained prescriptions for 196 and 224 tablets respectively of oxycodone 30. GX 3, at 2–3. The sequential prescription numbers also support the inference that J.P. and T.P. presented their prescriptions to Mr. George one after the other, which he then filled.[36] GX 3, at 2–3.

Mr. George asserted that he remembered the case of J.P. and T.P. ''in detail.'' Tr. 468. He asserted that T.P. had a bulged disc from an accident in 1998 and ''was our patient from 2009'' and that J.P. had a ''motor vehicle accident'' and ''had problems with his neck and . . . back''; however, he offered no evidence as to when J.P.'s accident had occurred and how long he had been a patient. *Id.*

Here, notwithstanding Mr. George's statement that he remembered the case ''in detail,'' he offered no testimony as to why T.P. and J.P. needed to travel 196 miles each way to obtain medication for their purported conditions when there were likely a number of other clinics where they could have obtained treatment that are located far closer to St. Augustine then the 24th Century clinic. And while Mr. George asserted that he filled the prescriptions because he ''was comfortable within [his] professional judgment'' ''after doing all the due diligence and following the protocols, talking to the doctors,'' *id.*at 573, Respondent produced no evidence to corroborate his testimony, not even the two-page due diligence checklists for T.P. and J.P.

Notably, the ALJ did not find Mr. George's testimony credible,[37] nor do I. Indeed, I conclude that the exact opposite of what Mr. George testified to is true. *See, e.g., NLRB* v. *Walton Manufacturing Co.,* 369 U.S. 404, 408 (1962) (quoting *Dyer* v. *McDougall,* 201 F.2d 265, 269 (2d Cir. 1952) (''the demeanor of a witness . . . 'may satisfy the tribunal, not only that the witness' testimony is not true, but that the truth is the opposite of his story; for the denial of one who has a motive to deny, may be uttered with such hesitation, discomfort, arrogance or defiance, as to give assurance that he is fabricating, and that, if he is, there is no alternative but to assume the truth of what he denies' '')).[38] I therefore conclude that Mr. George either knew that the prescriptions T.P. and J.P. presented lacked a legitimate medical purpose or subjectively believed that there was a high probability that the oxycodone prescriptions he filled for T.P. and J.P. on August 4, 2011 lacked a legitimate medical purpose and that Mr. George deliberately avoided learning of this fact.

On April 21, 2011, Mr. George dispensed a prescription for 196 oxycodone 30 to C.B., which was written by Dr. P.C. of the 24th Century clinic. Tr. 569; GX 3, at 16. C.B. lived in Big Pine Key, which is near Key West and a distance of 400 miles from Respondent. GX 3, at 16; R.D. at 6.

Asked if he knew where Big Pine Key is, Mr. George answered that he knew it was in Florida. Asked if he recalled investigating why C.B. had travelled from Big Pine Key to Tampa to get the prescription, Mr. George asserted that he didn't ''remember particularly this patient again.'' Tr. 569. He then offered a generalized explanation as to why patients had addresses indicating that they lived a considerable distance from Tampa, such as ''their [sic] spouse are [sic] living in Tampa, they're [sic] in job assignment, or their [sic] doctor is here and they like the doctor,'' before acknowledging that ''I don't particularly remember'' the patient. *Id.* Here again, he asserted that ''definitely I did counsel the patient and record it in the due diligence sheet why they travel.'' *Id.* at 573. However, Respondent failed to produce the due diligence sheets to corroborate Mr. George's testimony.

Here again, I conclude that the exact opposite of what Mr. George testified to is true—that he did not determine why C.B. had travelled from Big Pine Key to fill the prescription. *Walton Manufacturing Co.,* 369 U.S. at 408 (quoting *Dyer* v. *McDougall,* 201 F.2d at 269). And I further conclude that Mr. George either knew that the prescription lacked a legitimate medical purpose or subjectively believed that there was a high probability that the prescription C.B. presented lacked a legitimate medical purpose and that he deliberately avoided learning of that fact.

Mr. George did not otherwise address how he resolved the various red flags presented by any other specific

[36] Both prescription labels include the initials ''KG.'' GX 3, at 2–3.

[37] There are numerous examples that support the ALJ's finding that Mr. George's testimony was incredible. One such example is his story of how, in 2012, he discovered that J.P. had been discharged from 24th Century clinic after the clinic determined that J.P. had tested positive for cocaine during an admission to a hospital in St. Augustine. According to Mr. George, this occurred when J.P. attempted to fill a prescription. Mr. George did not explain why J.P. would even have a prescription if he had been discharged by the clinic.

[38] I thus reject Respondent's contention (Resp. Exceptions, at 11–13) that the ALJ improperly drew the adverse inference that Mr. George's testimony was not credible when he testified that he ''always'' conducted his due diligence. Respondent also argues that the ALJ's credibility finding is not supported by substantial evidence because ''the record lacks any evidence that Mr. George *failed* to utilize a system for resolving the red flags presented by the prescriptions at issue'' and that his testimony was unrefuted. *See also id.* at 38–39. Contrary to Respondent's understanding, the ALJ, who observed Mr. George testify, could reasonably find that ''the opposite of his story'' is true based solely on her observation of him. *Walton Manufacturing,* 369 U.S. at 408 (quoting *Dyer,* 201 F.2d at 269).

prescription. As for the remaining prescriptions, he testified that he had used the protocol he described in dispensing the prescriptions, Tr. 451, that he resolved all of the red flags, and that he documented his resolution of all of the red flags on the due diligence checklists which were in the binder in the pharmacy. *Id.* at 552–53. The ALJ specifically found that Mr. George did not ''credibly assert[ ] that he took this action for each of the prescriptions entered into this record.'' R.D. 48. And she further found that he did not provide any other ''evidence that he utilized this system in regards to the 85 prescriptions in this record that contain red flags.'' *Id.*

Relying on *International Union (UAW)* v. *NLRB,* 459 F.2d 1329, 1336 (D.C. Cir. 1972), the ALJ concluded that ''an adverse inference'' was warranted as ''[e]ither the due diligence files do not exist, or the files present evidence that is adverse to the Respondent's case.'' R.D. 49. The ALJ thus concluded that ''[t]he Government has . . . proved that the Respondent filled prescriptions that presented red flags, and the red flags were not otherwise resolved prior to the pharmacy dispensing such prescriptions. Respondent's inaction in failing to resolve these red flags violates the pharmacy's corresponding responsibility.'' *Id.* (citing 21 CFR 1306.04(a); *Holiday CVS, LLC, d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62316 (2012)).

I agree with the ALJ that an adverse inference is warranted based on Respondent's failure to produce the due diligence checklists and her assessment of Mr. George's credibility on the issue of whether he resolved all of the red flags. I nonetheless do not adopt her conclusion that Respondent's pharmacists violated their corresponding responsibility with respect to *each* of the 85 prescriptions in the record.

In *Superior,* I noted that *Holiday CVS* defines the term ''red flag'' to mean ''a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription.'' 81 FR at 31335. I further explained that ''[a]ll red flags do not have the same hue'' and that ''proof that a pharmacist dispensed a controlled substance prescription without resolving a red flag which only created a 'reasonable suspicion' that the prescription lacked a legitimate medical purpose, is not enough to establish that a pharmacist acted with the requisite scienter'' of willful blindness, and thus violated 21 CFR 1306.04(a). *Id.* at n.54; *see also Global-Tech,* 563 U.S. at 769. However, I also noted that even ''where there are multiple red flags, none of which alone would establish the requisite scienter, the combination of red flags may well create a subjective belief that there is a high probability that a prescription lacks a legitimate medical purpose.'' 81 FR at 31335 n.54.

