DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–28]

Trinity Pharmacy II; Decision and Order

On July 10, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Trinity Pharmacy II, Inc. (hereinafter ''Trinity II'' or Respondent), which proposed the revocation of its DEA Certificate of Registration FT0531586, pursuant to which Trinity II is authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered location of 1474 South Belcher Road, Clearwater, Florida. Administrative Law Judge Exhibit (ALJ Ex.) 1b, at 1. As grounds for the proposed action, the Show Cause Order alleged that Respondent's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f) and 824(a)(4)).

More specifically, the Show Cause Order set forth seven independent reasons why Respondent's registration should be revoked. *Id.* at 2–17. *First,* the Show Cause Order charged that, between February 2012 and February 2014, Trinity II ''committed acts as would render its continued registration inconsistent with the public interest'' pursuant to 21 U.S.C. 824(a)(4) because Respondent (1) ''failed to comply with applicable federal and Florida state laws relating to controlled substances'' (citing 21 U.S.C. 823(f)(4)) and (2) ''exhibited negative experience in its dispensing of controlled substances'' (citing 21 U.S.C. 823(f)(2)). *Id.* at 1, 2. During this period, the Order alleged that pharmacists at Trinity II ''filled [prescriptions for] and dispensed controlled substances on numerous occasions outside the usual course of pharmacy practice and in contravention of their corresponding responsibility,'' and that such pharmacists did so even when such prescriptions ''contained one or more 'red flags' [f]or drug abuse or diversion without resolving the red flag(s) and, in certain circumstances, w[h]ere the red flags were unresolvable.'' *Id.* at 2–3 (citing *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62316, 62321–22 (2012)).

The Show Cause Order listed six red flags of diversion which Respondent's pharmacists allegedly failed to resolve before dispensing prescriptions, including: (1) ''[e]arly [f]ills,'' in which nine customers sought ''to fill a new controlled substance prescription or refill an existing controlled substance prescription well before the customer should have exhausted the supply . . . obtained from the previous prescription;'' (2) unusual distance traveled, in which six customers ''present[ed] a prescription bearing an address for the customer and doctor showing that the customer had travelled an unusual or suspicious route to obtain their prescriptions and fill them at Trinity II;'' (3) ''[c]ocktail prescriptions,'' in which eight customers ''present[ed] multiple prescriptions that provided the individual with the cocktail of an opioid, a benzodiazepine, and a muscle relaxer;'' (4) ''[d]uplicative drug therapies,'' whereby eight customers ''present[ed] multiple prescriptions which provided the person duplicative drug treatment;'' (5) ''[t]wo prescriptions for the same drug,'' in which 10 ''customers present[ed] two prescriptions for the same drug on the same date;'' and (6) ''pattern prescribing,'' or a lack of individualized drug therapy, in which two sets of ''two individuals present[ed] prescriptions on the same day for the same drugs that were issued by the same prescriber.'' *Id.* at 3–14.

Second, the Show Cause Order charged Trinity II with violating federal law when it dispensed ''a Schedule II controlled substance outside the usual course of professional practice . . . and in contravention of its corresponding responsibility . . . [when it] filled a prescription for customer D.G.'' on November 8, 2013 for ''7 patches of Duragesic 50 mcg/hr (fentanyl).'' *Id.* at 14 (citing 21 CFR 1306.04(a), 1306.06). The Order alleged that Trinity II filled this prescription even though D.G. had 12 days left on a prescription issued by a different doctor and filled by Trinity II on October 21, 2013 for a ''thirty-day supply'' of fentanyl patches that should have lasted D.G. until November 20, 2013. *Id.* The Order further alleged that when Trinity II filled the second prescription for D.G. 12 days early, Trinity II ''ignored the bright red flags that D.G. was abusing and/or diverting the fentanyl by doctor-shopping and seeking an early fill of fentanyl.'' *Id.*

Third and *fourth,* the Show Cause Order charged that Trinity II violated federal law when it twice dispensed to D.G. ''a Schedule II controlled substance without a valid prescription,'' ''outside the usual course of professional practice,'' ''and in contravention of its corresponding responsibility.'' *Id.* at 14, 15 (citing 21 U.S.C. 829; 21 CFR 1306.04(a), 1306.06, 1306.11(a)). In the third charge, the Order alleged that D.G. presented Trinity II with a prescription dated November 15, 2013 ''for 15 patches of Duragesic 50 mcg/hr (fentanyl), a Schedule II controlled substance,'' that also contained the following instruction from the prescribing practitioner: ''NO EXCEPTIONS DO NOT FILL UNTIL 12–06–2013.'' *Id.* at 14. The Order alleged that Trinity II nevertheless filled the prescription on November 20, 2013. *Id.* In the fourth charge, the Order alleged that D.G. presented Trinity II with a prescription in December 2013, also ''for 15 patches of Duragesic 50 mcg/hr (fentanyl), a Schedule II controlled substance,'' that also contained the following instruction from the prescribing practitioner: ''NO EXCEPTIONS DO NOT FILL UNTIL 1–05–2014.'' *Id.* at 15. The Order alleged that Trinity II nevertheless filled the prescription on December 18, 2013. *Id.* As a result, and with respect to each of these charges, the Order alleged that Trinity II ''filled and dispensed this controlled substance to D.G. approximately two weeks before the prescriber had authorized it to do so, and, thus, before the prescription was valid for filling.'' *Id.* at 15.

Fifth, the Show Cause Order charged that, on eight occasions between July 12, 2012 and January 25, 2013, Trinity II violated federal law when it dispensed to J.T. ''a Schedule II controlled substance without a valid prescription'' and ''outside the usual course of professional practice.'' *Id.* (citing 21 U.S.C. 829; 21 CFR 1306.06, 1306.11(a)). Specifically, the Order alleged that Trinity II dispensed to J.T. ''a morphine sulfate solution'' ''that was five times more potent than the doctor had prescribed, and instructed J.T. to take a dosage amount that would result in him receiving five times the amount'' prescribed. *Id.* The Order further alleged that such prescriptions ''placed the health and safety of J.T. at risk and, thus, engaged in conduct that may have threatened the public health and safety'' pursuant to 21 U.S.C. 823(f)(5). *Id.* at 16.

Sixth, the Show Cause Order charged that ''Trinity II unlawfully distributed controlled substances in violation of federal and Florida state law by utilizing non-pharmacists to fill controlled substances prescriptions on numerous occasions between February, 2012 and February, 2014.'' *Id.* The Order alleged that when Trinity II allowed its non-pharmacist ''pharmacy interns'' to fill a prescription, it was not filled by a pharmacist ''acting in the usual course of his professional practice,'' pursuant to 21 CFR 1306.06, nor were Trinity II's pharmacists properly exercising their ''corresponding responsibility'' under 21 CFR 1306.04(a). *Id.* The Order further

alleged that such prescriptions violated Florida law's requirement that ''[a] pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances.'' *Id.* (citing Fla. Stat., Ch. 893.04(1)).

Seventh, and lastly, the Show Cause Order charged that, ''if Trinity II's pharmacists in fact filled the prescriptions referenced in [the sixth charge], then Trinity II violated federal and Florida state law on numerous occasions between February 2012 and February 2014 by failing to maintain accurate records of the controlled substances it dispensed because they do not identify a pharmacist who filled the controlled substance prescription.'' *Id.* at 16–17 (citing 21 CFR 1304.22(c), 1306.06; Fla. Stat., Ch. 893.04(1)(c)(6)).

In a letter from its counsel dated August 12, 2015, Trinity II acknowledged receipt of the Show Cause Order and requested a hearing on the allegations. ALJ Ex. 2b. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ), who proceeded to conduct pre-hearing proceedings as follows.[1]

On August 13, 2015, the CALJ issued an Order for Prehearing Statements (hereinafter, Prehearing Order). *See* ALJ Ex. 3b. In the Prehearing Order, the CALJ directed the Government to file its Prehearing Statement no later than 2 p.m. on August 24, 2015, Respondent to file its Prehearing Statement no later than 2 p.m. on September 8, 2015, and scheduled a Prehearing Conference for 1:30 p.m. on September 9, 2015. *Id.* at 1–2. The Order also directed the parties to provide the ''[n]ames and current addresses of all witnesses whose testimony is to be presented,'' and that if the Respondent's corporate representative intends to testify, the representative ''must be listed as a witness, and a summary of his/her testimony as described below must be provided.'' *Id.* at 2. The CALJ's Order provided the following instruction regarding the summaries of testimony:

> Brief summary of the testimony of each witness (counsel for the Government to indicate clearly each and every act, omission or occurrence upon which it relies in seeking to revoke the Respondent's [Certificate of Registration]; counsel for Respondent to indicate clearly each and every matter as to which Respondent intends to introduce evidence in opposition). The summaries are to state what the testimony will be rather than merely listing the areas to be covered. The parties are reminded that testimony not disclosed in the prehearing statements or pursuant to subsequent rulings is likely to be excluded at the hearing.

Id. The Order further emphasized that ''[f]ailure to timely file a prehearing statement *that complies with the directions provided above* may be considered a waiver of hearing and an implied withdrawal of a request for hearing.'' *Id.* at 3.

On August 21, 2015, the Government filed its Prehearing Statement. ALJ Ex. 4b. On August 24, 2015, the CALJ issued an ''Order Rescheduling Prehearing Conference'' moving the prehearing conference up to 10:30 a.m. on September 3, 2015 in light of Respondent's counsel's August 20, 2015 notice of a conflict with the scheduled hearing on October 26, 2015. ALJ Ex. 8b at 1.[2] Although this Order stated that ''[a]ll other dates specified in the [Prehearing Order], including the filing date for the Respondent's Prehearing Statement, remain in effect,'' *id.* at 1 n.1, the CALJ (through his staff) later requested that Respondent file its Prehearing Statement early. ALJ Ex. 10 at 1 n.1 (''Upon my realization that the status conference was now scheduled several days prior to the date that the Respondents' prehearing statements were due under the terms of the [Prehearing Order], chambers staff (at my direction) reached out to Respondents' counsel and requested (but not directed) that, if it was possible to do so, their prehearing statements be filed prior to the commencement of the now-rescheduled Status Conference . . . with the assurance that (as is customary) both sides would be permitted to file supplemental prehearing statements'').

Per the CALJ's request, Trinity II filed its ''Preliminary Prehearing Statement'' on September 3, 2015. ALJ Ex. 9b. Trinity II proposed to call 77 witnesses in addition to ''[a]ny and all witnesses identified in the Government's Prehearing Statement.'' *Id.* at 3–7. Trinity II then provided a ''Summary of Anticipated Testimony'' for nine of these witnesses, all of whom were the owners or employees of Trinity II. *Id.* at 7–14. Trinity II stated that it anticipated calling an expert witness but had not yet identified one ''given the preliminary nature of this statement.'' *Id.* at 14. Trinity II offered an identical one-sentence summary of the testimony for each of 39 ''patients,'' and a separate identical one-sentence summary of the testimony for each of 32 ''prescribing physicians.'' *Id.* at 14–15. Trinity II also proposed as documents for the hearing copies of ''all prescriptions, patient profiles and related documents maintained by Trinity Pharmacy II in connection with each patient described in the [Show Cause Order].'' *Id.* at 16.

On September 3, 2015, the CALJ conducted an on-the-record prehearing conference. During that conference, the CALJ noted the Government's motion to consolidate the hearings for Trinity II and Trinity Pharmacy I[3] (hereinafter, collectively, Respondents) and asked Respondents' counsel to file something confirming that Trinity I and Trinity II waive any potential conflict in having him represent them both at a consolidated hearing. Transcript (''Tr.'') 5; ALJ Ex. 10 n.4 (same).[4] The CALJ also noted during the proceedings that the Government was seeking an ''Order of Protection'' to limit disclosure of personally identifiable information of patients and confirmed that Respondent had no objection to such an order. Tr. 55–56. Lastly, the CALJ accepted Respondents' counsel's representation that neither Trinity I nor Trinity II were the subject of pending state administrative cases or ''criminal parallel proceedings.'' *Id.* at 63.

On September 4, 2015, the CALJ issued a ''Consolidation Order, Prehearing Ruling, and Protective Order'' (hereinafter ''Consolidation Order''). ALJ Ex. 10 at 2. In this Order, the CALJ granted the Government's request for the aforementioned protective order and the Government's motion to consolidate the hearings, and the CALJ directed all parties to file a consolidated exhibit and witness list by October 16, 2015. *Id.* at 2, 9–11. The Order noted that the parties would be able to cross-examine the others' witnesses and stated that the ''parties are also reminded that testimony not

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

[2] According to the CALJ, ''[t]he hearing commencement date [was] continued on multiple occasions at the Respondents' request.'' ALJ Ex. 34, at 1 n.1. The hearing was ultimately noticed to begin on January 4, 2016. ALJ Ex. 27.

[3] Trinity Pharmacy (''Trinity I''), located in Seminole, Florida, was served with a separate July 10, 2015 Order to Show Cause by the Government. ALJ Ex. 1a. Although the CALJ eventually ordered the consolidation of the evidentiary hearings for Trinity I and Trinity II, *see* ALJ Ex. 10 at 2, the CALJ wrote separate recommendations regarding each Respondent, and I therefore have written a separate Order regarding the disposition of the Show Cause Order directed at Trinity I.

[4] On November 13, 2017, Mr. Michael Stanton filed a ''Notice of Appearance on Behalf of Respondents'' in which he entered ''an appearance as co-counsel for Respondents, Trinity Pharmacy I and Trinity Pharmacy II, along with Dale Sisco of Sisco Law.'' ALJ Ex. 35b, at 2. Although both counsel maintained that they represented both Respondents, at the evidentiary hearing, Mr. Sisco stated that ''[f]or the purposes of this hearing, I will be representing Trinity I and questioning witnesses on behalf of that pharmacy,'' and Mr. Stanton stated that ''for purposes of this hearing and to avoid any duplication, I will be handling the objections and the questioning on behalf of Trinity II.'' Tr. 83–84.

summarized in prehearing statements, or supplements thereto, may be excluded at the hearing.'' *Id.* at 4. The Order also directed the parties to serve each other with all documents it intends to identify as exhibits no later than September 11, 2015, and directed Respondents to supply the identity and curriculum vitae of their proposed expert witness by September 18, 2015. *Id.* at 4, 8. The Order further directed the parties to file supplemental prehearing statements and any additional exhibits, as well as any motions seeking relief, by 2 p.m. on October 16, 2015, and any responsive filings by 2 p.m. on October 23, 2015. *Id.* at 8. Finally, the Order reminded the parties that ''documents not noticed in prehearing statements, or supplements thereto, or not timely supplied to the opposing party may (and likely will) be excluded at the hearing.'' *Id.* at 4.

Although the Prehearing Order had directed Trinity II to supply a compliant prehearing statement by September 8, 2015, ALJ Ex. 3b at 1, and the Order Rescheduling Prehearing Conference iterated that Trinity II's prehearing statement filing deadline remained the same, ALJ Ex. 8b at 1 n.1, Trinity II failed to do so. On September 24, 2015, the Government filed a Motion to Compel Respondents' Compliance with the Prehearing Order and the Consolidation Order and a Motion Requesting a New Supplemental Prehearing Statement and Motion Deadline. ALJ Exs. 11a, 11b.

On September 28, 2015, Respondents filed their response. ALJ Ex. 13. On the same day, the CALJ issued an Order that generally denied the Government's motions and stated that honoring the CALJ's request for an earlier prehearing statement may have caused Respondents to have had the:

> mistaken impression that compliant prehearing statements were no longer required until the filing of supplemental prehearing statements. To alleviate any remaining misunderstanding in this regard and to afford the Respondents the time and ability to file both a fulsome prehearing statement and a supplemental prehearing statement, it is ORDERED that Respondents are to file prehearing statements that comply with the terms of the [Prehearing Statement] no later than 2 p.m. on October 5, 2015.

ALJ Ex. 14, at 3–4.

On October 5, 2015, Trinity II filed its Prehearing Statement. ALJ Ex. 15b. Trinity II provided the names and address of 79 proposed witnesses, in addition to ''[a]ny and all witnesses identified in the Government's Prehearing Statement.'' *Id.* at 4–7. Trinity II also provided a ''Summary of Anticipated Testimony'' for nine witnesses who were either owners or employees of Trinity II, a putative expert, and short but similar descriptions of testimony for 39 patients and 32 prescribing physicians. *Id.* at 7–54.[5] The Prehearing Statement also identified 70 documents ''intended to be used at the consolidated hearing regarding both Trinity Pharmacy I and Trinity Pharmacy II.'' *Id.* at 55–57, 55 n.2. On October 15, 2015, Respondents filed a ''Consolidated Witness and Exhibit List'' that listed 133 witnesses, in addition to ''[a]ny and all witnesses identified in the Government's Prehearing Statement,'' 69 exhibits of ''[d]ocuments and information related to'' various individuals, and one exhibit that would be the CV of their putative expert. ALJ Ex. 15e.

On October 16, 2015, the Government filed its ''Consolidated Supplemental Prehearing Statement.'' ALJ Ex. 16a. In this filing, the Government proposed two new witnesses, provided a summary of their testimony, and provided additional summaries for the testimony of the fact and expert witness identified in the Government's original Prehearing Statement. *Id.* at 6–10. Lastly, the Government supplemented its list of proposed Government exhibits with a list of additional documents that it intended to introduce as exhibits at the hearing. *Id.* at 10–12. The Government also filed its consolidated witness list and exhibit list. ALJ Exs. 16b, 16c.

Trinity II did not file a supplemental prehearing statement or any other prehearing statement by October 16, 2015 as required by the CALJ's Consolidation Order. As a result, the Government filed a ''Motion in Limine to Exclude Certain Testimony.'' ALJ Ex. 28. In its Motion, the Government contended that Respondents had failed in their prehearing statements to follow the requirements set forth in the CALJ's prehearing orders; namely, to ''state what the testimony will be rather than merely listing areas to be covered'' for each proposed witness.'' *Id.* at 2 (internal citations omitted). For example, the Government noted that Respondents proposed 69 witnesses identified as patients and that ''nearly every single patient of the sixty-nine listed by the Respondents is expected to testify identically.'' *Id.* at 4. The Government contended that, not only did the proposed patient ''testimony fail to make clear exactly what 'information' each patient will 'confirm,' thus preventing the Government from determining what specific defense(s) Respondents allege; the [proposed] testimony also fails to provide any basis upon which the Government can evaluate [whether] such information is even relevant or material to this case.'' *Id.* at 4–5. Such proposed testimony, the Government argued, ''is nothing more than 'merely areas to be covered,' rather than any substantive recitation of 'what the testimony will be,' '' as the prehearing orders required, ''offering no facts that, if proven, would rebut the Government's *prima facie* case or offer credible evidence in mitigation. *Id.* Finally, the Government argued that ''it is unclear from the Respondents' Prehearing Statements how the purported testimony of these various patients related to each of the dispensing events charged in the [Show Cause Orders], and how it affected the pharmacist's compliance with the standard of care and exercise of his corresponding responsibility in each charged instance.'' *Id.*

With respect to the prescribing physicians that Respondents had proposed as witnesses, the Government noted that Respondents ''intend to call fifty-nine doctors as witnesses, who, again, will each testify identically. . . . Other than to blithely forecast that the physicians will approve their own prescriptions, Respondent provides no facts which, if proven, would rebut the Government's *prima facie* case.'' *Id.* at 6. This too, the Government contended, violated the requirement of the prehearing orders that the parties set forth ''what the testimony will be''

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[5] For example, for patient S.B., Trinity II stated that it anticipated her testimony to be as follows:

> [S.B.] was a patient whose prescriptions are identified in the various categories of allegations contained in the July 10, 2015 Order to Show Cause issued to Trinity Pharmacy II. It is anticipated that [S.B.] will testify regarding the inquiry done by the pharmacists and the staff at Trinity II regarding verification of her prescriptions and for the resolution of any potential red flags. [S.B.] will further confirm the information obtained from her by Trinity Pharmacy II prior to any prescription being dispensed, including but not limited to explanations for any significant distances traveled, the type of payment they made for the prescriptions, the circumstances of any refills and physician authorization for same.

ALJ Ex. 15b, at 29. The proposed testimony of most of the other patients used similar language. *See id.* at 27–43. Likewise, the physician summaries used language similar or identical to the following example:

> [J.M.], M.D. was a prescribing physician for one or more of the patients who tendered prescriptions to Trinity Pharmacy II. [J.M.], M.D. will confirm the prescriptions he authorized were for a legitimate medical purpose and issued in the usual course of professional practice to patients that were known to him. Further, [J.M.], M.D. will describe his interaction with the pharmacists and staff at Trinity Pharmacy II, the authorization of refills or early fills, if any, and explanations for any duplicative drug therapy, combinations of medications or alleged ''drug cocktails.''

Id. at 45.

rather than ''areas to be covered.'' *Id.* The Government argued that the summary of the physicians' proposed testimony failed to disclose sufficient facts to allow the Government to determine what specific defenses Respondents allege, nor provide any basis upon which the Government can evaluate how such information is relevant to the charges in the Show Cause Order. *Id.* at 6–7.

In its Motion, the Government also challenged the adequacy of Respondents' disclosure of the proposed testimony of its owners and employees, contending that it too set forth ''a generalized statement of 'areas to be covered' '' rather than ''a summary of 'what the testimony will be' for each witness.'' *Id.* at 9. These generalized statements, the Government contended, failed ''to reveal the specific 'actions' each employee purportedly is going to 'describe' '' or ''to provide the Government (or the ALJ) any information upon which it can discern the relevance and materiality of the 'actions' to the issues to be litigated in this case.'' *Id.* Although Respondents stated in their prehearing statements that certain employees would testify to describe the ''process'' Trinity II used ''to verify prescriptions and resolve concerns, if any, regarding the validity of those prescriptions,'' the Government argued that the statements ''fail[ed] to provide any information about the 'process' '' employed to verify prescriptions and resolve concerns. *Id.* at 9–10. Similarly, the Government observed that Respondents' offer of testimony from employees who would provide ''a description and demonstration of the computer software used by the pharmacy in this process'' was not matched by a proposed ''exhibit containing each pharmacy's computer software that each witness purportedly would demonstrate for the court.'' *Id.* And while Respondents proposed its co-owners would testify about their knowledge of both their customers' medical conditions and the treating physicians efforts to ''resolve[ ] any concerns,'' the Government further alleged that Respondents failed to disclose ''each customer's medical condition . . . , how it related to each dispensing activity, or how and when each pharmacy purportedly became 'aware' of it.'' *Id.* at 11.

In its Motion, the Government also sought to preclude Respondents' proposed expert, Mr. Sam Badawi, from rendering an opinion concerning whether the prescriptions referenced in the Show Cause Orders ''were filled in compliance with federal and/or state law requirements.'' *Id.* at 14. Specifically, the Government alleged that Respondents failed to give the Government ''notice [of] a proposed opinion from Mr. Badawi as to the lawfulness of each prescription alleged in each'' Show Cause Order. *Id.* at 17 (''Respondents have had multiple opportunities to provide a compliant disclosure, yet have repeatedly failed to do so.'').

As a result of these alleged deficiencies, the Government requested that the CALJ exclude ''the non-conforming testimony'' set forth in its Motion because Respondents had only provided ''vague summaries of areas to be covered by the Respondent's witnesses'' that unduly prejudiced the Government. *Id.* at 18–19 (''Agency precedent favors exclusion of evidence when the names of witnesses and 'an adequate summary of their testimony' has 'not been previously disclosed as required by the ALJ's Order for Pre-Hearing Statements.' '') (citing *East Main Street Pharmacy,* 75 FR 66149, 66150 (2010)).

On November 5, 2015, the CALJ issued an ''Order Granting the Government's Unopposed Motion *in Limine* to Exclude Certain Testimony.'' ALJ Ex. 29. After noting the Government's timely filed Motion and that Respondents' deadline to file a responsive pleading was October 23, 2015, the CALJ noted:

> Respondents never filed a response. Not even a late or unpersuasive response. Nothing. The language of the [Prehearing Order] about the nature of the required notice proffers is clear and unambiguous; yet, notwithstanding multiple opportunities to do so, the Respondents have elected not to comply. The [Prehearing Statement] plainly states that ''testimony not disclosed in the prehearing statements or pursuant to subsequent rulings is likely to be excluded at the hearing.''

ALJ Ex. 29, at 2. Although the CALJ posited that Respondents' repeated failure to comply with his orders could constitute a waiver of a hearing request, the CALJ also noted that the Government ''does not seek (as it could have) the draconian remedy of hearing waiver, but asks for the lesser sanction of preemptive exclusion of a limited subset of the noticed evidence,'' and the CALJ deemed the Motion unopposed and granted it. *Id.* at 3–4. Specifically, the CALJ's Order precluded Respondents from offering the following:

1. ''testimony from sixty-nine patients identified as proposed witnesses;''
2. ''testimony from fifty-nine physicians identified as proposed witnesses;''
3. ''testimony from proposed witness Nina Ghobrial;''
4. ''evidence regarding the actions of DEA personnel and the cooperation of pharmacy staff during the Administrative Inspection of both pharmacies;''
5. ''evidence regarding the process the pharmacies used to verify prescriptions and resolve concerns, including a description and demonstration of the computer software utilized;''
6. ''evidence regarding the medical condition of patients who received early refills;''
7. ''evidence of the pharmacy's knowledge of cocktail prescription and duplicative drug therapy patients, their medical condition, and their treating physicians;''
8. ''evidence regarding circumstances surrounding an early fill for patient T.B.;''
9. ''evidence regarding circumstances surrounding an early fill for patient C.F.;''
10. ''evidence regarding information that Trinity I allegedly possessed relating to an early fill for patient J.K.;''
11. ''evidence regarding circumstances surrounding an early fill for patient G.S.;''
12. ''evidence regarding distances traveled by patients who either commuted, lived, or worked close to both pharmacies;'' and
13. ''evidence from the Respondents' proposed expert, Sam Badawi, regarding the lawful or unlawful nature of the numerous prescriptions referenced in each of the [Show Cause Orders].''

Id. at 3–4 (citing ALJ Ex. 28 at 4–18).

Over a month later, on December 7, 2015, Respondents filed their ''Motion for Reconsideration on Behalf of Respondents'' in which they ''request[ed] an order reconsidering [the CALJ's] order granting the Government's motion *in limine,* and allowing Respondents to provide [the CALJ] with the necessary evidence needed for [the] final determination.'' ALJ Ex. 32, at 1. Respondents stated that ''due process requires that Respondents be entitled to present testimony from its witnesses, which were properly disclosed.'' *Id.* at 3. Respondents also stated that they ''recognize that the physician and patient disclosures lack particularity'' because ''Respondents cannot exercise sufficient control over these witnesses without first having them under subpoena to provide more detail.'' *Id.* at 3 n.1. Respondents added that ''[n]either the Government nor the Respondents should fear the Court learning the full truth . . . even if there may not be a way for any party to control that message before the hearing.'' *Id.* Respondents also contended that ''those same deficiencies . . . do not apply'' to their employee, expert, and owner witness disclosures. *Id.* Indeed, Respondents argued that ''it is disingenuous for the Government to alleged [sic] that the [expert witness] disclosure fails to provide adequate notice to allow it to prepare for a cross-examination when its prehearing statements provide a comparable

opportunity for notice to Respondents.'' *Id* at 4–5. Respondents contend that their ''representatives and pharmacist'' witness disclosures were ''similarly robust and detailed,'' and that their ''remaining pharmacy employees[']' [witness] disclosures are brief.'' *Id.* at 5. Finally, Respondents claim that ''an intermediate remedial order requiring supplementation or a limit to the testimony would have been more appropriate than granting the motion *in limine* in its entirety.'' *Id.*

The Government filed its ''Opposition to Respondents' Motion for Reconsideration'' on December 10, 2015. ALJ Ex. 33. In its Opposition, the Government argued that, as a threshold matter, ''Respondents have not even provided a basis—not to mention a plausible one that would demonstrate good cause—upon which to reconsider the decision.'' *Id.* at 4 (Respondents gave no ''explanation or justification for their failure to file a timely response on October 23, 2015.''). *Id.* ''Respondents[']' Reconsideration Motion is a request for the ALJ to reconsider his decision on a Motion that they did not see fit to oppose in the first place, and have not seen/did not see fit [ ] to oppose for the past month.'' *Id.* In response to Respondents' concession that their patient and physician witness disclosures lacked particularity because they lacked subpoena authority, the Government contended that ''Respondents are unable to explain why they needed a subpoena to talk to their own customers and the physicians about prescriptions Respondents contend were lawfully issued. Nor do Respondents indicate that they attempted to contact these individuals and were rebuffed.'' *Id.* And finally, with respect to Respondents' Due Process argument, the Government noted that, ''despite hav[ing] been given multiple opportunities to correct their mistakes and provide the Government the requisite notice it was due,'' Respondents were attempting ''to shift the blame'' by ''now claiming that the ALJ is denying them a fair hearing.'' *Id.* at 4–5.

On December 10, 2015, the CALJ issued his ''Order Denying the Respondents' Motion for Reconsideration.'' ALJ Ex. 34. In this Order, the CALJ noted that Respondents ''filed neither a response to the Government's motion [in *Limine*] nor a motion for an extension of time to do so. Indeed, the Respondents filed nothing.'' *Id.* at 1. The CALJ also observed that he waited an additional 13 ''days after the responsive filing deadline'' before issuing his Order granting the Government's Motion *in Limine,* ''perhaps hoping in vain for even a late response.'' *Id.* Indeed, the CALJ emphasized that Respondents did not file their Motion for Reconsideration until ''over forty-five days from the date their motion response was due and less than a month prior to the . . . commencement of the hearing.'' *Id.* (Respondents ''do[ ] not even mention the fact that no response was filed, as if it never happened''). The CALJ noted that Respondents asked for another order to give Respondents additional opportunities to cure any alleged deficiencies in their disclosures ''[u]nder th[e] theory[ ] this new, additional order would somehow carry more force and would result in compliance where the other orders had failed. Enough.'' *Id.* at 2. The CALJ found that Respondents ''have tendered no explanation for their failure to answer the Government's motion and no basis upon which to base good cause for reconsideration, even if such relief was warranted—which it is not.'' *Id.* Accordingly, the CALJ denied Respondents' reconsideration motion. *Id.* at 3.[6]

The CALJ conducted an evidentiary hearing on January 4–8, 2016, in Arlington, Virginia, and on January 11–12, 2016, in Tampa, Florida. *See* Recommended Decision (R.D.), at 2. At the hearing, both parties elicited testimony from multiple witnesses, and the Government submitted various exhibits. Following the hearing, on February 26, 2016, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument. ALJ Exs. 40a, 41. On February 29, 2016, the CALJ issued an ''Order Regarding the Exhibit (and Appended Attachments) Included with the Government's Closing Brief'' noting that the Government's proposed findings of fact and conclusions of law had attached a declaration from the Government's lead attorney as well as six attachments thereto and asking Respondents if they intended ''to take a position on the Agency's consideration of factual matters set forth'' in the declaration and attachments. ALJ Ex. 40b, at 1. Respondents filed joint objections to the declaration and attachments. ALJ Ex. 40c. On March 4, 2016, the CALJ issued an Order sustaining Respondents' objections, ruling that the declaration and attachments are ''EXCLUDED from the record, and will not be considered as evidence in these matters'' and ''will not be considered by this tribunal in its recommended decision.'' ALJ Ex. 40d, at 1 & n.3.

On May 12, 2016, the CALJ issued and served his Recommended Decision. Specifically, the CALJ found that the Government had ''supplied sufficient evidence to make out a *prima facie* case that maintaining the Respondent's [DEA Registration] would be contrary to the requirements of 21 U.S.C. 823 and 824'' based on the third, fourth, and fifth charges set forth in the Show Cause Order. R.D. at 51. The CALJ further held that the testimony of the Government's expert was ''insufficiently reliable to establish a breach of the Respondent pharmacy's corresponding responsibility regarding the dispensing of controlled substances'' pursuant to 21 CFR 1306.04 as set forth in the first two charges of the Order. *Id.* at 43.[7] Although the CALJ acknowledged that his decision not ''to rely on the Government's expert witness dramatically pared down the number of noticed transgressions that could be and were established by a preponderance'' of the evidence, the CALJ concluded that ''the evidence demonstrates a culture in the Respondent pharmacy of ignoring regulations deemed inconvenient . . . this pharmacy is dangerous, and the owners have given not even the smallest indication to the Agency that there is any inclination to change.'' *Id.* at 53–54. The CALJ also concluded that the Respondent ''fail[ed] to accept responsibility.'' *Id.* at 54. Thus, the CALJ recommended that I revoke Respondent's registration and deny any pending applications for renewal. *Id.* On June 2, 2016, the Government and Respondents each filed Exceptions to the CALJ's Recommended Decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the record in its entirety, including the parties' Exceptions (which I discuss throughout this decision), I do agree with the CALJ's conclusions that the Government sustained the Order's third, fourth and fifth charges. I also agree with the CALJ's conclusions that the Government failed to sustain the Order's second, sixth and seventh charges. And I further agree with his legal conclusion that Trinity II has failed to accept responsibility for the misconduct which has been proven on the record of the proceeding. However, I disagree with the CALJ's conclusion that the

[6] On December 11, 2015, the CALJ granted Respondents' requests for subpoenas for their pharmacy employees and denied Respondents' requests vis-à-vis their proposed practitioner witnesses pursuant to the Order granting the Government's Motion *in Limine.* ALJ Ex. 36.

[7] The CALJ also found that the Government failed to sustain the sixth and seventh charges of the Show Cause Order related to prescriptions filled by pharmacy interns. R.D. at 43–46.

Government did not prove the first charge of the Show Cause Order alleging that Trinity II violated its corresponding responsibility pursuant to 21 CFR 1306.04(a).[8] Accordingly, I agree with the ALJ's ultimate conclusion that Trinity II has committed acts which render its continued registration inconsistent with the public interest and will adopt his recommendation that I revoke Trinity II's registration and deny any pending applications. As the ultimate fact finder, I make the following findings of fact.

Findings of Fact

Trinity II is the holder of DEA Certificate of Registration FT0531586, pursuant to which it is authorized to dispense controlled substances in schedules II through V, as a retail pharmacy, at the registered location of 1474 Belcher Rd., Clearwater, Florida. Government Exhibit (''GX'') 34; Tr. 120, 685–86. Respondent's registration was due to expire on November 16, 2016, R.D. at 3; however, having reviewed the Agency's registration records, I take official notice that on October 3, 2016, Trinity II submitted a renewal application.[9] Because Trinity II has timely submitted a renewal application, I find that Trinity II's registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c). No evidence was put forward as to Trinity II's current licensure status with the Florida Department of Health.

The Investigation of Trinity II

On February 10, 2014, DEA Investigators (''DI'' or ''DIs'') conducted inspections of Trinity II. Tr. 119–20, 684–86, 709. The Government called three DIs as witnesses in its case-in-chief. *See id.* The lead investigator testified that when the DIs arrived at Trinity II for the inspection, they asked to speak to Trinity II's pharmacist-in-charge (''PIC'') or owner and were greeted by Mr. Mark Abdelmaseeh, who identified himself as Trinity II's PIC. *Id.* at 124–26. The DIs presented Trinity II's PIC with a Notice of Inspection, and the PIC consented to the inspection after reviewing the Notice. *Id.* at 126. The lead investigator also testified that the DIs obtained, by consent from Trinity II, photocopies of the driver's licenses of the employees present when the investigators arrived and the original prescriptions for the two-year period of February 2012 to February 2014. *Id.* at 127–32, 135–36.[10] Another DI separately testified that his role during the inspection included identifying employees at the pharmacy and obtaining copies of their drivers' licenses. *Id.* at 686–88, 694. He also spoke with some of Trinity II's employees to obtain their job descriptions. *Id.* at 688–89.

The lead investigator also testified that during the inspection at Trinity II, some employees represented to him that the pharmacy only dispensed controlled substances to patients with Florida addresses, that the pharmacist inspected each prescription for alteration or forgery, and that each physician's status was confirmed through the Florida Department of Health website. *Id.* at 577–78, 595–97. He also testified that someone at Trinity II claimed that its computer software ''automatically confirmed the prescriber's DEA registration.'' *Id.* at 578, 595–97. He further testified that the owners of the pharmacy, Mina and Emad Yousef, told him that they would call the doctor's office—a practice followed at Trinity I and Trinity II; however, the DI also testified that he did not recall either of them telling him that the owners called a doctor's office for every controlled substance prescription and exactly what they would discuss with the doctor. *Id.* at 126, 133, 579, 595–97, 666–67. He testified that the majority of prescriptions contained no evidence that anyone at Trinity II had called a doctor's office, and that neither the patient profiles nor the dispensing reports that he reviewed reflected such contacts. *Id.* at 666–68. He also testified that Yousef told him during the inspection that the pharmacist would check the patient profile for medication history. *Id.* at 597.