As explained above, establishing the requisite scienter for a violation requires more than simply showing that a prescription presented a red flag. The ALJ, however, simply concluded that because each of the prescriptions presented a red flag or flags, without any assessment of the level of suspicion created by the red flag or flags, a violation was established because she found Mr. George not credible when he testified that he resolved all of the red flags. This approach is too untethered to the text of 21 CFR 1306.04(a) to support findings that Respondent's pharmacists either acted knowingly or with willful blindness when they dispensed each of the prescriptions.

To demonstrate, the record contains multiple prescriptions for MS Contin. The record is, however, devoid of any evidence as to why the quantities prescribed were suspicious, and certainly the prices paid for the prescriptions are not so outlandish as to support the conclusion that only a person who was abusing the drugs or selling them to others would be willing pay the amount charged by Respondent for the drug.[39] Nor, despite its placement in Schedule II of the CSA, is there any evidence that MS Contin was known to be highly sought after by drug abusers. Thus, the only red flag presented are the distances travelled by the patients. Even then, however, a number of the persons filling the prescriptions lived in towns, such as Tarpon Springs and Spring Hill, which are within commuting range of Tampa. As to these prescriptions, it is unclear why the distance travelled by the patient was enough to establish that the pharmacist (whether Mr. George or others) subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose.[40] This is so even when coupled with Mr. George's knowledge that 90 percent of the prescriptions were being issued by Mr. Obi's employees.

The record does, however, establish that Respondent filled multiple prescriptions for Dilaudid (hydromorphone) which authorized the dispensing of high quantities and called for daily dosing well above the 12–24 milligrams average daily dose. Specifically, Mr. George dispensed 240 tablets of Dilaudid 8 mg to D.K., which would provide a daily dose of 64 mg, and 196 tablets of Dilaudid 8 mg to G.C., which would provide a daily dose of approximately 52 mg.

As noted previously, Mr. Parrado provided unrefuted testimony that Dilaudid 8 mg is an ''extremely, extremely potent opioid,'' that the dose was ''almost double the recommended upper daily dose'' (it was actually more), and that the prescription provided ''a high dose because mostly people don't take Dilaudid 8 [mg] unless they're in a terminal stage of cancer.'' Tr. 90. Mr. Parrado then testified that ''[t]o see multiple prescriptions for 200 tablets would be almost a non-resolvable red flag to me.'' *Id.* I conclude that Mr. Parrado's unrefuted testimony on this issue provides substantial evidence that Mr. George subjectively believed that there was a high probability that these prescriptions were not issued for a legitimate medical purpose.

As for whether Mr. George resolved the high probability that the prescriptions were illegitimate raised by their dosing and quantity, Mr. George did not specifically address these two prescriptions. To be sure, Mr. George testified as a general matter that he resolved the suspicion presented when a prescription authorizes the dispensing of a controlled substance in quantities and dosing which exceed the maximum recommended dose in opioid naïve patients by looking at the patient profiles to see if the patient had developed tolerance. However, while looking at a patient profile to determine how large a quantity a patient had previously been prescribed might well resolve whether a patient has developed tolerance, it does not conclusively resolve the issue of whether a prescription was issued for a legitimate medical purpose. *See T.J. McNichol,* 77 FR 57133, 57148 (2012). Indeed, just as legitimate patients may, over time, require larger prescriptions to obtain the same level of analgesia, so too, addicted persons require larger doses to obtain the same high. Also, a patient who seeks prescription narcotics for the purpose of reselling them has an economic incentive to seek large quantities.

Moreover, Mr. George testified that while he always documented how he resolved the suspicion presented by a prescription, and, consistent with Mr. Parrado's testimony as to the standard of

[39] The most expensive prescription was for 84 tablets of MS Contin 100 mg and cost $218.40. GX 14, at 23–24. Yet other prescriptions cost as little as $25.20. GX 13, at 5–6.

[40] It is acknowledged that some of the patients who filled the MS Contin prescriptions came from such places as Ocala, Gainesville and St. Augustine (196 miles). However, I deem it unnecessary to decide whether each of these prescriptions was unlawfully dispensed.

practice, that he had formerly done so on the prescriptions themselves, Mr. George then maintained that from 2010 onwards he started doing so on the due diligence checklists. Yet, even though Respondent knew what prescriptions were at issue, it failed to produce the due diligence checklists for the patients who received these prescriptions. And while Respondent chose to put Mr. George on the stand, Mr. George did not address how he resolved the suspicious circumstances presented by these two prescriptions.[41]

Thus, I find that Mr. George either knew that the Dilaudid prescriptions issued to D.K. and G.C. lacked a legitimate medical purpose or subjectively believed that there was a high probability that the prescriptions lacked a legitimate medical purpose. I further find that an adverse inference is warranted that Respondent did not conclusively resolve the high probability that the Dilaudid prescriptions issued to D.K. and G.C. lacked a legitimate medical purpose. I therefore conclude that substantial evidence supports a finding that Mr. George violated 21 CFR 1306.04(a) when he dispensed these two prescriptions.[42]

Mr. Parrado also identified as suspicious two instances in which patients (B.W. and T.F.) presented prescriptions for both Dilaudid 8 and methadone 10 which were issued on the same day. Tr. 107–11. Mr. George filled B.W.'s prescriptions, which were for 100 Dilaudid 8 mg and 60 methadone 10 mg, notwithstanding that: (1) B.W. had travelled from Tallevast (54 miles from Respondent); (2) the dosing instruction for the Dilaudid was to take one tablet every four hours for pain, thus resulting in a daily doses of 48 mg, double the upper recommended dose; and (3) that Dilaudid and methadone ''are immediate release opioids, both of which could contribute to respiratory depression, which could be a serious concern,''; and (4) while methadone's analgesic effect peaks at ''three to four hours and tapers off rather quickly,'' the respiratory depression effects continue to grow. Tr. 107, 174.

Notably, even Mr. Badawi agreed that the simultaneous prescribing of two immediate release narcotics presents a red flag which requires further investigation. *Id.* at 418–19. And while the record includes evidence that there may be instances in which it is appropriate to prescribe two short-acting narcotics due to kidney failure (and perhaps an allergy), Mr. George offered no explanation as to how he resolved the high probability that the prescriptions lacked a legitimate medical purpose and decided to dispense the prescriptions.[43]

In addition to the oxycodone 30 prescriptions Respondent dispensed to T.V., J.P., T.P., H.C., Jr., and C.B., the record contains an additional 29 oxycodone prescriptions which provided for the dispensing of quantities and dosing in excess of the 80 mg daily limit. Notably, 25 of the prescriptions provided for the dispensing of 168 du or more, and 13 of the prescriptions provided for the dispensing of 224 du or more. *See generally* GX 3; GX 13. Moreover, most of the prescriptions for 168 du provided a dosing instruction of one tablet every four hours, for a total of 180 mg per day, and the prescriptions for 224 du typically provided a dosing instruction of one tablet every three to four hours, for up to 240 mg per day. *See* GX 3, at 8–9, 12–13, 19, 23, 30; GX 13, at 39 (prescriptions for 168 du); *see also* GX 3, at 3, 4–5,10–11, 14–15, 17, 20, 24, 26, 28, 29; GX 13, at 1–2, 3–4, 37–38 (prescriptions for 224 du or more).[44]

As Mr. Parrado testified, ''[o]ne of the things that a pharmacist knows or should know is that oxycodone . . . 80 milligrams a day has been listed in the literature as a lethal dose for or an opioid naïve patient. So, when being presented with a prescription for a dose that would exceed 80 milligrams in one day, that pharmacist would need to stop and take a look and verify that the patient[ ] is not opioid naïve and has been on a regimen[ ] that has led him to develop a tolerance to that dose.'' Tr. 57. Mr. Badawi did not refute Mr. Parrado's testimony as to the maximum recommended dose for an opioid naïve patient and he agreed that when a prescription calls for the dispensing of a ''very large or larger than normal amounts of a narcotic,'' or an amount ''larger than the manufacturer's recommended dosage,'' a pharmacist must make an inquiry. *Id.* at 402–03. While Mr. Badawi then testified that looking at the patient profile would show whether the patient has developed tolerance, as explained previously, even if the profile shows that the patient has previously received large doses, this does not conclusively resolve the issue of whether the prescription was issued for a legitimate medical purpose.