The lead investigator testified that he reviewed the original prescriptions and ''looked for the red flags of diversion that we had been trained on,'' such as distances, drug cocktails, drug interactions, and short fills. *Id.* at 147. He also reviewed them to make sure that the prescriptions included all of the required information such as the doctor's signature, patient name, patient address, and drug strength. *Id.* He then identified any prescriptions that were of interest and copied such prescriptions for review by the expert. *Id.* at 147–48, 538. He testified that the investigators did not make a forensic image of Trinity II's computer system. *Id* at 137.

In addition to the prescriptions obtained by DEA during the inspection of Trinity II, the DIs obtained dispensing reports[11] in May 2014 pursuant to a DEA administrative subpoena issued to Trinity II by facsimile. *Id.* at 156–57, 543 (''global dispensing report''), 544–45. The May 9, 2014 subpoena specifically asked for Trinity II to provide, for the time period of February 10, 2012 through February 10, 2014, ''[d]ispensing records of controlled substances in schedules II–V to include: Prescription number; patient's full name, date of birth, and address; drug name, strength, dosage form, quantity prescribed, and directions for use; prescriber's full name, address, and DEA number; method of payment; whether it is a new prescription or refill; and the pharmacist who filled [the] prescription.'' GX 95, at 4; Tr. 157–58, 201–02, 608. On May 21, 2014, counsel for Respondents Trinity I and Trinity II, Mr. Dale Sisco, emailed to the lead investigator Trinity II's response to the administrative subpoena, which included a Microsoft Excel spreadsheet of Trinity II's dispensing report (hereinafter, ''global dispensing report'') as an attachment to that email. GX 96; Tr. 158, 172–73, 175, 627, 643.[12] The DI testified that after receiving this global dispensing report, he created individual dispensing reports for individual patients to see the dispensing history for certain patients, and then he matched the original prescriptions with the dispensing report. Tr. 180–81, 219, 227.[13] He also noted that the global dispensing report included a ''Filled By'' column which either contained the initials ''EFY,'' ''MAG,'' or ''MIA.'' *Id.* at 271–72, 338, 344, 345.

On October 16, 2014, two DIs and Government counsel met with Trinity II's counsel, Mr. Sisco, and the co-owners of Trinity II—Emad Yousef and

[8] Although I do not rely on the Government expert's testimony in making my ruling, as set forth *infra,* I also disagree with the CALJ's conclusion that the Government's expert was not reliable.

[9] In accordance with 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).

[10] The lead investigator also testified that during the inspection of Trinity II, DIs reviewed DEA–222 order forms and the CSOS electronic ordering system. Tr. 134. He testified that CSOS, which stands for Controlled Substance Ordering System, provides an electronic version of the DEA–222 order form. *Id.* at 134–35.

[11] Because witnesses and counsel used the phrases ''dispensing report'' and ''dispensing log'' interchangeably throughout the hearing, I also use those phrases interchangeably in this decision.

[12] Government Exhibit 84 is a printed copy of the global dispensing report entered into evidence. Tr. 177–79.

[13] The lead investigator also testified that when he created the individual dispensing reports, using the global dispensing report, he did not alter any of the information in the global dispensing report, and that the individual dispensing reports are true and accurate representations of the information contained in the global dispensing report. *Id.* at 241, 247–48, 253, 256, 259, 264, 268, 278, 285, 291–92, 297, 303–04, 348–49.

Mina Yousef [14]—at Mr. Sisco's office. *Id.* at 186–88. The purpose of the meeting was to ask the Yousefs about information contained on the fill stickers of the prescriptions. *Id.* at 188–89. Emad Yousef was asked what ''MAG'' stood for, and the lead investigator testified that Yousef responded that it stood for Mina Ghobrial, a pharmacist intern at Trinity II. *Id.* at 339, 446–47. The DI testified that he conducted a license verification on Florida's Department of Health license verification website and learned that Mina Ghobrial is a pharmacist intern in Florida. *Id.* at 339, 444. Another DI testified that he also conducted the same license verification search on August 20, 2015 that confirmed Mr. Ghobrial's status as a licensed pharmacy intern. *Id.* at 711; GX 78. The lead investigator also testified that ''EFY'' are the initials for Emad Yousef, and ''MIA'' are the initials for pharmacist Mark Abdelmaseeh. Tr. 271–72, 338, 345.

On December 4, 2014, the lead investigator issued an administrative subpoena to Trinity II asking that the pharmacy ''provide a copy of the complete patient profile your pharmacy maintained pursuant to Florida Administrative Rule 64B16–27.800 ('Requirement for Patient Records')'' for 23 specific patients. GX 98, at 2; Tr. 159, 548–49. The CALJ took official notice of the version of this Rule applicable between February 2012 and February 2014. ALJ Ex. 38. The Florida Board of Pharmacy adopted the Florida Administrative Rules pursuant to its authority under Chapters 465.022 and 465.0155 of the Florida Statutes. This Rule requires ''all pharmacies'' to ''maintain[ ]'' ''[a] patient record system . . . for patients to whom new or refill prescriptions are dispensed'' that ''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.'' ALJ Ex. 38, at 1 (Rule 64B16–27.800(1)). The Rule also states that the ''pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain'' certain patient-related information, including ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* (Rule 64B16–27.800(1)(f)). This Rule further requires the pharmacist to ''record any related information indicated by a licensed health care practitioner.'' *Id.* (Rule 64B16–27.800(2)). Finally, this Rule requires pharmacists to maintain ''[a] patient record for a period of not less than two years from the date of the last entry in the profile record'' in ''hard copy or a computerized form.'' *Id.* (Rule 64B16–27.800(3)).

The lead investigator testified that he requested the patient profiles because ''another place to resolve red flags, from my training and experience, was in the patient profiles,'' and ''a lot of pharmacists, instead of writing it on the prescription, they will actually type it into a note section in the patient profile in the computer.'' Tr. 182, 572–73. He further testified that the patient profile is generally ''part of the pharmacy's electronic system, where it will list out the prescriptions that the individual patient has received. It also contains note sections and other information regarding the patient.'' *Id.* at 159. On December 22, 2014, Mr. Sisco sent an email to the lead investigator stating that ''[e]nclosed please find documents responsive to the referenced subpoena.'' GX 98, at 1. Attached to this email were patient profiles stored in portable document format (''PDF''). *Id.;* Tr. 159–60, 175, 182–83.

The lead investigator testified that he reviewed all the prescriptions, dispensing reports, and patient records obtained from Trinity II and received from its counsel. Tr. 183–84, 241, 247–48, 253–54, 256, 259, 264, 268, 278, 285, 291, 297, 303, 572–73, 666–67. He testified that none of the patient records received in response to the December 4, 2014 administrative subpoena contained a ''notes and comment section'' or documentation of contact with a doctor's office. *Id.* at 183–84, 667–68. He also testified that the majority of the prescriptions did not contain evidence that a doctor's office had been called. *Id.* at 666–67.

Finally, he testified that he created Google Maps printouts to show certain patient's travel. *Id.* at 238. Specifically, he testified that when he created these maps, he would use the patient's home address as the starting point, the physician's address as the next stop, the pharmacy as the stop after that, and sometimes the patient's home address as the final stop. *Id.* at 237. The CALJ found that the testimony of each of the DIs called by the Government ''was sufficiently detailed, plausible, consistent and cogent to be fully credited in this recommended decision.'' R.D. at 14.

The Allegations of Dispensing Violations

The lead investigator testified that DEA investigators provided the following information to Professor Paul Doering, M.S., the Expert for the Government: (1) Copies of the original prescriptions for certain patients flagged by the lead investigator, (2) a copy of all of the E–FORCSE [15] data for the Respondent from February 2012 to February 2014, (3) the aforementioned individualized dispensing reports prepared by the lead investigator, (4) a copy of one of his DEA–6 [16] forms, (5) the subpoenaed patients' profiles, and (6) maps for certain patients. Tr. 581, 589–90, 597–98, 601–02. Professor Doering testified that he also received an electronic copy of the ''master dispensing report'' for Trinity II. *Id.* at 861. He further testified that he relied on the following materials in forming his opinion in this case: ''the dispensing logs, the copies of the individual prescriptions, the patient profiles, and what could best be called as Google Maps and/or MapQuest indicators of distances between two spots.'' *Id.* at 863.

Professor Doering was retained by the Government to be its Expert and was tendered as such at the hearing. Tr. 147, 834. Professor Doering has taught the practice of pharmacy in Florida for 40 years and at one time also worked in a retail pharmacy. *Id.* at 812–13, 824, 830–31; GX 32. His teaching has included courses related to the standards of pharmacy practice in the State of Florida. Tr. 814–15. He has also conducted research and published extensively regarding the standards of pharmacy practice in Florida. *Id.* at 816–17; GX 32. Professor Doering was also the one professor to have ever been given the honorary title of Distinguished Service Professor Emeritus in the 95-year history of the University of Florida's School of Pharmacy, a status he received in 2011.[17] Tr. 811–12.

[14] The lead investigator testified that, during the inspection of Trinity II, he spoke with Emad Yousef, and that Yousef had stated that he and his brother, Mina Yousef, were co-owners of Trinity I and Trinity II. Tr. 128, 133.

[15] E–FORCSE stands for ''Electronic-Florida Online Reporting of Controlled Substances Evaluation'' and is the prescription drug monitoring program in Florida. Tr. 553, 857.

[16] A DEA–6 is the form where DIs write their report of an investigation. Tr. 582. Pursuant to 21 CFR 1316.46(b)(4), the information contained in investigatory reports are not available for inspection as part of the administrative record. Thus, the CALJ properly precluded Respondents' counsel from asking the agent on cross-examination to reveal the contents of his DEA–6. Tr. 583 (''He can't be compelled to answer or reveal anything that's in his DEA–6.''), 584 (''he can't be compelled to discuss the investigative contents of the DEA–6'').

[17] According to his CV, he was ''[a]warded 'Emeritus' status upon official retirement on January 31, 2011. Despite retirement, [he] continues to teach the same course as before retirement, except on a volunteer basis. [He e]ngages in special

Professor Doering testified that he keeps current on the latest developments in pharmacy practice. *Id.* at 817.

At the hearing, the CALJ accepted Professor Doering as an expert in the practice of pharmacy in the State of Florida and in the standard of care for pharmacists in the dispensing of controlled substances in Florida. *Id.* at 843–844. In his Recommended Decision, the CALJ also stated that Professor Doering ''has decades of experience in academia with honors and numerous publications'' and that ''[h]is credentials are extremely impressive, and the pride and commitment he displayed toward the field of pharmacy were undeniable and palpable in his testimony.'' R.D. at 14.

In that capacity, Professor Doering testified that he sought to ''identify[ ] individual patients that might demonstrate some of the activities and issues that have come to be called red flags'' or ''indicators.'' *Id.* at 864. In his opinion, a red flag is ''anything that raises concern.'' *Id.* ''In the area of pharmacy it's a term that's come to be used to give examples to pharmacies of things that might indicate or suggest that prescriptions were filled outside the usual course of pharmacy practice.'' *Id.* He also testified that a red flag ''could be indicative of abuse or misuse,'' ''over or under compliance,'' ''drug-drug interactions,'' or a ''forged'' or ''altered'' prescription. *Id.* at 869. He further testified that these issues would be reviewed and resolved by a pharmacist ''before filling any prescription'' as part of the ''prospective drug utilization review, or prospective drug use review.'' *See id.* Resolution of red flags, he continued, ''would be documented on the face of the prescription, on the rear of the prescription, or in the patient profile.'' *Id.* at 882. Professor Doering testified that the standard of practice in Florida regarding the contents of such documentation is that it has to include ''a reason that makes sense that, to the average pharmacist, is understandable how a person could find themselves in that predicament,'' and the standard of practice also requires documentation of ''potentially reasonable removals of red flags'' and some link back to the prescribing physician. *Id.* at 1169–70. He further testified that ''if it's not written down[,] you didn't do it.'' *Id.* at 1353.

Professor Doering testified that the standard of care for a prospective drug utilization review (also referred to as a prospective drug use review) is already ''specified in the Florida Administrative Code,'' which requires pharmacists to perform a prospective drug utilization review before dispensing a medication. *Id.* at 869–70 (''It says, pharmacists shall, before dispensing a medication, perform what [is] called . . . prospective drug utilization review.''), 958–59 (''it's crystal clear what it says, the pharmacist shall before dispensing any prescription do a drug utilization review''). The CALJ took official notice of (and entered into evidence) the applicable version of Florida Administrative Code Rule 64B16–27.810, entitled ''Prospective Drug Use Review,'' which states that ''[a] pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying: (a) Over-utilization [ ]; (b) Therapeutic duplication; . . . (d) Drug-drug interactions; (e) Incorrect drug dosage or duration of drug treatment; . . . (g) Clinical abuse/misuse.'' ALJ Ex. 38 (Fla. Admin. Code Rule 64B16–27.810(1)); Tr. 946, 1852. This Rule also states that, ''[u]pon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'' *Id.* (Fla. Admin. Code Rule 64B16–27.810(2)). This prospective drug use review, according to Professor Doering, applies to all prescription drugs, including prescriptions for controlled substances and narcotics.[18] *See* Tr. 870.

Professor Doering testified that the drug utilization review process ''begins when the prescription is presented'' and should be ''performed at the time the information is given to the pharmacist.'' *Id.* at 873. He also stated that the standard of care in Florida requires pharmacists to use the notes and comments fields in a patient profile to document the resolution of issues identified during the drug utilization review process. *Id.* at 1015–16. In the absence of notes resolving such issues in the patient profile, Professor Doering testified that he would also look to the front and back of the prescription to determine whether a pharmacist had resolved a red flag. *Id.* at 1055, 1101. He further testified that he did not find any notes and comments section in any of the patient profiles he reviewed.[19] *Id.* at 1054, 2087.

Professor Doering testified that only after the pharmacist has identified, resolved, and documented his/her resolution of red flags of diversion and other issues identified during the drug utilization review process can the pharmacist fill the prescription. *Id.* at 873–74, 1093–94, 1099–1100. If the pharmacist cannot resolve the issue, then the standard of care calls for pharmacists not to fill the prescription. *E.g., id.* at 879.

Professor Doering also explained some specific issues, or red flags, that pharmacists must look for as part of the prospective drug review process pursuant to Rule 64B16–27.810. For instance, he testified that the term ''over-utilization'' in this Rule is a red flag, and he explained that it ''can be two things. So it can be taking more of the medication at a single administration. Or it could be obtaining more medication than the physician had desired, and using it in a time span that is less than the medication was supposed to last.'' ALJ Ex. 38 (Fla. Admin. Code Rule 64B16–27.810(1)(a)); Tr. 872, 876. He offered the following example: ''So if it's a 30-day supply of medicine, having lasted only 15 days is suggestive of one of two things. One, is taking too much of it. Or two, might be distributing it to other persons. That would be over[-] utilization.'' *Id.* at 872. He testified that when a pharmacist identifies an over-utilization issue when a patient presents a prescription, the pharmacist must resolve that issue (and document that resolution) before filling the prescription. *Id.* at 873–74, 879.

Professor Doering also explained that the term ''therapeutic duplication,'' as set forth in Rule 64B16–27.810(1)(b), ''is the presenting of two prescriptions, either for the identical drug, or drugs that are so closely allied that they would be overlapping in their actions in the body.'' *Id.* at 884–85, 1520 (therapeutic duplication'' occurs when ''two drugs with the same action [are] being prescribed under the same circumstances''), 1541 (''Essentially two drugs with the same net effect.''). ''[F]rom a pharmacist's standpoint, [that] is duplication of therapy.'' *Id.* at 885. Professor Doering testified that therapeutic duplication is a red flag. *Id.* at 886. ''Therapeutic duplication signifies that there are two or more

projects for the College of Pharmacy, Shands Hospital, and other agencies and organizations.'' GX 32, at 1.

[18] Professor Doering testified that ''[n]arcotics prescriptions . . . are referred to as high alert medications'' that ''have a higher than ordinary potential to cause harm if used inappropriately.'' Tr. 865, 867–68.

[19] Professor Doering testified that he also reviewed dispensing logs, which are typically ''spreadsheet[s] that contain[ ] information regarding drugs that were dispensed by the pharmacy,'' and that the data in the dispensing log should ''correspond'' to the patient profile's data. Tr. 1018–19.

drugs that appear to be essentially doing the same thing, that together might pose the issue of adverse drug-drug interactions.'' *Id.* at 883; *see* ALJ Ex. 38 (Fla. Admin. Code Rule 64B16–27.810(1)(b), (d)). ''[I]t also may involve intentional duplication of drugs.'' Tr. 883. In this way, he added that a prescription raising a ''therapeutic duplication'' concern might lead to another issue for the pharmacist to resolve regarding drug-drug interactions. *Id.* at 883–84. As a result, Professor Doering stated that therapeutic duplication raises many concerns, including the ''safety of the patient. But it could also indicate an attempt to obtain more medication for over[-]utilization, which touches upon some of the other issues, which means clinical use or abuse, or diversion to some other use.'' *Id.* at 885–86. As with other red flags, he reiterated that the standard of care requires pharmacists receiving a prescription raising the red flag of therapeutic duplication to resolve that issue (and document such resolution) before filling the prescription. *Id.* at 886–91.

Professor Doering next explained the term ''[d]rug-drug interactions.'' ALJ Ex. 38 (Fla. Admin. Code Rule 64B16–27.810(1)(d)). He testified that this ''refers to the fact that two drugs, when given together, can have outcomes that are not what was intended initially by either one or the other drug together.'' Tr. 893. He testified that when presented with prescriptions presenting potentially harmful drug-drug interactions, the standard of care requires the pharmacist to either (1) resolve this red flag and document the resolution once the pharmacist is satisfied that it is in the best interest of the patient, or (2) not fill the prescriptions. *Id.* at 1419–20.

Professor Doering also testified, however, that drug cocktails that include an opioid, benzodiazepine, and a muscle relaxer present red flags that must be resolved. *See, e.g., id.* at 1413–16, 1427. ''[F]or example, oxycodone, or some other potent narcotic, along with a tranquilizer drug, such as alprazolam or Xanax, combined with a muscle relaxant, say for example, Soma,'' also known as carisoprodol. *Id.* at 894. ''[T]hose three drugs, which have been come to be called the unholy trinity, or . . . cocktail prescriptions, whatever you want to call them, are symbolic of drug interactions that might cause harms to the patient.'' *Id.; see also id.* at 1416–17. According to Professor Doering's testimony, these drugs ''have added central nervous system depressant properties and can present a real and present danger to the patient.'' *Id.* at 1417. Moreover, he testified that this combination of drugs ''constitute what I would call drugs with abuse potential, serious abuse potential'' and ''are often diverted to non-medical or recreational use.'' *Id.* at 1416.[20] During the prospective drug utilization review process, pharmacists, ''check for drug/drug interactions. And this would be subject to, in my opinion, very severe drug/drug interactions.'' *Id.* at 1418.

Professor Doering testified to what a pharmacist would look for in identifying ''[c]linical abuse/misuse'' as part of the prospective drug use review. ALJ Ex. 38 (Fla. Admin. Code Rule 64B16–27.810(1)(g)). He defined clinical abuse or misuse as ''recreational use'' or ''drug abuse'' which ''typically involves taking more of the prescribed drug or focusing on certain drugs that have [ ] mood altering properties . . . that individuals . . . will use for other than medical purposes.'' Tr. 952, 953 (it is ''any time you use the drug outside the conditions for which it could be prescribed''). To identify such clinical abuse/misuse as part of the drug utilization review process, Professor Doering testified that a pharmacist ''would look for quantities of drugs that are being sought beyond those which were authorized by the prescriber or they might look for certain combinations of drugs that are known to be used frequently for non-medical reasons.'' *Id.* at 953. Again, as with the other red flags that may arise during a prospective drug use review (*i.e.,* the drug utilization review process), if the pharmacist cannot resolve the clinical abuse/misuse red flag, then he or she must not fill the prescription. *Id.*at 955.

Professor Doering also offered testimony regarding patient address information that appears on a prescription and the distance a patient travels to a pharmacy to fill a prescription. He testified that both Florida and federal law require a patient's address to appear on prescriptions ''so that the pharmacist has some idea of where this patient resides and that can be useful for a couple of different reasons . . . it's also useful to know what geographic area this patient lives in because that may become important information as the prospective drug use review takes place.'' *Id.* at 973. In the same vein, he testified that a physician's address must also appear on the prescription to indicate where the patient met with the practitioner. *Id.* at 970. ''Typically you would look to patients that are in the same geographic area [as the pharmacy]. I would say within the same county or geographic area.'' *Id.* at 1692. ''[W]hen the distances are very great, it raises . . . a question of why is somebody needing to travel this far to get this prescription filled.'' *Id.*

Professor Doering also explained what type of information is generated after a pharmacist has decided to fill a prescription. ''When the computer prints out the information there are different versions of the [fill sticker]. One version of it doesn't contain necessarily all this information, but that's the one that gets applied to the prescription vial. Th[e other version] is the one for pharmacists' record keeping purposes. It has additional info that the one on the vial does not.'' *Id.* at 978.

Significantly, he testified that the fill sticker is generated after the drug utilization review process has been completed, and that the date appearing on the fill sticker represents the date when the pharmacy filled the prescription. *Id.* at 979–80. He explained that the fill sticker is ''generated one step before the prescription label is actually applied to the vial . . . by the pharmacist. The significance of that is that the prescription has gone through all the proper steps and its certified ready for dispensing to the patient.'' *Id.* at 979. Professor Doering further testified that, in his opinion, the date on the fill sticker also represents when the prescription is dispensed. *Id.* at 1186.

Respondents did not proffer an expert witness at the hearing, and I find that Professor Doering's testimony was credible.[21]

The Prescription Evidence

At the hearing, the Government introduced into evidence copies of dispensing logs, patient profiles, and the front and back of prescriptions for controlled substances which it alleged Trinity II filled in violation of 21 CFR 1306.04(a) and 1306.06 because they presented red flags of diversion that Trinity II failed to resolve as set forth in the first two charges of the Show Cause Order. As already noted, the first charge of the Show Cause Order outlined six different categories of red flags of diversion that the Government alleged

[20] He also testified that ''[t]he nature of the drug combination, a potent narcotic analgesic, along with a potent anxiolytic medicine, along with a potent muscle relaxant . . . It's just come to be associated with a high potential for abuse.'' Tr. 1417.

[21] Although the CALJ expressly declined to offer a view of Professor Doering's credibility, he nonetheless disregarded his opinions as ''insufficiently reliable to form the basis of a sanction under the APA.'' R.D., at 33 (''To be clear, however, this is not an issue of credibility, and no credibility determination is entered here.''). As I discuss *infra,* I disagree with the CALJ's assessment of the expert's reliability.

that Trinity II failed to resolve before filling the pertinent prescriptions. When taken together, the Government alleged that Trinity II's failure to resolve these red flags before filling these prescriptions demonstrated that Trinity II knowingly filled prescriptions for controlled substances in contravention of its corresponding responsibility and outside the usual course of pharmacy practice.

Early Fills

The Government introduced prescription evidence to show that Trinity II failed to resolve the first alleged red flag of diversion, ''early fills,'' with respect to at least four of its customers identified in the first charge of the Show Cause Order and whose patient records the Government had requested pursuant to its December 4, 2014 subpoena.[22] For one such customer, J.T., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that Trinity II filled early at least nine prescriptions issued to J.T. for oxycodone 30 milligrams (hereinafter, ''mg''), a schedule II controlled substance, under the brand name Roxicodone. GX 35; Tr. 1198–1234. Specifically, the Government introduced evidence that on February 23, 2012, Trinity II filled a prescription issued by physician W.F. to customer J.T. for 336 pills of ''Roxicodone 30 mg,'' and with directions from the prescribing physician for J.T. to take up to eight pills per day. GX 35, at 1, 3, 10, 11; Tr. 1199–1202. Although the fill sticker and patient profile both state that the prescription was for a 30-day supply, in fact, the 336 pills prescribed to be taken at the rate of eight pills per day constitutes a 42-day supply that should have lasted J.T. until at least April 6, 2012. *Id.* Nevertheless, on March 22, 2012, Trinity II then filled another prescription (from the same prescriber) for another 336 pills of Roxicodone 30 mg with instructions to take up to eight pills per day. GX 35, at 1, 3, 16, 17; Tr. 1202–05. Thus, I find that when Trinity II filled this second prescription on March 22, 2012, Trinity II filled it 15 days early. *Accord* Tr. 1205.[23] I also find that the front of the prescription, the back of the prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the prescription early. GX 35, at 1, 3, 15, 16; Tr. 1198, 1199, 1205–06.

Professor Doering testified that, in Florida, whereas a fill (or refill) that is 2–3 days early may not signify a problem, a fill that is more than two-to-three days early is a red flag that a pharmacist is expected to resolve during the drug utilization review process ''to avoid overuse or misuse.'' *See* Tr. 989–91, 1009. ''If someone is coming back fifteen days early, then that signifies a problem.'' *Id.* at 990. In the case of J.T.'s presentation of the aforementioned March 22, 2012 Roxicodone 30 mg prescription 15 days early, the evidence established that there are no notes or comments—much less any evidence that Trinity II resolved this red flag—reflected in J.T.'s patient profile, dispensing log, or the front-and-back of this prescription. GX 35, at 1, 3, 15, 16; Tr. 1198–99, 1205–06. As a result, Professor Doering testified that this prescription was inconsistent with Florida's standard of care, not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1206.

In each of the next eight months, J.T. presented prescriptions to Trinity II for Roxicodone 30 mg in the same quantities and with the same dosing instructions; and in each instance, I find that Trinity II filled those prescriptions 14, 15, or 16 days early. GX 35, at 1, 3, 16, 17, 20, 21; Tr. 1208–09 (prescription for 42-day supply that Trinity II filled 15 days early on April 19, 2012); GX 35, at 1, 3, 20, 21, 30, 31; Tr. 1209–12 (prescription for 42-day supply that Trinity II filled 15 days early on May 17, 2012); GX 35, at 1, 3, 30, 31, 36, 37; Tr. 1213–17 (prescription for 42-day supply that Trinity II filled 15 days early on June 14, 2012); GX 35, at 1, 3, 36, 37, 44, 45; Tr. 1220–23 (prescription for 42-day supply that Trinity II filled 15 days early on July 12, 2012); GX 35, at 1, 3, 44, 45, 50, 51; Tr. 1223–25 (prescription for 42-day supply that Trinity II filled 16 days early on August 8, 2012); GX 35, at 1, 3, 50, 51, 54, 55; Tr. 1225–28 (prescription for 42-day supply that Trinity II filled 14 days early on September 6, 2012); GX 35, at 1, 3, 54, 55, 62, 63; Tr. 1228–31 (prescription for 42-day supply that Trinity II filled 16 days early on October 3, 2012); GX 35, at 1, 3, 62, 63, 70, 71; Tr. 1231–34 (prescription for 42-day supply that Trinity II filled 14 days early on November 1, 2012). When considering the cumulative effect of these consecutive monthly early fills from March–November 2012, I find that Trinity II filled prescriptions for J.T. that resulted in the filling of 135 days of extra oxycodone 30 mg.

And as with the earlier prescription that Trinity II filled for J.T. on March 22, 2012, I find that the prescriptions (front or back), patient profile, and dispensing log do not reflect any notes or comments, much less documentation, explaining how Trinity II resolved the early refill red flag presented by these prescriptions over the eight subsequent months. *See* GX 35, at 1, 3, 16, 17, 20, 21, 30, 31, 36, 37, 44, 45, 50, 51, 54, 55, 62, 63, 70, 71; Tr. 1198–99, 1205–06, 1212, 1216, 1218, 1222, 1225, 1228, 1230, 1234. And in each instance, Professor Doering testified that, because all of these early fills were well beyond 3 days early, Trinity II should have identified these early fills as red flags during the drug utilization review process to avoid drug abuse, overuse or misuse. Tr. 1208–09, 1211–12, 1215–17, 1222–25, 1227–28, 1230–31, 1234. He further testified that Trinity II's decision to fill these prescriptions without resolving these red flags was inconsistent with Florida's standard of care, not in the usual course of professional practice, and did not reflect the proper exercise of the pharmacist's corresponding responsibility. *Id.*

For a second customer, M.A., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that Trinity II filled early at least 8 prescriptions issued to M.A. for hydromorphone 8 mg, a schedule II controlled substance, under the brand name Dilaudid. GX 36; Tr. 1237–68. The Government introduced evidence that on May 2, 2013, Trinity II filled a prescription issued by physician R.A. at the Genesis Medical Clinic to customer M.A. for 165 pills of ''Dilaudid Oral Tablet 8 MG,'' with directions from the prescribing physician for M.A. to ''[t]ake one tablet every 5 to 6 hours for 30 days.'' GX 36, at 1–2, 4–5; Tr. 1237–42. Although the prescription and the fill sticker both stated that the prescription was for a 30-day supply, in fact, the 165 pills prescribed to be taken at the rate

[22] For reasons I discuss *infra,* and as it relates to the first and second charges of the Show Cause Order only, I limit my fact findings to evidence related to those patients discussed at the hearing who were also identified in the December 4, 2014 subpoena.

[23] Notably, the CALJ failed to make recommended fact findings related to the alleged early fills, or most of the other allegations set forth in paragraphs 7–8 of the Show Cause Order (*i.e.,* the first two charges of the Order) because of his concerns related to Professor Doering's reliability as an expert. R.D., at 43. However, as discussed further *infra,* this concern, even if well-founded, does not categorically relieve the Agency from making fact findings on allegations about Trinity II's filling conduct that can be decided without expert opinion. Accordingly, I will make such ultimate fact findings, even where the CALJ chose not to recommend any.

of five pills [24] per day constitutes a 33-day supply that should have lasted M.A. until at least June 4, 2013. *Id.* Nevertheless, on May 28, 2013, Trinity II then filled another prescription (from another prescriber, J.S., at the same practice group—Genesis Medical Clinic) for another 165 pills of Dilaudid 8 mg with instructions to take one tablet every five to six hours for 30 days. GX 36, at 1–2, 4–7; Tr. 1242–45. Thus, I find that when Trinity II filled this second prescription on May 28, 2013, Trinity II filled it seven days early. I also find that the front of the prescription, the back of the prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the prescription early. GX 36, at 1–2, 6–7; Tr. 1236, 1237, 1245.

In each of the next seven months, M.A. presented to Trinity II prescriptions from the same Genesis Medical Clinic for Dilaudid 8 mg in the same quantities and with the same dosing instructions; and in each instance, I find that Trinity II filled those prescriptions six days early. GX 36, at 1–2, 6–9; Tr. 1245–49 (prescription for 33-day supply that Trinity II filled six days early on June 25, 2013); GX 36, at 1–2, 8–10; Tr. 1249–51 (prescription for 33-day supply that Trinity II filled six days early on July 23, 2013); GX 36, at 1–2, 10–11; Tr. 1251–54 (prescription for 33-day supply that Trinity II filled six days early on August 20, 2013); GX 36, at 1–2, 11, 13–14; Tr. 1254–55 (prescription for 33-day supply that Trinity II filled six days early on September 17, 2013); GX 36, at 1–3, 13–16; Tr. 1256–58 (prescription for 33-day supply that Trinity II filled six days early on October 15, 2013); GX 36, at 1, 3, 15–18; Tr. 1259–61 (prescription for 33-day supply that Trinity II filled six days early on November 12, 2013); GX 36, at 1, 3, 17–20; Tr. 1262–64 (prescription for 33-day supply that Trinity II filled six days early on December 10, 2013). When considering the cumulative effect of these consecutive monthly early fills from May 2013 to December 2013, I find that Trinity II filled prescriptions for M.A. that resulted in the filling of 50 days of extra hydromorphone 8 mg.

As with the earlier prescription that Trinity II filled for M.A. on May 28, 2013, I find that the prescriptions (front or back), patient profile, and dispensing log do not reflect any notes or comments, much less documentation, explaining how Trinity II resolved these early refill red flags over the seven subsequent months. *See* GX 36, at 1–3, 4–11, 13–20; Tr. 1236–37, 1245, 1248, 1251, 1253, 1255, 1258, 1261, 1263. Professor Doering testified that, because all of these early fills were well beyond three days early, Trinity II should have identified these early fills as red flags during the drug utilization review process to avoid drug abuse, overuse or misuse. Tr. 1240–41, 1245, 1248–49, 1251, 1253–54, 1255, 1256, 1258, 1261, 1263–64. He further testified that Trinity II's decision to fill these prescriptions without resolving these red flags was inconsistent with Florida's standard of care, not in the usual course of professional practice, and did not reflect the proper exercise of the pharmacist's corresponding responsibility. *Id.*

For a third customer, J.G., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that Trinity II filled early or refilled early prescriptions issued to J.G. at least seven times—one time for a prescription of lorazepam 2 mg, and six times for prescriptions of alprazolam 2 mg, both of which are schedule IV controlled substances. GX 39; Tr. 1364–84. Regarding the lorazepam prescription, the Government introduced evidence that on May 29, 2012, Trinity II filled a prescription issued by physician G.C. to customer J.G. for 30 pills of lorazepam 2 mg, and with directions from the prescribing physician for J.G. to ''[t]ake ½ [one-half of one] tablet(s) . . ., 2 times per day, for 30 days.'' GX 39, at 1–2, 4; Tr. 1365–66. Hence, the 30 pills prescribed to be taken at the rate of one pill per day constitute a 30-day supply that should have lasted J.G. until at least June 28, 2012. *Id.* Nevertheless, on June 19, 2012, Trinity II then filled another prescription from the same prescribing physician for another 30 pills of lorazepam 2 mg with the same instructions—one pill per day. GX 39, at 1–2, 4–5; Tr. 1366–70. Thus, I find that when Trinity II filled this second prescription on June 19, 2012, Trinity II filled it nine days early. *Accord* Tr. 1367. I also find that the front of the prescription, the back of the prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the prescription early. GX 39, at 1–2, 5; Tr. 1364–65, 1369.

With respect to the alprazolam prescriptions for J.G., the Government introduced evidence that on September 18, 2012, Trinity II filled a prescription issued by physician G.C. to customer J.G. for 30 pills of Xanax 2 mg, which is the brand name for alprazolam 2 mg, that could be refilled twice and with directions from the prescribing physician for J.G. to ''[t]ake ½ [one-half of one] tablet(s) . . ., 2 times per day, for 30 days, as needed for anxiety.'' GX 39, at 1–2, 6; Tr. 1370–71. Hence, the 30 pills prescribed to be taken at the rate of one pill per day constitute a 30-day supply that should have lasted J.G. until at least October 18, 2012 (assuming J.G. needed to take it every day for 30 days). *Id.* Nevertheless, the dispensing log and patient profile show that on October 10, 2012, Trinity II then refilled the prescription for another 30 pills of alprazolam 2 mg. GX 39, at 1–2, 6; Tr. 1371–73. Thus, I find that when Trinity II refilled this prescription on October 10, 2012, Trinity II refilled it eight days early. *Accord* Tr. 1372. The dispensing log and patient profile also establish that on October 29, 2012, Trinity II refilled the prescription again for another 30 pills of alprazolam 2 mg. GX 39, at 1–2, 6; Tr. 1373. Thus, I find that when Trinity II refilled this prescription on October 29, 2012, Trinity II refilled it 10 days early because the earlier refill should have lasted until November 8, 2012. *Accord* Tr. 1374. I also find that the front of the original prescription, the back of the original prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II refilled the prescription early on October 10 and October 29, 2012. GX 39, at 1–2, 6; Tr. 1373.