Here, the Government produced numerous prescriptions which provided quantities and dosing instructions that were two to three times the 80 milligram level. Moreover, Mr. George acknowledged that a prescription that exceeds the manufacturer's recommended daily dosage presents a red flag, and I conclude that when a narcotic prescription exceeds that dosage by the amounts present here, that red flag establishes that there was a high probability that the prescription lacks a legitimate medical purpose and that Mr. George subjectively believed as much.

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[41] While I rejected similar allegations in *Superior I and II* because the evidence that the pharmacists had failed to resolve the suspicious circumstances was limited to the absence of such documentation on the prescriptions and faulted the Government for failing to produce the patient profiles, in that matter, neither party called any of the pharmacists who dispensed the prescriptions.

I also note that after the Government rested, Respondent sought partial summary disposition on the dispensing allegations arguing that the Government did not ''meet its burden of proof to show that the red flags were not resolved'' and that all that ''the Government has proven is that the resolution of the red flags was not present on the back of the prescriptions.'' Tr. 336. The ALJ denied the motion, ruling that ''Respondent has not provided any legal authority that supports [its] position that I can grant summary disposition of an issue in the course of this hearing,'' and that she only had authority to recommend that I grant summary disposition. *Id.* at 340.

Even if the ALJ committed error when she denied Respondent's motion, Respondent had the option of not putting forward evidence on the dispensing allegations. Respondent nonetheless chose to present Mr. George's testimony and submit the partial medical records. *Cf. United States* v. *Sherod,* 960 F.2d 1075, 1076 (1992) (''It is the universal rule in the federal circuits that 'a criminal defendant who, after denial of a motion for judgment of acquittal at the close of the government's case-in-chief, proceeds to the presentation of his own case, waives his objection to the denial.' '') (quoting *United States* v. *Foster,* 783 F.2d 1082, 1085 (D.C. Cir. 1986) (en banc)). Thus, I am not required to ignore this evidence in adjudicating the dispensing allegations.

[42] The record also contains a number other Dilaudid 8 mg prescriptions which were for quantities and dosages that exceeded the upper recommended dosage by nearly two fold or more. *See* GX 13, at 23 (168 du); 27 (240 du); and at 35 (196 du); GX 14, at 29 (168 du); 31(180 du); 33 (180 du); 35 (168 du); 37 (180 du); and 41 (180 du); GX 15, at 13 (180 du); 15 (168 du); 17 (180 du); 19 (168 du); 21 (168 du); 23 (168 du); and 25 (180 du). For the same reasons set forth in my discussion of the Dilaudid prescriptions filled by D.K. and G.C., I conclude that Respondent's pharmacists violated their corresponding responsibility when they filled these prescriptions. As for the remaining Dilaudid prescriptions, with the exception of the prescriptions dispensed to B.W. and T.F., I decline to address whether Respondent's pharmacists violated 21 CFR 1306.04(a) when they dispensed them.

[43] With respect to the Dilaudid 8 mg and methadone 10 mg prescriptions which Mr. George filled for T.F., Mr. Parrado identified, *inter alia,* the simultaneous prescribing of these two-short acting medications together and the dosing of the methadone (2 tablets in the morning, one at bedtime) as raising concerns over the legitimacy of the prescriptions. Of note, on the back of each prescription, there are notations dated ''1/21/13'' (the same day the prescription was filled), as well what appears to be ''ILKA,'' and ''Director—Operation.'' Mr. George did not, however, explain the meaning of the notations.

[44] There were also prescriptions for quantities ranging from 180 du to 210 du. *See generally* GX 3.

As for the issue of whether Mr. George conclusively resolved that the prescriptions were issued for a legitimate medical purpose, as previously explained, Mr. George offered only his generalized and not credible testimony that he always checked the patient profiles and did his due diligence and failed to specifically address how he resolved any of these other prescriptions. That, plus Respondent's failure to produce the purported due diligence checklists to corroborate his testimony, support the adverse inference that he failed to do so. I therefore find that Respondent's pharmacists violated 21 CFR 1306.04(a) when they dispensed numerous other oxycodone prescriptions.[45]

While I conclude that the quantities and dosing of these prescriptions alone support a finding that there was a high probability that the oxycodone prescriptions lacked a legitimate medical purpose, Mr. Parrado also identified another red flag—the high prices Respondent charged for the oxycodone prescriptions and the fact that patients were paying for them in cash or cash equivalents. Tr. 71–72, 75–76, 87–89, 112, 132–33, 165. As the evidence shows, the price Respondent charged for a 180 du prescription ranged from $675 in April 2011 to $1350 in in December 2012, and many of the prescriptions costs $800 or more. GX 3, at 1, 3, 5,11,15,17, 20, 24, 26, 28, 29, 30, 34, 35. As Mr. Parrado explained with respect to a prescription for 196 du which, at that time, cost $784:

> You don't see people paying $784 in cash. You tell a person they have a $50 co-pay and they go ballistic on you. And for a person to willingly pay $784 and not have any documentation as to why they did that and to see that over and over every day is a concern to me. . . . That's a red flag I couldn't resolve.

Tr. 71. And when asked on cross-examination if he had ever filled a prescription for someone who did not have insurance, Mr. Parrado answered that he was not going to give ''a yes or no answer because . . . a person who . . . can't afford insurance . . . is not going to pay 1,200 or 1,300 for a prescription.'' *Id.* at 132.

Notably, Mr. Badawi offered no testimony refuting Mr. Parrado's testimony that the cost of the prescriptions was also a red flag. Indeed, were these patients legitimate chronic pain patients, they would presumably require oxycodone on a monthly basis and would have spent $7,000 to $10,000 a year for this medication in 2011 (when Respondent's prices were lowest) and thousands more the following year.[46] This evidence further supports the conclusion that Respondent's pharmacists either knew that the prescriptions lacked a legitimate medical purpose or subjectively believed that there was a high probability that the prescriptions were illegitimate and deliberately failed to investigate further.

Against this evidence, Respondent points to the changes it made in its due diligence procedures after the AIW was served, the data it submitted showing that it has substantially decreased its dispensing of controlled substance prescriptions, and its decision—made three weeks before the hearing—to stop dispensing controlled substance prescriptions issued from pain management clinics. While Mr. George explained that he made these changes because ''[a]s a professional provider,'' he had ''a part to do to prevent the abuse and misuse and diversion of . . . controlled substances,'' even were I to accept his testimony as true, it does not outweigh the substantial evidence that he and Respondent's other pharmacists violated their corresponding responsibility and knowingly diverted controlled substances. 21 CFR 1306.04(a).

Other Allegations

The Government also alleged that Respondent violated various recordkeeping provisions of the CSA and DEA regulations. The allegations included that Respondent: (1) Had failed to complete a biennial inventory, (2) did not notate on its schedule II order forms the date and quantity it received of schedule II drugs, (3) failed to retain Copy 3 of its order forms, and (4) its records were not readily retrievable. The Government further points to the results of an audit it conducted which found multiple overages and a shortage of schedule II drugs.