On February 26, 2013, Trinity II filled another prescription issued by physician G.C. to customer J.G. for 30 pills of alprazolam 2 mg (a 30-day supply), even though the dispensing log and J.G.'s patient profile show that Trinity II had already filled a 30-day supply of alprazolam 2 mg for J.G. on February 14, 2013.[25] GX 39, at 1–2, 8–9; Tr. 1375–77. I find that when Trinity II filled the February 26, 2013 prescription, Trinity II filled it at least 17 days early because the February 14, 2013 refill should have lasted J.G. until at least March 15, 2013. *Accord* Tr. 1377. Over the next two months, Trinity II then refilled this prescription twice (on March 18, 2013 and on April 12,

[24] If M.A. took the tablets every six hours as instructed, then the daily tablet dosage would be four tablets/day; if M.A. took the tablets every five hours as alternatively instructed, then the daily dosage would be 4.8 tablets per day. *Accord* Tr. 1239–40. For purposes of this early fill fact-finding, I will round up to and use the rate of five tablets/day—a calculation that offers Trinity II the greatest lenity for purposes of calculating an early fill.

[25] The February 14, 2013 filling by Trinity II was the second refill of a December 18, 2012 prescription (also issued by physician G.C.) that J.G. had filled at Trinity II on December 18, 2012. *See* GX 39, at 1–2, 8.

2013), and in each instance I find that Trinity II refilled it 10 and five days early, respectively. GX 39, at 1–2, 9; Tr. 1377–79 (prescription for 30-day supply that Trinity II filled 10 days early on March 18, 2013); GX 39, at 1–2; Tr. 1377–79 (prescription for 30-day supply that Trinity II filled five days early on April 12, 2013). I find that the front of the original prescription, the back of the original prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the February 26, 2013 prescription early, and twice refilled that prescription early on March 18 and April 12, 2013. GX 39, at 1–2, 8–9; Tr. 1373, 1379.

In addition, even though Trinity II filled a new prescription for a 30-day supply of alprazolam 2 mg issued by physician G.C. to J.G. on May 14, 2013 that should have lasted J.G. until at least June 12, 2013, Trinity II refilled this prescription with another 30-day supply of alprazolam 2 mg on June 6, 2013. GX 39, at 1, 3, 10; Tr. 1380–83. Thus, I find that the June 6, 2013 refill by Trinity II was six days early. *Accord* Tr. 1383. As with the other prescriptions and early fills and refills related to J.G., I find that the front of the original prescription, the back of the original prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled and refilled the prescription early. GX 39, at 1, 3, 10; Tr. 1383.

With respect to all the early fills and refills by Trinity II with respect to lorazepam 2 mg and alprazolam 2 mg prescriptions issued by physician G.C. to J.G., Professor Doering testified that, because all of these early fills and early refills were well beyond three days early, Trinity II should have identified them as red flags during the drug utilization review process to avoid drug abuse, overuse or misuse. Tr. 1369, 1372, 1374, 1377, 1383. He further testified that Trinity II's decision to fill these prescriptions without resolving these red flags was inconsistent with Florida's standard of care, not in the usual course of professional practice, and did not reflect the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1370, 1373–74, 1377, 1379, 1384.

For a fourth customer, L.H., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that Trinity II filled early at least 2 prescriptions issued to L.H. for hydromorphone 8 mg, a schedule II controlled substance, under the brand name Dilaudid. GX 40; Tr. 1384–94. The Government introduced evidence that on June 5, 2012, Trinity II filled a prescription issued by physician J.I. at the Creative Health Center to customer L.H. for 180 pills of ''Dilaudid Tablet 8 mg,'' and with directions from the prescribing physician for L.H. to take one tablet by mouth every four hours as needed. GX 40, at 1, 3, 12–13; Tr. 1387–88. Hence, the 180 pills prescribed to be taken at the rate of six pills per day constitute a 30-day supply that should have lasted L.H. until at least July 5, 2012 (assuming L.H. needed to take every dose, every day). *Accord* Tr. 1392. Nevertheless, on June 28, 2012, Trinity II filled another prescription (dated June 18, 2012 from another prescriber, E.P. at Morton Plant Hospital) [26] for another 84 pills of Dilaudid 8 mg with instructions to take one tablet every 4 hours for 14 days. GX 40, at 1, 4, 14–15; Tr. 1388–89, 1392. Thus, I find that when Trinity II filled this second prescription on June 28, 2012, Trinity II filled it at least seven days early. *Accord* Tr. 1389. On July 3, 2012, Trinity II filled a third prescription, this time from physician J.I. (who issued the June 5, 2012 prescription) to L.H., for another 96 pills of Dilaudid 8 mg with instructions to take one tablet every four hours for 16 days. GX 40, at 1, 4, 16–17; Tr. 1392–93. As a result, I find that when Trinity II filled this third prescription on July 3, 2012, Trinity II filled it nine days early because the June 28, 2012 fill should have lasted L.H. until July 12, 2012. *Accord* Tr. 1393. I also find that the front of these prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled these prescriptions early. GX 40, at 1–4, 12–17; Tr. 1391, 1393–94.

Therapeutic Duplication

The Government introduced prescription evidence at the hearing to show that Trinity II failed to resolve the red flag of ''therapeutic duplication'' with respect to one of its customers, R.H., identified in the first charge of the Show Cause Order and whose patient records the Government had requested pursuant to its December 4, 2014 subpoena. The Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that Trinity II filled two therapeutically duplicative prescriptions issued by physician J.I. for R.H. on December 2, 2013. The first prescription was for 120 tablets of hydromorphone 8 mg, an immediate release opioid under the Dilaudid brand name, with directions to ''Take 1 Tablet by Mouth Every 6 Hours As Needed.'' GX 63, at 1, 4–6; Tr. 1560–61. The second prescription was for 120 tablets of oxycodone 30 mg, another immediate-release opiate, with the same directions to take one tablet every six hours as needed. GX 63, at 1, 4, 7–8; Tr. 1561–63. I find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled these two schedule II opiate prescriptions on December 2, 2013. GX 63, at 1, 4–8; *accord* Tr. 1563–64.

According to Professor Doering, when a Florida pharmacist receives two prescriptions from the same individual for two different opioids, both with the same or similar directions for use, and those two are immediate release dosage forms, the standard of care requires the pharmacist to identify that as a red flag and to initiate steps to resolve that red flag. Tr. at 2111. However, Professor Doering also testified that, in his opinion, the therapeutic duplication of hydromorphone and oxycodone with respect to R.H., or any other pharmacy customer, is not a resolvable flag. *Id.* at 1520, 1563. ''[P]harmacists would fall below the standard of care to dispense these two [opioids] together because of the inherent dangers that go along with giving both of these very potent narcotic analgesics . . . [t]hat could in fact be used together, at the same time.'' *Id.* at 1520. He also testified that therapeutic duplication should be identified during the drug utilization review process. *Id.* at 1526, 1541–42. Professor Doering testified that Trinity II's filling of these prescriptions for R.H. were inconsistent with the standard of care, not filled in the usual course of professional practice, and inconsistent with the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1563–64.

[26] The fact that the same patient, L.H., went to two different prescribers in the same month for the same schedule II drug also demonstrates the appearance of doctor shopping—another red flag of overuse or misuse. Professor Doering testified that this too should have been identified during the drug utilization process as indicative of overuse, misuse, or abuse. Tr. 1390. There is no evidence in the record that Trinity II attempted to resolve this red flag before filling the second of these prescriptions on June 28, 2012. Professor Doering also testified that Trinity II's decision to fill the June 18, 2012 prescription on June 28, 2012 without resolving these red flags was inconsistent with Florida's standard of care, not in the usual course of professional practice, and did not reflect the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1391.

Two Prescriptions for the Same Drug on the Same Date

The Government introduced prescription evidence at the hearing to show that Trinity II failed to resolve the red flag of receiving two prescriptions for the same drug on the same date from the same customer (J.K.)—another form of ''therapeutic duplication.'' The customer, J.K., was identified in the first charge of the Show Cause Order, and the Government had requested his patient records pursuant to its December 4, 2014 subpoena. The Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that Trinity II filled two prescriptions issued by physician M.L. for J.K. on the same day—December 4, 2013. The first prescription was for 100 tablets of hydromorphone 8 mg, under the Dilaudid brand name, with instructions that the patient take one tablet every four to six hours—a 16-day supply. GX 69, at 1, 3–5; Tr. 1584–86. The second prescription was for 50 tablets of Dilaudid 8 mg with the same directions for use—an eight-day supply. GX 69, at 1, 3, 6–7; Tr. 1584–86. The dispensing log also shows that J.K. paid ''cash'' for these two prescriptions, just as he had for every other prescription that Trinity II had filled for J.K. between March 5, 2012 and February 3, 2014. GX 69, at 1. According to Professor Doering, two prescriptions for the same medication filled on the same date for the same customer is an unresolvable red flag of diversion that should have been identified during the drug utilization process. Tr. 1568, 1586–87. Regardless of whether it is resolvable, I find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled these two prescriptions for the same drug and for the same customer (J.K.) on December 4, 2013. GX 69, at 1, 3–7; *accord* Tr. 1584–85, 1587.

Distances

The Government introduced prescription evidence at the hearing to show that Trinity II failed to resolve the red flag of customers who had allegedly travelled unusually long distances and/or had taken suspicious routes for the purpose of obtaining, presenting, and filling prescriptions for controlled substances. Specifically, the Government introduced evidence exhibiting this red flag with respect to four of Trinity II's customers identified in the first charge of the Show Cause Order and whose patient records the Government had requested pursuant to its December 4, 2014 subpoena.

For one such customer, S.S., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that on June 5, 2013, Trinity II filled a prescription for S.S. for 150 tablets of hydromorphone 8 mg, with instructions to take one tablet every four hours as needed for breakthrough pain. GX 44, at 1, 2, 8–9; Tr. 1676–80. Although the front of the prescription did not include S.S.'s address,[27] the other prescription evidence—the fill sticker attached to the back of the prescription, the dispensing log, and the patient profile—all show S.S.'s address to be in Orange Park, Florida, which is a city located near Jacksonville, Florida. GX 44, at 1, 2, 9; Tr. 1680.

It is undisputed that Trinity II is located in Clearwater, Florida, and that both the front of the prescription and Trinity II's dispensing log show that the prescribing physician's address was in Tampa, Florida. GX 44, at 1, 8. The Government also introduced Google Maps evidence showing that S.S. would have traveled: (1) 175 miles from his home address to the prescribing physician, (2) about 23 miles from there to Trinity II, and then (3) 199 miles from Trinity II back to his home address. GX 44, at 4–7; Tr. 1681–83. Indeed, S.S. would have to travel across the entire state of Florida—from the Jacksonville area on the East Coast of Florida to the greater Tampa Bay area on the West Coast of Florida—to obtain and to fill this schedule II prescription. Thus, I find that S.S. would have to travel approximately 397 miles roundtrip to obtain the June 5, 2013 hydromorphone 8 mg prescription from his physician, and that S.S. would have to travel at least 198 miles after picking up his prescription to return home. *See id.* I also find that Trinity II knew the addresses of both S.S. and his prescribing physician. *See* GX 44, at 1, 2, 8–9. I further find that the front of the prescription, the back of the prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the prescription given the unusual distances S.S. traveled to obtain and to fill this prescription. GX 44, at 1, 2, 8–9; *accord* Tr. 1676–77, 1685, 2113.

Although Professor Doering testified that there is no magical ''distance cutoff'' in determining when a particular distance constitutes a red flag, Tr. 1692–93, in response to hypothetical questions, he did testify that when a pharmacist in Florida receives a prescription for a controlled substance from a customer whose address is, for example, 75 miles away, ''[t]he standard of care calls for the pharmacist to identify that as a red flag and to initiate steps that may resolve that red flag'' and to document any such resolution. Tr. 2112. He testified that this standard of care ''requires the pharmacist to find out the address of where the person resides'' and ''to ask the patient for that address information'' by, for instance, ''ask[ing] for identification.'' Tr. 2119–20; *see also id.* at 1684. He further testified that in his opinion the distance red flag for this prescription should have been identified as part of the drug utilization process, and the fact that S.S. also paid cash [28] raised an additional red flag. Tr. 1684, 1686 (''patients paying cash for their prescriptions is a recognized red flag''), 1696. As a result, Professor Doering testified that filling this prescription was inconsistent with Florida's standard of care, that it was not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1701–02.[29]

For a second customer, D.W., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that on March 8, 2012, Trinity II filled two prescriptions for D.W.—one for 120 tablets of oxycodone 30 mg with

[27] *See* GX 44, at 8. The Show Cause Order alleges that Trinity II's filling of this prescription also constitutes an independent violation of 21 CFR 1306.05, which requires, *inter alia,* all prescriptions for controlled substances to bear the full name and address of the patient and imposes a corresponding liability ''upon the pharmacist . . . who fills a prescription not prepared in the form prescribed by DEA regulations.'' *Id.* at § 1306.05(a), (f). As set forth more fully *infra,* I agree.

[28] Trinity II's own dispensing report states that S.S. paid ''cash'' for the July 5, 2013 prescription, and I find that S.S. did indeed pay for this prescription (rather than a third-party payer). *See* GX 44, at 1. The prescription evidence also does not reflect that Trinity II ever attempted to resolve the ''paying cash'' red flag. Tr. 1686.

[29] As discussed *infra* in the context of cocktail prescriptions, on June 27, 2013 and July 23, 2013, Trinity II also filled prescriptions for S.S. on each date for carisoprodol 350 mg, hydromorphone 8 mg and Xanax 2 mg. GX 44, at 1, 2, 14–19, 22–27; Tr. 1697–98; 1703–05. I also find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments whatsoever explaining why Trinity II filled these prescriptions given the unusual distances S.S. traveled to obtain and to fill these prescriptions. GX 44, at 1, 2, 14–19, 22–27; *accord* Tr. 1700, 1705. Professor Doering also testified that filling the June 27, 2013 and July 23, 2013 prescriptions were inconsistent with Florida's standard of care, that they were not filled in the usual course of professional practice or in the proper exercise of the pharmacist's corresponding responsibility. Tr. 1701, 1705.

ginger [30] (with instructions to take one capsule four times daily) and the other for 30 tablets of carisoprodol 350 mg under the brand name Soma (with instructions to take one tablet every night). GX 45, at 1, 2, 8–11; Tr. 1710, 1713–14.

According to the front of the oxycodone prescription,[31] the fill sticker attached to the back of both prescriptions, the dispensing log, and the patient profile, D.W.'s address was in Wellborn, Florida. GX 45, at 1, 2, 8, 9, 11; Tr. 1708–09. It is undisputed that the front of both prescriptions and Trinity II's fill stickers show that the prescribing physician's address was in Tampa, Florida. GX 45, at 8–11; Tr. 1709–1712. The Government also introduced Google Maps evidence showing that D.W. would have traveled: (1) 184 miles from his home address to the prescribing physician, (2) about 18 miles from there to Trinity II, and then (3) 202 miles from Trinity II back to his home address. GX 45, at 4–7.

Thus, I find that D.W. would have to travel approximately 404 miles roundtrip to obtain the March 8, 2012 oxycodone and Soma prescriptions from his prescribing physician, fill them at Trinity II, and then return home. *See id.* I also find that Trinity II knew the address of both D.W. and his prescribing physician. *See* GX 45, at 1, 2, 8–11. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the prescriptions given the unusual distances D.W. traveled to obtain and to fill these prescriptions. GX 45, at 1, 2, 8–11; *accord* Tr. 1712.

Professor Doering testified that in his opinion ''[t]he long distance between the patient's home and the doctor's office'' was a red flag that was presented by D.W.'s prescriptions and which Trinity II should have identified as part of the drug utilization process. Tr. 1712. As a result, Professor Doering testified that filling these prescriptions was inconsistent with Florida's standard of care, that they were not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1712–13.

On April 5, 2012 and on May 3, 2012, Trinity II also filled prescriptions for D.W. for 120 tablets of oxycodone 30 mg with ginger each time—with the same instructions and from the same prescribing physician as in the March 8, 2012 oxycodone prescription that Trinity II had filled for D.W. GX 45, at 1, 2, 12–13, 16–17; Tr. 1714–17. On April 19, 2012 and May 11, 2012, Trinity II filled prescriptions for D.W. for 30 tablets of Soma 350 mg each time—again, with the same instructions and from the prescribing physician as the Soma prescription that Trinity II had filled for D.W. on March 8, 2012. GX 45, at 1, 2, 14–15, 18–19; [32] Tr. 1716, 1718. As with the March 8, 2012 prescriptions for oxycodone and Soma, I find that D.W. would have traveled approximately 404 miles roundtrip to obtain the April 5, 2012 and May 3, 2012 oxycodone prescriptions, as well as the April 19, 2012 and May 11, 2012 Soma prescriptions, from his prescribing physician, and that D.W. would have traveled at least 202 miles after picking up his prescription to return home. *See* GX 45, at 4–7. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the prescriptions given the unusual distances D.W. traveled to obtain and to fill these prescriptions. GX 45, at 1, 2, 12–19; *accord* Tr. 1715, 1717.

Professor Doering testified that these four prescriptions also presented the same unusual distance red flag that Trinity II should have identified as part of the drug utilization process. *See* Tr. 1715–18. He also testified that, unlike the March 8, 2012 oxycodone and Soma prescriptions that Trinity II had filled on the same day, the fact that D.W. had to make two separate trips in April and in May to get the same prescriptions further emphasized the significance of the distance red flag of diversion. *See id.* at 1716 (''it sort of adds emphasis to that long distance thing because that meant two trips instead of one''). As a result, Professor Doering testified that filling these prescriptions was inconsistent with Florida's standard of care, that they were not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1715–19.

For a third customer, C.V., the Government introduced a dispensing log, patient profile, and the front and back of a prescription to establish that on May 10, 2012, Trinity II filled a prescription for C.V. for 90 tablets of hydromorphone 8 mg, under the brand name Dilaudid, with instructions to take one tablet every eight hours. GX 46, at 1–2, 7–8; Tr. 1719–21. According to the front of the prescription, the fill sticker attached to the back of the prescription, the dispensing log, and the patient profile, C.V.'s address was in Port Charlotte, Florida. GX 46, at 1–2, 7–8; Tr. 1720–21. It is undisputed that the front of the prescription and Trinity II's fill stickers show that the prescribing physician's address was in Tampa, Florida. GX 46, at 7–8; Tr. 1720–21. The Government also introduced Google Maps evidence showing that C.V. would have traveled: (1) 105 miles from his home address to the prescribing physician, (2) about 22 miles from there to Trinity II, and then (3) 97 miles from Trinity II back to his home address. GX 46, at 3–6. Thus, I find that C.V. would have to travel approximately 224 miles roundtrip to obtain the May 10, 2012 prescription from his prescribing physician, fill it at Trinity II, and then return to his home. *See id.* I also find that Trinity II knew the address of both C.V. and his prescribing physician, and that C.V. paid ''cash'' for the prescription. *See* GX 46, at 1–2, 7–8. I further find that the front of the prescription, the back of the prescription bearing the fill sticker, the patient profile, and the dispensing log do not reflect any notes or comments whatsoever explaining why Trinity II filled the prescription given the unusual distances C.V. traveled to obtain and to fill this prescription (or the fact that C.V. paid ''cash'' to fill it). *Id.; accord* Tr. 1719, 1722.

Professor Doering testified that this prescription presents ''the distance red flag'' that Trinity II should have identified as part of the drug utilization process. *See* Tr. 1722. As a result, he testified that filling this prescription was inconsistent with Florida's standard of care, that it was not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1722–23.

For a fourth customer, D.E., the Government introduced a dispensing log, patient profile, and the front and back of a prescription to establish that on June 13, 2013 and on July 3, 2013, Trinity II filled two prescriptions for D.E. for 120 tablets of hydromorphone 8 mg for each prescription, both under the brand name Dilaudid, with the same

[30] Professor Doering testified that physicians will issue a prescription calling for compounding with ginger ''to deter one from injecting the drug intravenously'' because ginger will ''make it sting and burn if someone were to try to inject it intravenously.'' Tr. 1265. It is also a deterrent to ''nasal insufflation'' (snorting) of the drug because ''it would be [an] irritant to the lining of the nasal mucous membranes.'' *Id.* at 1558.

[31] The front of the second prescription for Soma did not bear the patient's address. *See* GX 45, at 10.

[32] And like the March 8, 2012 Soma prescription to D.W., the front of these Soma prescriptions lacked the patient's address. *See id.*

instructions to take one tablet every six hours for 30 days. GX 48, at 1–2, 8, 10–11; Tr. 1724–25, 1728. According to the front of the prescriptions, the fill stickers attached to the back of the prescriptions, the dispensing log, and the patient profile, D.E.'s address was in Brooksville, Florida. GX 48, at 1–2, 8; Tr. 1724, 1728–29. It is undisputed that the front of the prescriptions show that the prescribing physician's address was in Tampa, Florida. GX 48, at 8, 10; Tr. 1725. The Government also introduced Google Maps evidence showing that D.E. would have traveled: (1) 44 miles from his home address to the prescribing physician,[33] (2) about 20 miles from there to Trinity II, and then (3) 55 miles from Trinity II back to his home address. GX 48, at 3–7. Thus, I find that D.E. would have to travel approximately 119 miles roundtrip to obtain the June 13, 2013 prescription from his prescribing physician, fill it at Trinity II, and then return to his home. *See id.* I also find that Trinity II knew the address of both D.E. and his prescribing physician, and that D.E. paid ''cash'' for the prescription. *See* GX 46, at 1–2, 8, 10. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled the prescription given the unusual distances D.E. traveled to obtain and to fill this prescription (or the fact that D.E. paid ''cash'' to fill it). *Id.; accord* Tr. 1727, 1732.

Moreover, I find that when Trinity II filled D.E.'s Dilaudid prescription on July 3, 2013, Trinity II filled that prescription early—yet another red flag. Specifically, D.E.'s prescription that Trinity II filled on June 13, 2013 was for 120 tablets of Dilaudid 8 mg and instructions for D.E. to take one tablet every six hours for 30 days. GX 48, at 1–2, 8; Tr. 1729–30. Hence, the 120 pills prescribed to be taken at the rate of four pills per day constitute a 30-day supply that should have lasted D.E. until at least July 12, 2013. Nevertheless, on July 3, 2013, Trinity II filled another prescription for another 120 pills of Dilaudid 8 mg with instructions to take one tablet every 6 hours for 30 days. GX 48, at 1–2, 10–11; Tr. 1731. Thus, I find that when Trinity II filled this second prescription on July 3, 2013, Trinity II filled it 9 days early. *Accord* Tr. 1731. I also find that the front of these prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled this prescription early. GX 48, at 1–2, 8, 10–11; Tr. 1731–32.

Professor Doering testified that this prescription presents ''[t]he combination of the red flags. It's too early and the distance red flag.'' Tr. 1731, 1727 (''the distance is a long ways. Which in the judgment of my opinion, the pharmacist, it should raise a red flag.''). As a result, he testified that filling these prescriptions was inconsistent with Florida's standard of care, that they were not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1727–28, 1732.

Cocktail Prescriptions

The Government introduced prescription evidence at the hearing to show that Trinity II failed to resolve the red flag of ''cocktail prescriptions,'' which the Government alleged occurs when a customer presents multiple prescriptions that would provide the same patient an opioid, a benzodiazepine, and a muscle relaxer. Specifically, the Government introduced evidence exhibiting this red flag with respect to three of Trinity II's customers identified in the first charge of the Show Cause Order and whose patient records the Government had requested pursuant to its December 4, 2014 subpoena.

For one such customer, S.S., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that on June 27, 2013, Trinity II filled three prescriptions issued by the same prescribing physician for him: (1) 150 tablets of hydromorphone 8 mg (with instructions to take one tablet ''every 4 hours as needed [for] breakthrough pain''); (2) 60 tablets of carisoprodol 350 mg, under the brand name Soma (with instructions to take one tablet ''twice daily as needed''); and (3) 45 tablets of alprazolam 2 mg, under the brand name Xanax (with instructions to take half of a tablet ''three times daily as needed for anxiety'') . GX 44, at 1, 2, 14–19; Tr. 1697–98. On July 23, 2013, Trinity II filled for S.S. the same three prescriptions from the same prescribing physician for hydromorphone 8 mg, carisoprodol 350 mg, and alprazolam 2 mg in the same amounts and with the same dosage instructions as for the June 27, 2013 prescriptions. GX 44, at 1, 2, 22–27; Tr. 1703–05. Thus, I find that the evidence establishes that Trinity II twice (on June 27, 2013 and on July 23, 2013) filled prescriptions for S.S. for the same combination of controlled substances—an opioid (hydromorphone), a benzodiazepine (alprazolam), and a muscle relaxant (carisoprodol). GX 44, at 1, 2, 14–19, 22–27. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled this combination, or cocktail, of prescriptions. *Id.; accord* Tr. 1700, 1705.

For a second customer, J.Ha., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that on March 7, 2012, Trinity II filled three prescriptions issued by the same prescribing physician for her: (1) 120 tablets of oxycodone 30 mg (with instructions to take 1 tablet every 6 hours as needed); (2) 30 tablets of carisoprodol 350 mg, under the brand name Soma (with instructions to take 1 tablet every night); and (3) 30 tablets of alprazolam 2 mg, under the brand name Xanax (with instructions to take one tablet daily). GX 73, at 1, 2, 4–9; Tr. 1594–98. On May 3, 2012 and May 31, 2012, Trinity II filled for J.Ha. prescriptions from the same prescribing physician for oxycodone 30 mg, carisoprodol 350 mg, and alprazolam 2 mg in the same amounts and with the same dosage instructions [34] as for the March 7, 2012 prescriptions. GX 73, 1–2, 10–21; Tr. at 1605–12. Thus, I find that the evidence establishes that on three separate occasions Trinity II filled for J.Ha. prescriptions for the following combination of controlled substances—an opioid (oxycodone), a benzodiazepine (alprazolam), and a muscle relaxant (carisoprodol). GX 73, at 1, 2, 4–21. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled this

[33] The street address of the prescribing physician reflected on the front of the prescriptions was different from what was shown on Trinity II's dispensing report and fill sticker; however, the identity and the city (Tampa, Florida) of the physician was the same in every address. *Compare* GX 46, at 1 *with id.* at 8, 10. Although the distance calculation from the same city (Tampa) would have been very similar using either Tampa address, I find that the address on the prescriptions themselves is the most reliable evidence of the prescribing physician's address because it came directly from the physician. I find that the calculation of the distances to and from D.E.'s prescribing physician—as reflected in the Government's Google Maps evidence—is based, appropriately, on the street address reflected on the front of the June 13, 2013 and July 3, 2013 prescriptions. *Id.* at 4.

[34] The fill sticker for the May 31, 2012 oxycodone 30 mg prescription for J.Ha. reflected the additional phrase ''for pain'' to the otherwise identical instruction that J.Ha. had received on the March 7, 2012 and May 3, 2012 prescriptions to take one tablet of oxycodone 30 mg every six hours as needed. GX 73, at 17.

combination, or cocktail, of prescriptions. *Id.; accord* Tr. 1594, 1597, 1604, 1608, 1612.

For a third customer, R.Ha., the Government introduced a dispensing log, patient profile, and the front and back of prescriptions to establish that on March 7, 2012, Trinity II filled the following three prescriptions issued by the same prescribing physician for him: (1) 180 tablets of oxycodone 30 mg (with instructions to take one tablet every four to six hours as needed); (2) 60 tablets of carisoprodol 350 mg, under the brand name Soma (with instructions to take one tablet twice daily); and (3) 30 tablets of alprazolam 1 mg, under the brand name Xanax (with instructions to take one tablet every night). GX 74, at 1, 2, 4–9; Tr. 1598–1600. On May 3, 2012 and May 31, 2012, Trinity II filled for R.Ha. the same three prescriptions from the same prescribing physician for oxycodone 30 mg, carisoprodol 350 mg, and alprazolam 2 mg in the same amounts and with the same dosage instructions [35] as for the March 7, 2012 prescriptions. GX 74, 1–2, 10–21; Tr. at 1606–08, 1611–12. Thus, I find that the evidence establishes that on three separate occasions Trinity II filled for R.Ha. prescriptions for the following combination of controlled substances—an opioid (oxycodone), a benzodiazepine (alprazolam), and a muscle relaxant (carisoprodol). GX 74, at 1, 2, 4–21. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled this combination, or cocktail, of prescriptions. *Id.; accord* Tr. 1597, 1604, 1608, 1612.

Professor Doering testified that the combination of these three drugs that Trinity II filled for customers like S.S., J.Ha., and R.Ha. constituted ''the unholy trinity'' or ''cocktail prescriptions'' that present a ''drug-drug interaction'' red flag because they are ''symbolic of drug interactions that might cause harm to the patient.'' Tr. 894–96. He emphasized that this ''combination of drugs'' risks harm to the patient because they ''have additive central nervous system depressant properties.'' *Id.* at 1698, *see also id.* at 1603 (''that's also the red flag of the so called accumulative additive effects of drugs with CNS depressant properties''). In his opinion, this is a red flag that Trinity II should have identified and resolved during the drug utilization review process with respect to customers S.S., J.Ha., and R.Ha. *Id.* at 1446, 1448.[36] As a result, he testified that filling these cocktail prescriptions without resolving the drug-drug interaction red flag was inconsistent with Florida's standard of care, that they were not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1604–05, 1609, 1612–13, 1701, 1705.

Pattern Prescribing to Patients With the Same Last Name and Address

The Government introduced prescription evidence at the hearing to show that Trinity II failed to resolve the red flag of ''pattern prescribing'' reflecting a lack of individualized drug therapy, and which the Government alleges occurs whenever two related individuals present prescriptions issued (1) by the same prescribing physician, (2) on the same day, and (3) for the same drugs. Specifically, the Government introduced evidence exhibiting this red flag with respect to two sets of Trinity II's customers, in which each set of two customers shared a last name and home address, and who were also identified in the first charge of the Show Cause Order and whose patient records the Government had requested pursuant to its December 4, 2014 subpoena.

For the first set of customers, J.Ha. and R.Ha., and as noted above in the ''cocktail prescription'' fact findings, the Government introduced dispensing logs, patient profiles, and the front and back of prescriptions to establish that on March 7, 2012, May 3, 2012, and May 31, 2012, J.Ha. and R.Ha. presented and Trinity II filled three prescriptions for the same controlled substances on each date: (1) Oxycodone, (2) carisoprodol, and (3) alprazolam. GX 73, at 1, 2, 4–21; GX 74, 1, 2, 4–21. The same evidence also shows that J.Ha. and R.Ha. share the same: (1) Home address in Clearwater, Florida; (2) last name; and (3) prescribing physician. *Id.* As a result, I find that on three separate occasions, the same prescribing physician issued prescriptions for the same combination of drugs (oxycodone, carisoprodol, and alprazolam) to J.Ha. and R.Ha. on the same dates. GX 73, at 1, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20; GX 74, at 1, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20. In addition, I find that on March 7, 2012, May 3, 2012, and May 31, 2012, Trinity II filled each of these prescriptions even though Trinity II knew that they came: (1) From the same prescribing physician; (2) for the same combination of drugs; and (3) for patients with the same last name and same home address. GX 73, at 1, 2, 5, 7, 9, 11, 13, 15, 19, 21; GX 74, at 1, 2, 5, 7, 9, 11, 13, 15, 19, 21. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II nonetheless filled these prescriptions. *Id.; accord* Tr. 1594, 1597, 1604, 1608, 1612.

For the second set of customers, M.W. and J.W., the Government introduced dispensing logs, patient profiles, and the front and back of prescriptions to establish that on November 20, 2013 and on December 18, 2013, M.W. and J.W. presented and Trinity II filled identical prescriptions for 150 capsules of oxycodone 30 mg compounded with ginger, with the same dosage instructions to take one capsule every four to six hours for pain.[37] GX 75, at 1, 3, 4–7; GX 76, at 1, 3, 4–7. The same evidence also shows that M.W. and J.W. share the same: (1) Home address in Clearwater, Florida; (2) last name; and (3) prescribing physician. *Id.* As a result, I find that on two separate occasions, the same prescribing physician issued prescriptions for the same controlled substance (oxycodone) to M.W. and J.W. on November 20, 2013 and on December 18, 2013. GX 75, at 1, 3, 4, 6; GX 76, at 1, 3, 4, 6. In addition, I find that on those same dates Trinity II filled each of these prescriptions, even though Trinity II knew that they came: (1) From the same prescribing physician; (2) for the same controlled substance; and (3) for patients with the same last name and home address. GX 75, at 1, 3, 5, 7; GX 76, at 1, 3, 5, 7. I further find that the front of the prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments whatsoever explaining why Trinity II nonetheless filled these

[35] The fill sticker for the May 3, 2012 and May 31 2012 alprazolam 1 mg prescriptions instructed R.Ha. to take one-half to 1 tablet every day as needed, which is slightly different from the instruction in the March 7, 2012 prescription to take one tablet every night. *Compare* GX 74, at 7 *with id. at* 13, 19. Professor Doering testified that, in his opinion, this was a labeling error. Tr. 1601–02.

[36] Professor Doering also testified that the fact that Trinity II filled the cocktail prescriptions for S.S. 14 days after the prescriptions were issued presented another red flag because patients who are legitimately ''in pain and or having symptoms that might require these medications[ ] will get the prescriptions filled soon after they're written.'' Tr. 1700; *compare* GX 44, at 14, 16, 18 (prescriptions dated June 13, 2013) *with id.* at 15, 17, 19 (corresponding fill stickers dated June 27, 2013). I find that the front of these prescriptions, the back of the prescriptions bearing the fill stickers, the patient profile, and the dispensing log do not reflect any notes or comments explaining why Trinity II filled this combination, or cocktail, of prescriptions 14 days after the prescriptions were issued. *Id.; accord* Tr. 1700.

[37] M.W.'s prescriptions also instructed a ''LIMIT [of] 5 [capsules] per day.'' GX 75, at 4, 6.

prescriptions. *Id.; accord* Tr. 1616, 1619–21, 1623.

Professor Doering testified that when two patients with the same last name and address, like J.Ha. and R.Ha. or M.W. and J.W., present prescriptions on the same day from the same prescribing physician for the same controlled substance and with the same dosage instructions, ''it's what some have come to call pattern prescribing.'' Tr. 1602–03; *see also id.* at 1608, 1612, 1620, 1623. In his opinion, this is a red flag that Trinity II should have identified and resolved during the drug utilization review process ''[b]y contacting the prescriber and/or discussing it with the patient'' before filling. *See id.* at 1603. As a result, he testified that filling these prescriptions without resolving the pattern prescription red flag was inconsistent with Florida's standard of care, that they were not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. *Id.* at 1604–05, 1609, 1612–13, 1620–21, 1623–24.

Controlled Substances Filled Before Authorized Date

At the hearing, the Government introduced into evidence copies of a dispensing log and the front and back of two prescriptions for controlled substances that the Government alleged Trinity II twice filled for customer D.G. before the date authorized by the prescribing physician and in violation of 21 CFR 1306.04(a), 1306.06, 1306.11, and 21 U.S.C. 829 as set forth in the third and fourth charges of the Show Cause Order. For example, the Government introduced a dispensing log and the front and back of a prescription dated November 15, 2013 showing that Trinity II filled a prescription for D.G. on November 20, 2013 for 7 patches of fentanyl-50 mcg/hr, a schedule II controlled substance, under the brand name Duragesic. GX 77, at 1, 6, 7; Tr. 1508–09, 1513–15. The front of the prescription, however, expressly instructed ''NO EXCEPTIONS DO NOT FILL UNTIL 12–06–2013.'' GX 77, at 6; Tr. 1514.

Although the CALJ did not recommend findings of fact related to the Government's allegations that Trinity II filled prescriptions early as set forth in the first two charges of the Show Cause Order, for this (third) charge of the Order, the CALJ did choose to recommend findings of fact. Specifically, he recommended that I find that Trinity II filled a prescription for a schedule II controlled substance for D.G. early because it was filled on November 20, 2013—contrary to the prescription's instruction that the prescription not be filled until December 6, 2013. R.D. at 48–49. I agree and make this finding of fact.