The Availability of Respondent's Records

The Government alleged that Respondent ''failed to maintain records of [s]chedule II prescriptions, inventory records, and receiving records . . . in a readily retrievable form at its registered location in violation of 21 CFR 1304.04(a) and (h)(2).'' ALJ Ex. 1, at 4 As found above, a DI testified that Respondent was not able to provide all of the records when the AIW was executed, specifically the prescriptions from February 4, 2011 through April 2011, the inventories from February 4, 2011 through the end of 2011, and the receiving records from February 4, 2011 through the end of 2011. Tr. 252. According to the DI, he personally witnessed an attorney for Respondent state that the records were offsite and that the office manager had the key but was not available that day. *Id.* at 253.

Reasoning that the attorney's statement was hearsay, the ALJ specifically found credible Mr. George's testimony that the records were locked in a storage room at the back of the pharmacy but that he did not have the key to the room on the date that the AIW was executed. R.D. at 45 n.30. While Mr. George testified that Respondent's owner showed up with the key within a couple of hours but after the Investigators had left, the Government put forward no evidence as to how long the Investigators were on the premises.

Under generally applicable regulations, except as otherwise provided, ''every inventory and other records required to be kept under [21 CFR 1304] must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by

[45] I do not adopt a categorical rule as to the distance a patient must have travelled to render a controlled substance prescription suspicious. Distance is just one of the factors that a pharmacist must evaluate, and while a patient's willingness to travel a long distance to obtain a prescription is highly suspicious, a patient who seeks drugs for other than legitimate medical purposes may live in the same city as the prescriber and/or pharmacy. Indeed, several of the patients who lived in Tampa presented prescriptions for such quantities of oxycodone 30 as 168 du, 180 du, 210 du, and 224 du. *See* GX 3, at 18, 19, 26, and 35.

[46] I do not adopt the Government's contention that the prescriptions also presented the red flag of pattern prescribing. At most, the Government identified 10 prescriptions for oxycodone 30 that were written by physicians from 24th Century and filled by Respondent on the same day—April 21, 2011. GX 3, at 16–25. Notably, the prescriptions ranged in dosage from 140 to 240 tablets. *See id.* Moreover, another Government Exhibit refutes this contention as it includes twenty prescriptions written by doctors from the 24th Century clinic and filled by Respondent from April 14 through April 20, 2011. *See generally* GX 13. Notably, the exhibit includes four prescriptions for oxycodone 30, nine prescriptions for Dilaudid (some in the 4 mg tablet, others in the 8 mg), and 7 prescriptions for MS Contin (some in 30 mg tablet, others in 60 mg). *See id.*

As the evidence shows, when the Government obtained Respondent's records, it took only the schedule II prescriptions and provided only these prescriptions to Mr. Parrado. Notably, during the period of 2011 through early 2013, combination hydrocodone drugs, which are among the most highly prescribed drugs overall and are prescribed for pain, were in schedule III of the CSA, and any such prescriptions were not provided to Mr. Parrado. So too, Mr. Parrado was not provided with the prescriptions, if any, written by the 24th Century doctors for other drugs they may have prescribed for pain such as Tylenol with codeine (also in schedule III), pregabalin (Lyrica, schedule V), as well as non-controlled medications such as ibuprofen and naproxen. Thus, there is no basis to conclude that the 24th Century doctors were engaged in pattern prescribing.

authorized employees of the Administration.'' 21 CFR 1304.04(a). Under the regulation applicable to a pharmacy, ''[i]nventories and records of all controlled substances in Schedule . . . II shall be maintained separately from all other records of the pharmacy.'' 21 CFR 1304.04(h)(1).

As to the schedule II order forms, ''[t]he purchaser must retain Copy 3 of each executed DEA Form 222'' and the forms ''must be maintained separately from all other records of the registrant'' and ''be kept available for inspection for a period of two years'' at the registered location. *Id.* § 1305.17(a) & (c). Moreover, ''[p]aper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.'' 21 CFR 1304.04(h)(2).[47] Unlike the provision applicable to prescriptions in schedules III though V, this provision does not authorize the maintenance of schedule II prescriptions ''in such form that they are readily retrievable from other prescription records of the pharmacy.'' 21 CFR 1304.04(h)(4). Indeed, none of the above regulations allows for these records to be kept with other records of the pharmacy as long as they are ''readily retrievable from [those] other'' records.

In the Order to Show Cause, the Government nonetheless alleged that Respondent ''failed to maintain records . . . in a readily retrievable form at its registered location.'' ALJ Ex. 1, at 4. I find the violation proved. As explained above, the ALJ reasoned that the attorney's statement was hearsay and therefore gave it less weight than Mr. George's testimony. However, contrary to the ALJ's understanding, the attorney's statement was not hearsay because it was an admission of a party-opponent. *Cf.* Fed. R. Evid. R. 801(d)(2). Attorneys typically do not make admissions on behalf of clients to Government investigators without a factual basis for doing so.[48] Moreover, the attorney's statement was made contemporaneously with the inspection, unlike Mr. George's testimony which was offered well after fact and during a proceeding in which he had ample motive to misstate the facts. Accordingly, I find that various records including some of the schedule II prescriptions and schedule II order forms were not kept on the premises of Respondent's registered location as required by federal regulations.

The Allegations That Respondent Failed To Complete a Biennial Inventory

According to the DI, during the inspection, Respondent produced a document for the audited drugs on which it kept a perpetual inventory, *i.e,* a running total of the balance on hand listed by the date of various transactions. Specifically, the log listed: (1) The results of inventories which were actual ''physical count[s] of what was on hand,'' Tr. 270; (2) dispensings by prescription number and the quantity dispensed; (3) the quantities received by each order form number and invoice numbers; and (4) returns by patients. GX 5. According to the DI, the inventories did not comply with federal law because ''there was not one date [when] every controlled substance was inventoried.'' Tr. 235.

More specifically, the records showed that methadone 10 was inventoried on January 2, 2012. GX 5, at 1. While morphine sulfate 30 mg immediate release and morphine sulfate 100 m extended release were inventoried on January 2, 2012, morphine sulfate 60 mg extended release was inventoried on January 3, 2012, and morphine sulfate 30 mg extended release was not inventoried until June 9, 2012. GX 5, at 2–5. As for hydromorphone 8 mg, the only inventory listed is one taken on July 24, 2012, and while an inventory of Dilaudid 4 mg was taken on January 2, 2012, the sheet for generic hydromorphone 4 mg lists an inventory date of June 6, 2012 and the quantity on hand as ''-4'' while also including the undated notation of ''60'' in the header for the ''balance'' column. *See id.* at 6–8. Finally, the sheet for oxycodone 30 lists the inventory date as June 27, 2012, yet there is also an undated entry in the header for the ''balance'' column with the notation of ''1030''; the sheet also lists multiple prescriptions, a receipt from a distributor and what appears to be a return from a patient. *Id.* at 9.

Against this evidence, Respondent introduced an exhibit which purports to be an ''Annual Inventory'' of its schedule II controlled substances which was taken on January 2, 2012 and which lists Mr. George as its pharmacist. *See* RX 4. Asked on cross-examination whether he had seen this document before, the DI answered ''no,'' and testified that the document was not provided to the Government during the execution of the AIW. Tr. 276. Respondent, however, points to a Florida Department of Health Inspection Report which states that during a September 14, 2012 inspection, the State Investigator found that Respondent had taken a controlled substance inventory on a biennial basis and that the inventory was available for inspection; the report also noted that ''[t]he most recent Biennial Inventory is dated 01–02–12.'' RX 4, at 6.