Similarly, the Government introduced the front and back of a prescription dated December 16, 2013 showing that Trinity II filled a prescription for D.G. on December 18, 2013 for 15 patches of fentanyl-50 mcg/hr under the brand name Duragesic. GX 77, at 8, 9; Tr. 1508–11. The Government also introduced a dispensing log showing that Trinity II filled the prescription on December 23, 2013. GX 77, at 1; Tr. 1511. The front of the prescription, however, expressly instructed ''NO EXCEPTIONS DO NOT FILL UNTIL 1–5–2014.'' GX 77, at 8; Tr. 1511–12. The CALJ recommended for this (fourth) charge of the Show Cause Order that I find that, regardless of whether Trinity II filled this prescription on December 18 or December 23, 2013, Trinity II nonetheless filled the prescription contrary to the prescribing physician's express instruction that the prescription not be filled until January 5, 2014. R.D. 48–49, 48 n. 114. I agree and make this finding of fact.

With respect to these two prescriptions filled by Trinity II, Professor Doering testified that filling these prescriptions before the date set forth in a ''DO NOT FILL UNTIL'' instruction was inconsistent with Florida's standard of care, that they were not filled in the usual course of professional practice, nor filled in the proper exercise of the pharmacist's corresponding responsibility. Tr. 1512, 1515–16.

Controlled Substances Filled in Stronger Concentration Than Authorized

At the hearing, the Government introduced into evidence copies of a dispensing log, patient profile, and the front and back of seven prescriptions for controlled substances that the Government alleged Trinity II filled for customer J.T. at dosages that were no less than five times stronger than authorized by the prescribing physician and in violation of 21 CFR 1306.06 and 1306.11 as set forth in the fifth charge of the Show Cause Order. For example, the Government introduced the front of a prescription dated July 11, 2013 showing that the prescribing physician issued to J.T. a prescription for 20 mg/5 ml of morphine liquid, which is a liquid dosage of morphine and a schedule II controlled substance, with instructions to take five milliliters every six hours for rescue pain. GX 35, at 40; Tr. 1394–96, 1412. However, the Government also introduced a dispensing log, patient profile, and the back of the same prescription to show that when Trinity II filled this prescription for J.T. on July 12, 2012, Trinity II filled the prescription for 20 mg/ml of morphine liquid—a concentration that is five times stronger than what the prescribing physician had authorized—and restating the same dosage directions to take five milliliters every six hours for pain. GX 35, at 1, 3, 41; Tr. 1396–98. The CALJ recommended that I find that, in fact, on July 12, 2013, Trinity II filled a prescription for J.T. for 20 mg/ml that was five times stronger than the authorized dosage. R.D. at 50. I agree and make this finding of fact.

The Government also introduced evidence at the hearing showing that Trinity II repeatedly filled prescriptions for J.T. for morphine liquid at the same concentration (20 mg/ml) that was either five or 15 times the prescribed concentration (20 mg/5 ml or 20 mg/15 ml) [38] on six other occasions—August 8, 2012, September 6, 2012, October 3, 2012, November 1, 2012, December 27, 2012, and January 25, 2012. GX 35, 1, 3, 52–53, 58–59, 66–67, 76–77, 84–87. The CALJ recommended that I find that, in fact, on each of these occasions Trinity II filled prescriptions for J.T. for 20 mg/ml and that this dosage was either five times or 15 times stronger than the authorized dosage.[39] R.D. at 50. I agree and make these fact findings.

[38] I agree with the CALJ that the prescribing physician's handwriting regarding the dosages for these prescriptions is not always clear because they appear to state either 20 mg/5 ml or 20 mg/15 ml. R.D. at 50. In the Show Cause Order, the Government alleged that the dosage for each of these prescriptions were for 20 mg/5 ml. ALJ Ex. 1b, at 15–16. However, in its Proposed Findings of Fact, the Government asked that the Agency find that all the prescriptions reflect a dosage instruction of 20 mg/5 ml except for the October 3, 2012 and November 1, 2012, prescriptions, which the Government claimed reflect a dosage instruction of 20 mg/15 ml. ALJ Ex. 40a, at 56–57. In any event, I agree with the CALJ's recommendation that for each of these prescriptions, the prescribed dosage strengths are either for 20 mg/5 ml or 20 mg/15 ml. R.D. at 50 n.120.

[39] The CALJ also recommended that I find that on November 29, 2012, Trinity II filled a prescription issued to J.T. for morphine liquid for 20 mg/ml when the dosage instruction on the corresponding prescription was for 20 mg/5 ml. R.D. at 50 & n.119 (citing GX 35, at 1, 80–81). Although this particular prescription was not the subject of testimony at the hearing nor included in the Government's Proposed Findings of Fact, the Show Cause Order does allege that on November 20, 2012, Trinity II received a prescription issued to J.T. for 20 mg/5 ml of morphine liquid but nonetheless filled it at the dosage strength of 20 mg/ml. ALJ Ex. 1b at 16. The CALJ acknowledged that the date in the Show Cause Order (November 20, 2012) does not match the date on the fill sticker (November 29, 2012), but he recommended this fact-finding anyway and implied that the discrepancy was the result of a scrivener's error in the Show Cause Order. R.D. at 50 & n.119. Because neither the dispensing log nor the patient profile for J.T. show that Trinity II filled

Professor Doering testified that the filling of these prescriptions at dosages that were at least ''five times more potent that it was supposed to be'' constituted ''a misfill.'' Tr. 1398. ''This issue has been communicated to pharmacists. Be careful when you fill liquid morphine solutions, because it's a very concentrated form of the drug.'' *Id.* He testified that the issue ''should have been identified in the global dispensing process.'' *Id.* at 1400. He further testified that these prescriptions were not filled consistent with the standard of care in Florida nor filled in the usual course of pharmacy practice. *Id.* at 1399, 1402, 1404, 1406–07, 1409, 1411–12.

Prescriptions Filled by Pharmacy Interns

The Government introduced prescription evidence at the hearing for the purpose of showing that Trinity II unlawfully allowed pharmacist interns, instead of pharmacists, to fill controlled substances prescriptions. The Government specifically alleged that Mina A. Ghobrial, a pharmacist intern at Trinity II, filled such prescriptions based on the presence of the initials ''MAG'' or ''MG'' in the ''filled by'' field of the fill stickers. *See, e.g.,* GX 79–82; *see also* Tr. 339, 452. The CALJ recommended that I find that the Government failed to present evidence to suggest that Ghobrial was not supervised by a registered pharmacist. R.D. at 46. I agree and make this finding of fact.

Respondent's Case

Respondent presented the testimony of Mark Abdelmaseeh, a pharmacist at Trinity II.[40] T. 2340–42. Abdelmaseeh testified that he worked two days per week as a pharmacist at Trinity II. *Id.* at 2342. He testified that, although technicians and interns worked with the pharmacists at Trinity II, pharmacy interns and technicians did not dispense any prescriptions. *Id.* at 2342–43. He further testified that his role included ''overlook[ing] and supervis[ing] what's going on in the pharmacy'' and ''keep[ing] open communication with the doctors to make sure that all prescriptions are legitimate and needed for the patient.'' *Id.* at 2355–56. ''I check to see if there are any contraindications or interactions, if the patient has allergies. I look to see if the prescription is valid or not. I look to see if the prescription is being filled early or not. I look to see if the prescription has any mistakes on it, and I call and verify with the doctor on every prescription that I fill.'' *Id.* at 2356.

Abdelmaseeh testified that Trinity II maintains ''records, notes and all types of other information other than just the plain prescription information'' and that ''[i]t's all documented in the computer system.'' *Id.* at 2345. He specifically testified that Trinity II ''maintain[ed] documentation regarding patient allergies'' and ''interactions with the physicians.'' *Id.* at 2360–61. He also testified that ''[w]hen the customer does pick up the medication they sign off for it that they picked up and that they do not have any questions in regards to the prescription that was picked up. . . . [a]t the point of sale.'' *Id.* at 2357. Specifically, he testified that the customer signs an electronic pad at the register confirming pick up and that the customer has no questions for the pharmacist. *Id.* at 2357–58. He further testified that he can access that information ''[a]t the register in the computer system.'' *Id.* at 2359.

The CALJ noted that Abdelmaseeh has some built-in bias because he was still an employee of Trinity II when he testified, giving him ''some stake in the proceedings.'' R.D. at 34. The CALJ found that this bias was reflected in the fact that Abdelmaseeh ''affirmatively and deliberately disregarded Respondent's counsel's . . . efforts to elicit testimony that stood within the bounds of the *in Limine* Order when there was no question pending in order to provide information that was directly the subject of the Government's objections.'' *Id.* at 34–35. The CALJ believed that this was Abdelmaseeh's ''effort to cram in as much objectionable testimony as possible'' to get around the terms of his *in Limine* Order. *Id.* at 35. As a result, the CALJ concluded that ''it is difficult to afford this witness's testimony the full weight that it otherwise might have received in this recommended decision.'' *Id.*

The CALJ sustained the Government's objections to Respondent's attempts to have Abdelmaseeh testify about evidence regarding the process the pharmacies used to verify prescriptions and resolve concerns, including a description and demonstration of the computer software utilized, because such testimony was excluded by the *in Limine* Order. *See generally* Tr. 2344–66. However, the CALJ nonetheless allowed Respondent's counsel to proffer how the witness would have testified on that topic. *Id.* at 2366–2372. Counsel proffered that Trinity II used computer software that requires a pharmacist to sign-in and approve prescriptions. *Id.* at 2367. Respondent's counsel also proffered ''that the software comes with a particular screen and tab for printing what is commonly referred to and has been referred to by Professor Doering as a patient profile which includes dispensing history, and it's limited to the dispensing history. It's a pre-programmed function of that software.'' *Id.* at 2368, 2370 (''It's an F–11 tab to print a profile.''). He also proffered that ''other fields that are maintained or other screens that are maintained'' by Trinity II's software ''include an area for notes on each prescription and that that information is maintained at the pharmacy in that . . . software.'' *Id.* at 2369, 2370–71 (''It has a tab for prescription notes, RX notes, and it operates not only by the tab but by a function key, F–3, and patient information tab that uses a function key, F–4'' and includes ''a date and time stamp entry so you can determine on which date those entries were made.''). According to counsel, Trinity II's pharmacists ''used this software as a mechanism to assist them . . . with identifying red flags and then documenting the resolution of those.'' *Id.* at 2371–72.

The proffered facts related to Trinity II's computerized record-keeping and prescription verification process are only relevant to the Show Cause Order's first two charges related to the identification and resolution of red flags of diversion. The CALJ properly stated that he would not consider the proffer as evidence in making his recommendation, but he allowed Respondent's counsel to make the proffer to preserve the issue for review. *See id.* at 2352.

Based principally on this proffer and the Government's failure to image Trinity II's computers, Trinity II contends that DEA cannot prove that it failed to document resolution of such red flags because ''DEA failed to request or obtain Respondent's records where such notes and comments were stored.'' Trinity II's Closing Submission and Proposed Findings of Fact and

any prescriptions for J.T. on November 20, 2012 (much less one corresponding to the morphine liquid prescription described in the Show Cause Order), GX 35, at 1, 3, I find that this mistake in the Show Cause Order was merely a scrivener's error. Thus, I agree that the Government intended to state in the Order that Trinity II filled this prescription on November 29, 2012. And I agree with the CALJ's recommendation that I find (and I do so find) that Trinity II filled this prescription on November 29, 2012 at a dosage that was five times stronger than the prescribing physician had instructed.

[40] Although Respondents presented the testimony of one other witness, Kristen Quinette, a former pharmacy technician at Trinity I, the CALJ did not consider her testimony in his Recommended Decision. After testifying that she had worked at one time at Trinity II, the CALJ sustained the Government's objection to her testimony since she was not noticed as a witness against Trinity II. Tr. 2232, 2247–49.

Conclusions of Law (hereinafter ''Trinity II's Post-Hearing Brief''), AJL Ex. 41, at 6. This general argument has some merit (again, assuming the proffered facts are true) regarding Trinity II's customers for whom the Government never requested ''records where such notes and comments were stored.'' *Id.*

However, Trinity II's argument does not account for the fact that the Government's December 4, 2014 subpoena required Trinity II to produce the complete patient profile that Trinity II maintained for 23 customers as required by Florida Administrative Rule 64B16–27.800, entitled ''Requirement for Patient Records.'' GX 98, at 2 (''For each of the following patients, please provide a copy of the complete patient profile your pharmacy maintained pursuant to Florida Administrative Rule 64B16–27.800''). As already noted, this rule expressly required Trinity II to maintain in its ''patient record system'' a record of every entry ''in the profile record'' for each patient for two years, including ''[p]harmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' ALJ Ex. 38; Fla. Admin. R. 64B16–27.800. This Rule also mandated that Trinity II ''obtain from the patient . . . and shall record'' patient information ''which may relate to prospective drug review. The pharmacist shall record any related information indicated by a licensed health care practitioner.'' *Id.* at 64B16–27.800(2).

In short, and as discussed more fully *infra,* Rule 64B16–27.800 required Trinity II to maintain patient records that included copies of any notes and comments reflecting their pharmacists' resolution of any red flags of diversion. I find that when the Government requested the complete patient profile Trinity II maintained pursuant to Rule 64B16–27.800 related to the 23 customers in the December 4, 2014 subpoena, the Government did in fact request all patient records maintained by Trinity II for those customers pursuant to that Rule—including the pharmacists' notes and comments for those customers. Thus, I reject Trinity II's contention that the Government failed to request records including Trinity II's notes and comments.[41]

Most significantly, Respondent's counsel never stated in his proffer that Trinity II did in fact maintain notes and comments resolving the alleged red flags for the 23 customers whose records were subpoenaed in this case. Although it is possible that Trinity II deliberately withheld this evidence in response to the December 4, 2014 subpoena,[42] I find that it is more likely than not that, in fact, Trinity II failed to produce notes and comments reflecting Trinity II's resolution of the red flags in response to the Government's subpoena because Trinity II did not actually resolve them and hence had no notes or comments reflecting any such resolution. Respondent's counsel was careful never to aver during cross-examination of the Government's witnesses that Trinity II actually had notes or comments regarding the 23 patients identified in the subpoena. The CALJ gave Respondent's counsel's more than enough latitude to make this claim during his proffer or during cross-examination, yet he chose not to do so. Respondent's counsel also chose not to impeach Government witnesses during cross-examination by using actual notes and comments (or any other information) reflecting Trinity II's resolution of red flags for any customer discussed at the hearing. Although the *in Limine* Order precluded Trinity II from, *inter alia,* offering such information as evidence in its case-in-chief (ALJ Ex. 29, at 3), nothing in that Order precluded Trinity II from using this information to impeach the Government's witnesses.[43] Indeed, it was in Trinity II's self-interest to use such notes and comments (if they existed) during cross-examination of the Government's witnesses because it would have been an effective way to impeach Government witnesses' testimony that they saw no evidence that Trinity II resolved any red flags of diversion. It would be a remarkable oversight for Respondent's counsel not to use such information during cross-examination if it did exist. As already noted, I find that it did not.[44]

Discussion

Before proceeding to analyze the evidence under the public interest factors, it is necessary to review the CALJ's discussion of two issues raised in the Government's Exceptions to the CALJ's Recommended Decision: (1) Whether the Government should have provided DEA–6s to Respondent that DEA had provided to its expert and (2) whether the expert's testimony was sufficiently ''reliable'' under the Administrative Procedure Act (''APA'')

[41] And it is also for this reason that I have limited my fact findings, *supra,* regarding the Show Cause Order's first two charges relating to violations of Trinity II's corresponding responsibility to allegations involving those 23 patients.

[42] During Respondent's counsel's cross-examination of Professor Doering regarding the scope of the Government's December 4, 2014 subpoena request for 23 customers' patient profiles maintained pursuant to Rule 64B16–27.800, Respondent's counsel asked ''Is the word 'profile' anywhere in that Florida administrative code provision?'' (Tr. 2174), expecting the witness to confirm counsel's own understanding regarding the rule. Professor Doering then validated that (mis)understanding by stating that the word ''profile'' ''does not appear'' to him as he quickly read the rule on the stand. Tr. 2176. This reading, of course, is incorrect—Rule 64B16–27.800(3) expressly references patient profiles. Government counsel immediately corrected this error on re-direct by asking Professor Doering to read that provision into the record: ''A patient record shall be maintained for a period of not less than two years from the date of the last entry in the *profile* record. This record may be a hard copy or a computerized form.'' Tr. 2207 (emphasis added). Although this exchange raises the possibility that Respondent's counsel advised his clients not to produce the notes and comments regarding the 23 customers referenced in the subpoena based on this misunderstanding of the rule, I find (for the reasons set forth in the text above) that it is more likely than not that Trinity II did not produce any notes or comments regarding these customers because they do not exist.

[43] In fact, the CALJ lacks the authority to preclude a respondent from using relevant information to impeach a witness during cross-examination. *See Farmacia Yani,* 80 FR 29053, 29063 n.25 (2015) (finding that it was prejudicial error to preclude a respondent from using a document to impeach a witness on cross-examination, even where respondent had failed to present the document to the Government in advance of the hearing). Moreover, the APA and our regulations preserve a respondent's right to present information on cross-examination for the purpose of impeaching the Government's witnesses. *See* 5 U.S.C. 556(d) (''A party is entitled . . . to conduct such cross-examination as may be required for a full and true disclosure of the facts.''); 21 CFR 1316.60.

[44] For the same reason, I reject Trinity II's Exception that the CALJ's *in Limine* Order ''did not permit the Respondents to present relevant evidence to the charges set forth in the show cause order. As a result, the Respondents were limited in their ability to explain the computer system used by the Respondents, which would have clarified the record keeping questions.'' Respondents Trinity Pharmacy (I)'s and Trinity Pharmacy (II)'s Exceptions to the Recommended Decision of the Administrative Law Judge (''Resp. Except.''), at 7. Although the CALJ did limit Trinity II's ability to present evidence as part of its case-in-chief, as already noted, the CALJ (1) gave Trinity II multiple opportunities to comply with his prehearing orders, (2) did not (and could not) limit its ability to present information during cross-examination of the Government's witnesses, and (3) even gave Trinity II the opportunity to provide an attorney proffer at the hearing in which Trinity II's counsel could have at least proffered facts which, if true, would have rebutted the Government's case. Again, as already noted, Trinity II chose not to do so. Accordingly, I find that the CALJ acted within his discretion when he issued his *in Limine* Order and denied Trinity II's reconsideration motion, and I reject Trinity II's Exception to the CALJ's *in Limine* Order.