The ALJ surmised that at the time of the AIW, either the DI did not request the biennial inventory or that Respondent's personnel did not understand the request. R.D. at 8–9 n.3. Nor does the record establish why this document was not turned over pursuant to the AIW (the AIW not being in the record either) with the documents that were subsequently turned over by Respondent's attorney. In any event, I find the evidence insufficient to support the allegation that Respondent failed to complete a biennial inventory as required by 21 CFR 1304.11(c). ALJ Ex. 1, at 4.

Allegations Related to Respondent's Maintenance of Its Schedule II Order Forms

The Government also alleged that Respondent's manner of keeping its schedule II order forms violated DEA regulations in two respects. First, it alleges that Respondent failed to document on the forms the ''receipt date or quantity received.'' *Id.* (citing 21 U.S.C. 827(b); 21 CFR 1305.13(e)). Second, it alleges that Respondent failed to retain Copy 3 of the order form. *Id.* (citing 21 U.S.C. 827(b); 21 CFR 1305.13(a) and 1305.17(a)).

As support for the allegations, the Government submitted copies of 11 ''purchaser's Copy 3'' of order forms Respondent submitted to various distributors. Under DEA's regulation, ''[t]he purchaser must record on Copy 3 . . . 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). However, under another DEA regulation, an order form is not valid ''more than 60 days after its

[47] While invoices (but not schedule II order forms) ''may be kept at a central location, rather than the registered location,'' to do so, a registrant must notify the Special Agent in Charge in writing ''of [its] intention to keep central records.'' 21 CFR 1304.04(a)(1). While the DI subsequently identified GX 10 (which contain only schedule II order forms as containing receiving records, it is otherwise unclear whether the DI's reference to receiving records also included the invoices. *See, e.g.,* GX 11. As to the invoices, there is no evidence in the record as to whether Respondent ever notified the Agency of its intent to keep records at other than its registered location.

[48] According to the DI, some of the Investigators attempted to interview Mr. George, but shortly into the interview, the attorney arrived and did not allow the Investigators to speak with Mr. George or any another employees and ''[a]ll questions were to be directed through [the attorney] at that point.'' Tr. 283. Thus, the attorney clearly acted as Respondent's authorized representative and made the statement that the missing records were offsite within the scope of his relationship with Respondent.

execution by the purchaser.'' *Id.* § 1305.13(b).

With respect to the 11 order forms, each of the forms includes notations indicating one or more items was filled by the supplier, with a handwritten notation as to the number of packages received, the date of receipt, and initials. *See generally* GX 10. Two of the order forms contain a notation that a number of packages were received but no entry for the date the package was received. *Id.* at 9 (entry for methadone 10); *id.* at 11 (line no. 1—indicating 12 packages of hydromorphone 8 were received but leaving blank the date received). Respondent thus violated 21 CFR 1305.13(e) by failing to notate the date these two packages were received.

The order forms also included line items that were not filled in any part by the supplier, and the forms were left blank in the columns for ''No. of Packages Received'' and ''Date Received.'' *See generally* GX 10. According to the DI, when Respondent did not ''receive a drug,'' it was required ''to write a zero'' in the column for the number of packages received. Tr. 255. The DI was, however, unsure if Respondent was required to also include a date. *Id.* at 256.

As to this contention, DEA regulations do not require a purchaser to notate on the order form that no portion of a particular item was received and a date. *See* 21 CFR 1305.13(e). Accordingly, to the extent this allegation relies on Respondent's failure to notate and date the non-receipt of items it ordered, the allegation is rejected.[49]

As for the allegations that Respondent ''failed to retain Copy 3 of the'' order forms, the Government proof was comprised of a single 222 form which, according to the DI, was a xerox and not the original Copy 3. GX 11, at 2. This is a violation, as under 21 CFR 1305.17(a), ''[t]he purchaser must retain Copy 3 of each executed DEA Form 222.'' However, this violation, as well as the two other violations based on Respondent's failure to notate the date on which the packages were received, are of minor consequence.[50]

The Audit Allegations

The Government also put forth evidence that it conducted an audit of Respondent's handling of seven controlled substances and found that it had overages in six drugs and a shortage in one drug. With respect to the latter, the audit found that Respondent was short 4,135 du of hydromorphone 4 mg. With respect to the overages, as alleged by the Government, the most significant were those of 8,758 du of hydromorphone 8 mg and 1,306 du of oxycodone 30 mg.

''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Fred Samimi,* 79 FR 18698, 18712 (2014) (finding, where physician ''had shortages totaling more than 40,000 dosage units'' of various drugs, that his ''inability to account for this significant number of dosage units creates a grave risk of diversion,'' and that ''even were there no other proven violations, the audit results alone are sufficient to . . . establish[ ] that [physician's] registration[ ] 'would be inconsistent with the public interest' '') (citations omitted).

Respondent raises a variety of challenges to the audit results. First, it asserts that the audits were flawed because they used figures from Respondent's perpetual inventory for the initial inventory rather than the inventory they produced at the hearing but had not provided to the Government previously. Resp. Exceptions, at 4. It further asserts that ''[h]ad DEA started with the record that the Agency actually requires registrant to keep . . . . (the biennial inventory), DEA would have had to use all of Respondent's records of receipt and dispensing during 2012, and DEA would not have found the alleged overages and shortages that its investigators claimed to find.'' *Id.*

Yet the Investigator testified repeatedly that the so-called perpetual inventory is all that Respondent provided to him. Most significantly, the Investigator testified that Mr. George ''stated that every line marked inventory was a physical count of what was on hand.'' Tr. 270. I therefore find no basis to reject the audit result because the Government used the physical counts listed on the perpetual inventory.

As for the Government's audit of the hydromorphone 4 mg, Respondent produced a listing by date, prescription number, and the quantity dispensed for the period of July 30, 2012 through February 4, 2013. *See* RX 5, at 2–3. Notably, each of the dispensings corresponds with the dispensings listed in the perpetual inventory and both documents show that Respondent dispensed a total of 4,659 du during the audit period, a figure which is 120 dosage units less than that determined (4,779) by the Government.[51] *See* GX 4. The effect, however, is that Respondent's shortage was even larger than that found by the Government. As for the closing inventory figures, while Respondent argues that I should reject the Government's figures because Mr. George did not attest to the accuracy of the figures (*see* Resp. Exceptions at 8–9, Resp. Post-Hrng Br. at 53), the difference between the Government's count (202) and Respondent's (200) was two (2) tablets, a difference of inconsequence.

By contrast, there is a substantial difference between the figures the Government and Respondent calculated for Respondent's receipts during the audit period. According to the Government, Respondent acquired 7,900 tablets during the period; according to Respondent, it acquired only 3,900 tablets. Compare GX 4 *with* RX 5, at 1.

This disparity is explained, however, by the Government's identification of an additional transaction on January 28, 2013, when Respondent acquired 4,000 du from Nucare Pharmaceuticals. GX 6, at 8. Notably, this transaction does not appear on Respondent's list of its acquisitions. *Compare id. with* RX 5, at 1. Significantly, Respondent put

[49] The Government put forward no evidence with respect to any of the order forms that Respondent had actually received any of the drugs listed in the line items which were left blank.

[50] Invoking a DEA regulation which grants the ALJ ''all power necessary'' to conduct a fair hearing, Respondent apparently argues that I should give no weight to the Government's documentary evidence, because following the execution of the AIW, the Investigators ''illegally retain[ed] the documents for 611 days'' and ''never provided a meaningful accounting of the documents seized.'' Resp. Exceptions, at 16. As Respondent further argues:

''To give any weight to the DEA's documentary evidence would be tantamount to sanctioning the unlawful conduct of the investigators and would work a great procedural and substantive injustice on Respondent. The only fair action (thus, a ''necessary action'') is to give no weight to the DEA's documentary evidence and to give no weight to the testimony about those documents.''

Id. at 18.

In its Exceptions, Respondent does not identify a single allegation that it has been unable to respond to because of the Government's delay in returning the documents or its failure to provide a meaningful accounting of the documents. Because Respondent has failed to establish prejudice, I reject its claim. *See Air Canada* v. *Department of Trans.,* 148 F.3d 1142, 1156 (D.C. Cir. 1998) (''As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error.'') (citing 5 U.S.C. 706).

[51] Respondent's perpetual inventory shows that an inventory was taken on July 24, 2012 of its stock of hydromorphone 4 mg, and that 1096 tablets were on hand; it also shows that Respondent did not dispense a prescription for the drug until July 30, 2012. RX 5, at 4. The evidence also shows that Respondent maintained a separate perpetual inventory log for Dilaudid (branded hydromorphone) 4 mg. GX 5, at 8. The log has only three entries; the entries provide inventory figures for January 2, 2012, June 9, 2012, and December 31, 2012. *See id.* On each date, Respondent had 120 tablets in stock. This figure, when added to the July 24, 2012 inventory for hydromorphone of 1096, equals 1216, the same figure which the Government used as its initial inventory.

forward no evidence refuting the Government's finding that the transaction occurred or that Respondent had received the drugs as of the date of the AIW. Thus, not only do I find no reason to reject the Government's finding with respect to Respondent's handling of hydromorphone 4 mg, I find that the shortage was even larger than alleged by the Government.[52]

As for the overage in hydromorphone 8 mg, Respondent disputed the Government's figure for the amounts received, the quantities distributed or dispensed, and the closing inventory. With respect to the amounts received, both the Government and Respondent provided a list of the shipments by date, order number, distributor's name, and quantity. Notably, Respondent's list includes four shipments which are not on the Government's list.

The first of these is an order purportedly filled by Harvard Drug on November 11, 2012 for 400 du pursuant to Order Form #121140458. RX 6, at 1. The order is, however, unsupported by an invoice, and notably, while Respondent submitted a copy of Order Form #121140458, that form was used to place an order with a different distributor, Red Parrot Distribution. *See id.* at 1; *see also id.* at 78, 80, 84 (invoices for the shipments received from Red Parrot on 11/17, 11/15, and 11/21/12); *id.* at 85 (DEA Form 222 #12114058). I thus find that Respondent did not receive 400 du from Harvard on November 11, 2012.

Respondent's list of receipts also includes shipments received from Attain Med on December 19 and 24, 2012, each of which was for 2,400 du, pursuant to Order Form #12x00003. RX 6, at 1. Respondent provided a copy of the order form and the invoices for each shipment. *Id.* at 92 (Order Form #12xx00003); *id.* at 91 (invoice for 24 packages shipped on 12/18/12 under same Order Form Number); *id.* at 90 (invoice for 24 packages shipped on 12/24/12 under same Order Form Number). The Government's list includes, however, only the first shipment for 2,400 du. GX 6, at 6. I therefore find that Respondent received both shipments and that the second shipment should have been credited by the Government.

Respondent's list also included two receipts of 2,500 du totaling 5,000 du from Nucare Pharmaceuticals pursuant to Order From #121140485. RX 6, at 1. According to the Government's list, Respondent received only one of these shipments. GX 6, at 6. Respondent, however, produced both a Form 222 (dated 12/17/12) which is annotated to reflect both shipments by date and quantity, as well as two invoices documenting its receipt of 5,000 du from Nucare pursuant to Order Form #121140485. *See* RX 6, at 97 (Form 222); *id.* at 96 (01/15/13 invoice for second shipment of 2500 du under Order #121140485); *id.* at 118 (12/26/12 invoice for first shipment of 2500 du under Order #121140485). I therefore find that Respondent received an additional 2,500 du pursuant to this order than was credited by the Government.

Respondent also listed a receipt of 2,400 du from Attain Med on January 19, 2013, pursuant to Order Form #13XX00001, RX 6, at 2; this shipment is not included on the Government's list. *See* GX 6, at 6–7. While Respondent did not produce the Order Form, it did produce an invoice showing that 2,400 du were shipped to it on January 19, 2013 pursuant to the aforesaid Order Form number and should have been credited by the Government. RX 6, at 102.

Finally, while the Government's list includes an order for 4,000 du which was filled by Nucare and received by Respondent on January 28, 2013 pursuant to Order Form #121140486,[53] Respondent's list also includes a shipment for 1,000 du pursuant to the same order form which it received on January 29, 2012. RX 6, at 2. While Respondent did not produce the order form, it did produce invoices for both shipments. RX 6, at 105–06. Thus, the additional 1,000 du should have been credited by the Government.

However, the Government also credited Respondent as having received two orders for 800 du each from Red Parrot on February 1, 2012 pursuant to Order Form #121140488. GX 6, at 7. Notably, while the DEA Form 222 shows that on January 29, 2013, Respondent ordered a total of 4,800 du, on the Order Form (as well as in his Perpetual Inventory), Respondent documented the receipt of only 800 du on February 1, 2013, an amount consistent with the invoice. *See* RX 6, at 108 (Form 222); *id.* at 107; *id.* at 37. According to Respondent's perpetual inventory, it did not receive an additional shipment from Red Parrot for hydromorphone 8 mg until February 6, 2013, after the closing date of the audit. *See id.* at 38. Thus, I have excluded this amount in calculating Respondent's receipts.

I therefore find that Respondent actually received an additional 7,500 du from its distributors than the amount calculated by the Government.[54] Moreover, the Government did not include the 433 du which were returned by the patients. Thus, Respondent was accountable for a total of 75,333 du.

As for the dispensings, the Government calculated the total at 71,759 du, Respondent at 72,195. Respondent's figure, however, includes six prescriptions totaling 858 du which were dispensed on February 4, 2013, the date of the AIW. RX 6, at 16–17. The Government's evidence shows, however, that the closing inventory was taken at the beginning of business, and thus these prescriptions are not properly included in the audit period. GX 7; Tr. 237. Thus, according to Respondent's data, its total dispensings during the audit period were 71,337 du, a difference of 422 du from the Government's figure.

The disparity is explained by five prescriptions, four of which are listed

[52] Respondent also challenges the audit results, arguing that the Investigator ''did not account for any controlled substances in the pharmacy's will-call bin, returns to stock, or those drugs quarantined for disposal.'' Resp. Post-Hrng. Br. 52; *see also* Resp. Exceptions at 5–6. It further argues that under the Agency's regulation, ''when conducting an inventory, the pharmacy must account for all controlled substances on hand at the pharmacy at the time of the inventory.'' *Id.* (citing 21 CFR 1304.11(a)).

As for Respondent's contention that the Agency was required to count the drugs in the ''will-call bin,'' by implication the regulation does not require counting these drugs. *See* 21 CFR 1301.11(a) (''Controlled substances shall be deemed 'on hand' if they are . . . ordered by a customer but not yet invoiced[.]''). Notably, those drugs in the ''will-call bin'' have a dispensing label attached and are otherwise accounted for as having been dispensed, even if the customer has yet to pick up the prescription.

As for Respondent's contention that the Government did not include those drugs that were returned to stock, where Respondent produced such documentation, I have considered the returns. Finally, Respondent produced no evidence that at the time the Investigators took the closing inventory, it had in its possession any dosage units of the drugs being audited that were quarantined for disposal.

Finally, Respondent argues that the DI ''willfully chose to ignore'' evidence in its ARCOS database regarding its purchases of schedule II drugs, apparently because he did not obtain Respondent's complete ARCOS data and compare it with his calculations. Resp. Exceptions, at 18. There is, however, no requirement that the Government obtain ARCOS data, which is not submitted by pharmacies but rather distributors and is thus dependent upon the accuracy of their submissions, and indeed, one of the purposes of doing an audit is to determine whether the registrant being audited is maintaining complete and accurate records. In any event, as I have carefully reviewed Respondent's invoices and credited Respondent for those receipts which were supported by its records but were omitted by the Government, this argument is moot.

[53] While the Government lists the Order Number as 121140497, GX 6, at 6; Respondent listed it as 121140486, which corresponds with the invoices. RX 6, at 2, 105–06.

[54] While this may have been caused by Respondent's failure to provide the records pursuant to the AIW, it may also have been caused by mistakes made by the Investigator who prepared the audit. The record does not, however, allow me to make a determination either way.

on the Government's list (GX 8, at 8–18) but not on Respondent's list (RX 6, at 4–17), as well as one prescription which is listed on Respondent's list but not the Government. More specifically, the Government's list includes: (1) RX #2039300 for 140 du (*compare* GX 8, at 8, *with* RX 6, at 5); (2) RX #2039764 for 150 du (*compare* GX 8, at 13, *with* RX 6, at 11); (3) RX #2039782 for 84 du (*compare* GX 8, at 13, *with* RX 6, at 11); and (4) RX#2039952 for 168 du (*compare* GX 8, at 16, *with* RX 6, at 14); Respondent's list includes RX#2039243 for 120 du (*compare* RX 6, at 4, *with* GX 8, at 8).[55] The four prescriptions on the Government's lists (which total 542 du) and the prescription on Respondent's list (120 du) thus account for the 422 du disparity in the dispensings (after subtracting out Respondent's post-audit dispensings).

As for the closing inventory figures, the Government put forward evidence that Respondent had 5,114 du on hand at the beginning of business, which included 48 full 100 count bottles and 314 other du. GX 7. Respondent asserted that it had on hand 4,086 du; however, this figure appears to have been determined after Respondent dispensed six prescriptions totaling 858 du on February 4, 2013. RX 6, at 17. Adding back in the 858 units Respondent represents that it dispensed on that date, yields a total of 4,944 du. And adding the 71,337 du Respondent represented that it had dispensed to its closing inventory figure of 4,944 du yields a total of 76,281 dosage units, this being the total Respondent accounted for. This compares with the total of Respondent's opening inventory, its receipts (including both its purchases and the dosage units returned by patients) of 75,333.

Thus, even using Respondent's figures for its receipts, dispensings, and closing inventory, it still had an overage of 948 dosage units. While this is substantially less that the figure calculated by the Government, it is still material and supports a finding that Respondent did not maintain complete and accurate records as required by 21 U.S.C. 827(a).

As for the audit's finding that Respondent had an overage of 1,306 du of oxycodone 30, GX 4, Respondent disputed the Government's finding that it received 17,200 du during the audit period. Instead, it put forward evidence that it received 18,300 du from distributors during the period and a comparison of the orders compiled by the Government with the orders compiled by Respondent shows that it placed two orders which totaled 1,100 du that were not included in the Government's count. More specifically, the Government's count did not include an order filled by PD–RX for 500 du on September 12, 2012 (Order Form Number 12X000019), and an order for 600 du filled by Attain Med on December 5, 2012. *Compare* GX 6, at 9, *with* RX 7, at 1. Moreover, Respondent provided the invoices to support its receipt of each order. *See* RX 7, at 40–41; *id.* at 87. Including the 12 dosage units that were returned by a customer, Respondent received a total of 18,312 dosage units during the audit period.

Notably, Respondent's Narcotic Control Sheet (RX 7, at 1) lists the same beginning count as the Government used (39 du), and the parties agreed that Respondent dispensed 18,322 du during the audit period. Including the orders that the Government did not include, Respondent was accountable for 18,351 du during the audit period and subtracting out the dispensings, should have had on hand 29 tablets at the time of the closing inventory. While Respondent's Narcotic Control Sheet lists the results of a physical inventory which was purportedly conducted on February 4, 2013 as 35 du (the same figure listed on Respondent's Perpetual Inventory as of February 4, 2013), this figure cannot possibly be accurate because on January 30, Respondent received an order of 300 du and its records show that it had only dispensed a single prescription for 140 du prior to the execution of the AIW and thus should have had at least 160 tablets on hand when the closing inventory was taken.[56] Thus, I find that the Government's closing inventory figure of 223 du is accurate and that Respondent had an overage of 194 du. While this overage is substantially smaller than that alleged by the Government, Respondent offered no explanation for the overage.

Sanction

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

The Agency has also repeatedly held that the level of candor exhibited by a registrant's principals during ''the hearing itself is an important factor to be considered in determining both whether [it] has accepted responsibility as well as for the appropriate sanction.'' *Michael S. Moore,* 76 FR 45867, 45868 (2011); *see also Robert F. Hunt,* 75 FR 49995, 50004 (2010); *Jeri Hassman,* 75 FR 8194, 8236 (2010); *Hoxie,* 419 F.3d at 483 (''Candor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.'').

Nor are these the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a

[55] Respondent's Perpetual Inventory included entries for RX#2039300 and RX#2039782. RX 6, at 20, 29. As for RX#2039300, the Perpetual Inventory included the notation ''wrong'' with a line drawn through the prescription number, the date, the quantity, and Mr. George's initials. RX 6, at 20. Respondent did not, however, add back in the quantity to the balance. *Id.* As for RX#2039782, the entry states ''voided'' to the left of the prescription number. *Id.* at 29. The record contains no further evidence establishing whether these prescriptions, or the other two prescriptions which were on the Government's list but not Respondent's, were actually dispensed.

[56] Given the impossibility that Respondent's closing inventory figure is accurate, and the Government's evidence that two investigators counted the oxycodone 30, I find the Government's inventory figure to be accurate.

However, Respondent argues that because Mr. George did not participate in counting the drugs for the closing inventory, ''the Government violated its own credibility safeguards.'' Resp. Exceptions at 6; *see also id.* at 4 (noting that this approach ''was contrary to the agency's internal guidance and customary practice'') (citation omitted). Even so, two Agency employees counted the drugs and vouched for the accuracy of the counts. Thus, while I do not condone the Investigators' failure to have Mr. George participate—at least in the absence of evidence that Mr. George was unwilling to do so—I nonetheless find no reason to conclude that the closing inventory figures found by the Government were unreliable.

registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

The Agency has also held that '''[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.''' *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36504); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Moore,* 76 FR at 45868. This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

Here, the ALJ found that Mr. George did not credibly accept responsibility for Respondent's misconduct. R.D. at 52. The ALJ specifically noted Mr. George's testimony that ''[a]s the pharmacist in charge . . . I accept the responsibility of conduct of the pharmacy. Again while I did all my due diligence and protocol, as I said before, still I'm less than perfect.'' *Id.* (citing Tr. 507). *See also* Tr. at 539–40 (''even though I did my best, our best to control that and prevent the abuse and misuse, that is not perfect. It is always less than perfect. Human beings are not perfect. I accept that responsibility.''). Asking whether this was a sufficient acceptance of responsibility, the ALJ concluded that Mr. George was ''still asserting that he had done all of his due diligence and had followed the Respondent's protocol'' and that his ''statement lacks credibility.'' R.D., at 52. And she also found that Mr. George's testimony that he had ''always'' done his due diligence lacked credibility.

I agree with the ALJ that Mr. George's testimony was not credible and that Respondent has not accepted responsibility. Indeed, much of Mr. George's testimony was contrived and other portions were plainly disingenuous.

Of particular note is Mr. George's testimony regarding the reason that Respondent filled the prescription (for 210 oxycodone 30) for T.V., who had traveled 472 miles from Pensacola. According to Mr. George, T.V. had been coming to Respondent since 2009 and the reason she was travelling this distance was because ''she used to come and see that doctor [Dr. Ruperto] *always. And while I was interviewing that patient she said she likes the doctor and she wanted to continue seeing that doctor.''* Tr. 588 (emphasis added). Yet the prescription which the Government submitted into evidence was written by Dr. P.C., and was written more than two and a half years after Dr. Ruperto's death. Indeed, while Mr. George testified that T.V. had been coming to his pharmacy since 2009, Tr. 494, 579; Dr. Ruperto died in December 2008, before T.V. even began filling her prescriptions at Respondent. Yet Mr. George maintained that he had done all of his due diligence with respect to T.V.'s prescription.

So too, with respect to H.C., Jr., Mr. George testified that notwithstanding that he no longer had insurance and had not filled a prescription at Respondent for two years, he was ''willing to pay whatever the cash price at that time'' was for his oxycodone 30 prescription—$1350—because he ''need[ed] this medication.'' Tr. 496–97. Mr. George thus stated that he ''filled this prescription for cash.'' *Id.* at 497. Yet based on the progress note Mr. George obtained, he knew that at the same visit, H.C., Jr. had also been prescribed three other controlled substances, including 112 OxyContin 40 mg, 84 Xanax 1 mg, and 84 carisoprodol. While Mr. George denied knowing anything about drug cocktails, as Mr. Parrado testified, the combination of an opioid, benzodiazepine and carisoprodol was widely known for its abuse potential. RX 3, at 47. Also unexplained by Mr. George is how a patient, who had lost his insurance, would be able to pay $1350 a month, each month, for this one prescription alone, as would be expected if the patient was a legitimate chronic pain patient. Here too, I do not believe his testimony.

In still other instances, Mr. George gave inconsistent testimony. For example, Mr. George testified that he looked at the partial medical records as ''an extra step to prevent the abuse and misuse of the controlled substances'' and that ''through experience, [he] learned to look through these forms and understand'' them. Tr. 481. However, when asked with regard to patient S.D. whether he had reviewed the medical record before filling an oxycodone 30 prescription and if he could tell from the record what other controlled substances were dispensed that day, Mr. George testified that he ''look[ed] only for my prescription which is received in my hand. That is only my concern.'' Tr. 561. He then added that ''[i]f I get the medical record, I have no way of saying and understanding where the patient had a different prescription unless I talk to the patient or doctors if he write any other prescriptions. I cannot guess where the prescription was filled for that patient.'' [57] *Id.* Yet the progress note in S.D.'s file clearly showed that the physician had also prescribed four other controlled substances to S.D. at this visit, including MS Contin, Soma, Xanax, and Dilaudid. RX 3, at 29.

Mr. George then testified that in ''looking [at] all these documents,'' he was ''going above and beyond what the duty'' of a pharmacist requires of him, and that ''it is not [a] pharmacist's job to read, that is doctor's job.'' Tr. 561–62. To be sure, as Mr. Parrado explained, pharmacists usually do not obtain medical records in the course of dispensing. Tr. 599. Nonetheless, registrants (and their principals such as Mr. George) are not excused from ignoring the information they do obtain and one does not need a degree in medicine to read S.D.'s progress note and recognize that S.D. had been prescribed five different controlled substances at the same visit, including not only duplicative therapy in the form of two short-acting narcotics (oxycodone 30 and Dilaudid 8 mg), *see* Fla. Admin Code r.64B16–27.810, but also a drug cocktail well known to be abused on the street.

[57] Mr. George, however, had also previously testified that under the protocol that was in place when he filled this prescription, ''we check that they have narcotic contract with the patient.'' Tr. 450. *See also id.* at 458. Notably, one of the terms of S.D.'s narcotic contract was that ''I will have prescriptions filled at only one pharmacy,'' and the contract then listed Superior (and not Respondent) as the only pharmacy. RX 3, at 30–31. Certainly, Mr. George knew from the progress note what other prescriptions were written on that date and whether they were being presented at Respondent for filling. Apparently, it was not a concern that S.D. was filling the prescription at his pharmacy, rather than the pharmacy listed on his narcotic contract.

At another point, Mr. George testified that ''[f]rom 2013 onwards,'' he had ''modified [his] protocol and changed it to print out patient's residence to less than 15 miles,'' Tr. 499, thus suggesting (although there is an argument that his answer was incoherent) that he would no longer fill the prescriptions if the patient lived more than 15 miles away. Yet he later testified that after DEA executed the AIW (on Feb. 4, 2013), he changed the protocol to fill only for patients who lived within 50 miles. *Id.* at 570–71.

I thus agree with the ALJ that Mr. George, as Respondent's principal, has not adequately accepted responsibility for its misconduct. This finding provides reason alone to conclude that Respondent has not rebutted the Government's *prima facie* showing that it has committed acts which render its continued registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). And having found that Mr. George and Respondent knowingly diverted controlled substances, there is no need to consider Respondent's remedial efforts as they are rendered irrelevant by its failure to acknowledge its misconduct. *See The Medicine Shoppe,* 79 FR 59504, 59510 (2014), *pet. for rev. denied* 626 Fed. Appx. 2 (Mem.) (D.C. Cir. 2015); *Jayam Krishna-Iyer,* 74 FR 459, 464 (2009) (''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.''). As the Tenth Circuit has recognized in the context of physician practitioners:

> 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 [DEA] to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether continued registration is in the public interest.

MacKay v. *DEA,* 664 F.3d 808, 820 (10th Cir. 2011) (citing *Hoxie* v. *DEA,* 419 F.3d at 483 (6th Cir. 2005)). See also *Hoxie,* 419 F.3d at 483 (''The DEA properly considers the candor of the physician . . . and admitting fault [to be] important factors in determining whether the physician's registration should be revoked.'').

I further find that the misconduct proven on this record is egregious and supports the revocation of Respondent's registration. More specifically, my finding that Respondent's pharmacists dispensed multiple prescriptions in violation of their corresponding responsibility and thereby knowingly diverted controlled substances is, by itself, sufficient to support the revocation of its registration. Revocation is also warranted by my finding that Respondent was short more than 4,000 du of hydromorphone 4 mg. And I also find that revocation is supported by Mr. George's lack of candor during his testimony.

I further find that the Agency's interest in deterring future misconduct both on the part of Respondent (and Mr. George) as well as the community of pharmacy registrants supports revocation. As for the issue of specific deterrence, the revocation of Respondent's registration is not a permanent bar, and as to Mr. George, because pharmacists are not required to be registered under the CSA, revocation is warranted to deter Mr. George from engaging in future misconduct in the event he procures employment elsewhere. As for the issue of general deterrence, those members of the regulated community who contemplate using their registrations to divert controlled substances need to know that there will be serious consequences if they choose to do so.

I therefore conclude that the revocation of Respondent's registration is necessary to protect the public interest. And I will further order that any application of Respondent to renew or modify its registration be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FH0772257 issued to Hills Pharmacy, LLC, be, and it hereby is, revoked. I further order that any application of Hills Pharmacy, LLC, to renew or modify its registration, be, and it hereby is, denied. This order is effective August 29, 2016.

Dated: July 19, 2016.

Chuck Rosenberg,

Acting Administrator.

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