Trinity II also raised in this Exception that the CALJ's *in Limine* Order precluded it from introducing evidence that ''would have corroborated Kristen Quinette that pharmacy technicians were not permitted to dispense prescriptions.'' *Id.* at 7. None of the allegations in the Show Cause Order relate to pharmacy technicians, and the CALJ limited her testimony's relevance to Trinity I. R.D. at 33 n. 86. In any event, and assuming Trinity II intended to state in its Exceptions that it would provide testimony related to pharmacy interns, I find that this Exception is moot because I find *infra* for Trinity II on the charges related to pharmacy interns.

to be given weight in my decision. *See* ''Government Exceptions'' (hereinafter ''Gov. Except.'') at 13–54.

Requirement To Produce Documents Relied Upon by the Expert

In his Recommendation, the CALJ included a discussion of whether the Government should have produced to Respondent copies of a DEA–6 related to Trinity II that DEA had provided [45] to the Government's expert witness, Professor Doering. R.D. at 27–28, 28 nn. 78–79.[46] In that discussion, the CALJ stated his belief that the DEA's intent in providing documents to an expert is relevant to determining whether the expert relied upon these documents in forming his opinion. R.D. at 28 n. 78 (''Like the other documents forwarded by DEA to Professor Doering, DEA–6s were furnished to him to assist him in formulating his expert opinion on the Government's theory of the case.''), *id.* at 28 (''The proposition that the Government would supply DEA–6s (or any other form) to an expert with the expectation that those documents would play no role 'whatsoever' is dubious at best. Professor Doering was sent DEA–6s so he would read, analyze, and utilize them in forming his expert opinion''). Contrary to the CALJ's belief, the Government's purported ''expectation'' that Professor Doering would rely on DEA–6s provided to him is both factually unsupported and legally irrelevant to the question at bar.

As a threshold matter, the record does not support the CALJ's statement that DEA expected Professor Doering to rely on the DEA–6s. The CALJ's opinion on this supposed expectation is based solely on the fact that the Government provided them to him. *See* R.D. at 27–28. However, the Government may provide an expert with any number of documents for reasons that have nothing to do with formulating the substantive basis of an expert opinion—such as an index or a table of contents. In his Recommended Decision, the CALJ failed to indicate where in in the almost 2,400-page transcript and more than 90 exhibits in the case there are facts establishing that DEA's ''expectation'' was that Professor Doering use the DEA–6s ''in formulating his expert opinion on the Government's theory of the case.'' *Id.* at 28 n.78. Thus, I find that the mere fact that the DIs provided a DEA–6 to Professor Doering regarding Trinity II is insufficient to establish that DEA did so with the intent that he rely upon it in forming his opinion.

More importantly, even if the record did support the CALJ's belief that DEA expected Professor Doering to rely on the DEA–6s in forming his opinion, it is legally irrelevant to the question of whether the Government should have produced the DEA–6s to Trinity II. ''DEA precedent has already made clear that where an expert relies on data or documents in forming his opinions, the failure of the sponsoring party to produce the data or documents denies the other party a meaningful opportunity to cross-examine the expert and show that his opinions are unfounded'' and ''runs the very substantial risk that the expert's conclusions will be rejected.'' [47] *T.J. McNichol, M.D.,* 77 FR 57133, 57146 n.18 (2012). Thus, the only fact that matters is whether Professor Doering actually relied on the DEA–6 in forming the substantive basis for his expert opinion. Accordingly, I find that, as a matter of law, the CALJ's unsupported belief that DEA expected Professor Doering to rely on the DEA–6s is irrelevant to the question of whether the Government was required to produce them to Trinity II because that legal question depends solely on whether Professor Doering, in fact, relied on the DEA–6 in forming the substantive basis for his opinion. *See T.J. McNichol, M.D.,* 77 FR at 57146 n. 18; *CBS Wholesale,* 74 FR at 36749.

The CALJ also contends that Professor Doering, in fact, relied on the DEA–6s in forming his expert opinion based on his response to the following question during direct examination:

> Q . . . What role did [the DEA–6s] play in your forming of the opinion as to the dispensings and fillings that you formed the opinion on in this case?
>
> A None whatsoever ultimately. I used the DEA Form 6 as what I would call, like a beacon or flashlight to help me understand where I might find that documentation, so I could peer upon that with my own two eyes, and not have to rely on or depend on other people's impressions or thoughts. I never rely on DEA Form 6s, because I think it's risky to do that.

Id. at 859–60. The CALJ found that, ''by his own account, [Professor Doering] used the investigative reports as a

[45] The Government also raised a separate Exception related to the CALJ's statement in his Recommended Decision that ''[i]t is unfathomable that the Agency counsel would gratuitously release a document as closely held by the Agency as a DEA–6 with no expectation that it would be used by that person for any purpose.'' Govt. Except. at 69 (emphasis omitted) (citing R.D. at 28 n. 78). The CALJ failed to indicate where the record indicates that Government counsel produced, much less ''gratuitously released,'' a DEA–6 to anyone. In fact, the record contradicts the CALJ's rendition of the facts. As Trinity II's counsel established during cross-examination of the lead DI at the hearing, it was the DIs, not ''Agency counsel,'' who provided a DEA–6 to Professor Doering.

> [Mr. Sisco:] All right. Would you describe for me all of the information that you initially provided to Professor Doering?
>
> [DI:] I believe we provided photocopies of the original prescriptions. I believe a copy of the E–FORCSE, the dispensing report. What else? And a copy of one of my 6s.
>
> Q When you say a 6, you're talking about a DEA–6. It's your report of an investigation?
>
> A Yes.

Tr. 581–82. Elsewhere in his Recommended Decision, the CALJ himself noted and accepted this same testimony. R.D. at 12 (accepting DI's testimony that he had ''provided . . . a copy of one of his DEA–6 forms . . . to Professor Paul Doering, the Government's expert witness. Tr. 581, 589–90''). Professor Doering corroborated the DI's response during his own testimony on direct and cross-examination, stating that he received DEA–6s from the DIs who had retained him on behalf of DEA and before he had made first contact with Government counsel regarding the case. *Id.* at 855–59, 1783–84, 1786–89, 1800–01. As the Government observed, ''[e]veryone is entitled to his own opinion, but not to his own facts.'' Govt. Except. at 1. I expect all the ALJs working for DEA to ensure that that the statements in their Recommended Decisions are well-grounded in fact, especially before making statements disparaging counsel who appear before them.

[46] This issue arose when, for the first time at the hearing, Respondent requested production of the DEA–6s that the Government had provided to its expert. R.D. at 28 n.79; *see* Tr. 586, 805–07. The Government responded at the hearing that Respondent's request was untimely because Government counsel had already notified Respondent's counsel by letter months before the hearing that DEA had previously provided DEA–6s to Professor Doering and that they would not be produced pursuant to *T.J. McNichol.* Tr. 807–08. The Government also proffered a copy of the contents of its unsigned expert discovery letter at the hearing. *Id.* The Government subsequently raised an Exception seeking a finding that it had provided notice to Respondent's counsel prior to the hearing, and the Government attached to its Exceptions an affidavit and a copy of the signed expert discovery letter addressed to Respondent's counsel consistent with its representation at the hearing. Gov. Except. at 64–69 & Attachment 1. In his Recommendation, the CALJ decided that ruling on whether this discovery request was timely was ''unnecessary'' because ''the Respondent has not sought to develop the record regarding the timeliness of the request or even asked for the testimony to be stricken as unavailable to constitute substantial evidence.'' R.D. at 28 n.79. I agree that Trinity II failed to carry its burden to prove that its request for production of the DEA–6s was timely. In any event, as discussed *infra,* I find that Professor Doering did not rely on any DEA–6 as the basis for his expert opinion, thereby obviating any putative production requirement.

[47] The CALJ cited to an earlier case, *CBS Wholesale Distributors,* 74 FR 36746, 36749 (2009), where the Agency found that expert testimony about whether a respondent was selling ''excessive quantities of combination ephedrine products'' was unreliable because the expert was unable to produce the data on which he, in turn, relied in forming his opinion of what the average monthly sales figure calculation was for such products. *Id.* at 28 n.79. Notably, nowhere in that case or in *T.J. McNichol* (or in any other case) has the Agency held that the sponsoring party must produce to the other party data or documents that had been provided to the expert based on the sponsoring party's ''expectation'' that the expert would rely on the information. Rather, as already noted, both cases set forth the same requirement: The sponsoring party must produce to the other party all information upon which the expert actually relied in forming the substantive basis for his/her opinion.

framework to examine other potential evidence.'' R.D. at 27. The CALJ concluded that this testimony ''leaves little doubt that the DEA–6s supplied to Professor Doering constituted underlying data that supported his conclusion, his assertions.'' *Id.* at 28 n.79.

Once again, the CALJ cites to the wrong legal standard under Agency precedent. The test is not whether Professor Doering used the DEA–6s ''as a beacon or flashlight'' to find other documents that constituted underlying data necessary to form his opinion. The question is whether Professor Doering, in fact, relied upon the DEA–6s as a substantive basis for his expert opinion. *See T.J. McNichol, M.D.,* 77 FR at 57146 n. 18; *CBS Wholesale,* 74 FR at 36749. Here, Professor Doering's testimony shows that he used the DEA–6 as a table of contents or an index ''to help [him] understand where [he] might find that documentation'' upon which he ultimately *did* rely upon in forming his opinion—dispensing reports, dispensing logs, copies of individual prescriptions, patient profiles, and Google Maps and MapQuest printouts of distances. Tr. 860, 862–63. He even went so far as to testify that he only used DEA–6s in this limited way so he would ''*not* have to rely on or depend on other people's impressions or thoughts'' reflected by or in the DEA–6. *Id.* at 860 (emphasis added). Simply put, if an expert uses a document like an index to ''find'' other ''documentation'' and nothing more, then the expert is not relying on that index in forming the substantive basis of an expert opinion. As a result, the other party could not use that document to show that the expert's opinion was unfounded, and the sponsoring party would not be required to produce it.

Here, the above testimony demonstrates that Professor Doering relied on dispensing reports, dispensing logs, copies of individual prescriptions, patient profiles, and Google Maps and MapQuest printouts in forming his opinions, not the DEA–6s that accompanied them. Tr. 860, 862–63. Accordingly, pursuant to *T.J. McNichol* and *CBS Wholesale,* I find that the record establishes that Professor Doering did not rely upon the DEA–6s in forming his expert opinion in this case, and thus the Government had no obligation to produce them to Trinity II.

Expert Opinions Must Be Supported by Reliable, Probative and Reliable Evidence

Under the APA, final agency action imposing a sanction must be ''supported by and in accordance with the reliable, probative, and substantial evidence.'' 5 U.S.C. 556(d). Like other evidence, the Agency has also held that an expert's opinion must be ''supported by substantial and reliable evidence.'' *CBS Wholesale,* 74 FR at 36749 (citing *id.*). I agree with the CALJ's decision to overrule Trinity II's objections in the hearing and in its closing brief to admitting the expert testimony of Professor Doering into evidence.[48] *See* R.D. at 15. After the CALJ evaluated ''the weight that should be accorded [to Professor Doering's] expert testimony in this matter,'' R.D. at 16 n. 51, he recommended that I give his testimony no weight because it was, in his view, ''insufficiently reliable to form the basis of a sanction under the APA.'' *Id.* at 33 (''To be clear, however, this is not an issue of credibility . . . There is no question that the Professor is an individual of impressive credentials . . . This aspect of this recommended decision addresses only the narrow issue of whether the expert opinions he rendered . . . are sufficiently reliable to support a sanction.''). Like the CALJ, I too do not need to rely upon Professor Doering's expert testimony to find that Trinity II's DEA registration must be revoked. However, unlike the CALJ, I do find that his testimony was nonetheless reliable under the APA and could have been accorded more evidentiary weight in his recommended fact findings.[49]

The CALJ identified six[50] reasons for his recommendation not to rely on Professor Doering's testimony, and the Government filed Exceptions in response to each of them. *First,* the CALJ believed that Professor Doering's supposed ''acknowledgment that the opinions he had rendered were not 'based on sufficient facts or data' critically undermines the weight that can be attached to those opinions.''[51]

[48] Trinity II objected to the admission of Professor Doering's expert testimony on the basis that ''[h]e does not currently have a license in effect in the State of Florida'' (Tr. 840) based on Professor Doering's testimony that his license had fallen into delinquent status for a couple of months as of the date of the hearing. *Id.* at 822–23, 1770. He stated that ''when the decks are cleared with this matter . . . I will clear up the delinquent status of my license, and it will revert to clear and active, before it goes to null and void.'' *Id.* at 844. He stated that this fact had no impact on his ability to work at the University of Florida's School of Pharmacy because he was only required to maintain an active pharmacist's license in one state, and he had an active license in North Carolina. *Id.* at 821–23. Even if Professor Doering had no license in any state, however, DEA regulations do not require an expert witness to be licensed in the state in which the alleged violations occurred, and Agency precedent authorizes ALJ's to admit expert testimony even where the expert was not licensed in the state where the violations were alleged to have occurred. 21 CFR 1316.59(b) (''Opinion testimony shall be admitted when the presiding officer is satisfied that the witness is properly qualified''); *Grider Drug #1 & Grider Drug #2,* 77 FR 44070, 44093 n.73 (2012) (finding that the Government's expert, who was licensed in Ohio but not Kentucky was nonetheless permissible and ''generally reliable and probative of whether Respondents (and their pharmacists) violated their corresponding responsibility''). Thus, the CALJ properly accepted Professor Doering ''as an expert in the practice of pharmacy in the State of Florida and the standard of care in the dispensing of controlled substances in Florida'' based on his expertise and the fact that he stays current in this area of expertise. *Id.* at 843; R.D. at 14. For the same reasons, I find that the fact that Professor Doering's CV may not have been up-to-date regarding the status of his Florida license is an insufficient basis to find that his testimony was unreliable. *See* R.D. at 28–30.

[49] The CALJ states that ''the factual findings set forth in this recommended decision are entitled to significant deference.'' R.D. at 38 (citing *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951)). However, nowhere does *Universal Camera* (or the APA) support this standard of review for the CALJ's recommended fact findings. Rather, it is axiomatic that an ALJ's recommended decisions are subject to *de novo* review by the agency. *See* 5 U.S.C. 557(b) (''On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule.''); *Universal Camera,* 340 U.S. at 492, 493 (the ALJ's recommended fact findings become part of the administrative record, just ''as the complaint or the testimony'' is part of the record, for the Agency's consideration), 494 (the APA states ''that an agency which reviews an examiner's [*e.g.,* ALJ's] report has 'all the powers which it would have in making the initial decision'''') (quoting 5 U.S.C. 557(b)); *Vineland Fireworks* v. *ATF,* 544 F.3d 509, 514 (3d Cir. 2008) (recognizing an agency's authority under the APA to ''exercise[ ] de novo review over the ALJ's decision''). ALJs are ''entirely subject to the agency on matters of law; they can be reversed by the agency on matters of fact, even where demeanor evidence is an important factor.'' Antonin Scalia, *The ALJ Fiasco—A Reprise,* 47 Univ. Chi. L. Rev. 57, 62 (1979). *See Kay* v. *FCC,* 396 F.3d 1184, 1189 (D.C. Cir. 2005) (the agency may disagree with an ALJ's factual findings, including credibility determinations); Tom C. Clark, *Attorney General's Manual on the Administrative Procedure Act* 83 (1947) (''In making its decision, whether following an initial or recommended decision, the agency is in no way bound by the decision of its subordinate officer; it retains complete freedom of decision—as though it had heard the evidence itself.'').

[50] The CALJ raised two other reasons to challenge the expert's reliability, one of which was the issue of DEA–6s, which I addressed *supra.* The other related to the CALJ's disagreement with Professor Doering on the question of whether an early fill calculation relates to when the pharmacist fills the prescription or to when the customer ultimately obtains the controlled substance. R.D. at 24–26. I find that this is a legal question and not a question of witness reliability, and it is one that I address *infra.*

[51] R.D. at 16 (quoting Fed. R. Evid. 702(b)). Although the CALJ properly framed the issue of reliability under § 556(d) as a question of how much weight to give to Professor Doering's expert opinions, the CALJ erroneously resorted to Federal Rule of Evidence 702 as the lens through which to make this determination. *Id.* at 14–15, 16 n.51. The CALJ stated that the ''Agency has long authorized resort to the Federal Rules of Evidence 'where they do not conflict with Agency regulations.'' *Id.* at 14–15 (citing *Rosalind A. Cropper, M.D.,* 66 FR 41040, 41041 (2001)). In *Cropper,* the Agency expressly rejected the ALJ's evidentiary ruling that the Federal Rules of Evidence ''generally apply'' to DEA administrative hearings and found ''instead that the Federal Rules of Evidence (FRE) do not apply directly to these proceedings . . . but may be used for guidance, where they do not conflict with

R.D. at 16. Specifically, the CALJ states that Professor Doering ''did not have all of the information that was necessary for him to render an expert opinion.'' *Id.* (citing Tr. 2186–87). In its Exceptions, the Government responds that a ''careful and thorough review'' of the hearing transcript ''shows that the Presiding Officer's [52] finding is a mischaracterization of Professor Doering's testimony.'' Gov. Except. at 13. I agree.

During the portion of cross-examination cited by the CALJ, it is clear that when Professor Doering testified that he ''d[id]n't know that [he'd] been provided enough information . . . to render'' expert opinions under the Florida standard of care regarding Trinity II's resolution of red flags was limited to prescriptions and customers where he did not have a corresponding patient profile. Tr. 2186–87, 2187; *accord* Gov. Except. 14–15. The record is clear that Professor Doering testified that he did have sufficient information to render expert opinions related to the Government's charges pursuant to 21 CFR 1306.04(a) for the 23 patients that were the subject of the December 4, 2014 administrative subpoena and for whom he had the corresponding patient profile. *See* Tr. 1054–55, 2217, 2224.[53] For this reason, and as noted *supra,* those are the only patients whose prescription evidence I have considered in evaluating the Government's charges pursuant to 21 CFR 1306.04(a). Accordingly, I reject the CALJ's recommended finding that Professor Doering lacked sufficient facts to render his opinions with respect to those patients.

Second, the CALJ believed that Professor Doering's expert opinions were not reliable because he had not ''reliably applied'' the relevant principles and methods to the facts of the case, particularly in the context of what constitutes a ''red flag.'' R.D. at 16–17. The CALJ stated that ''nothing in his definition of a 'red flag' suggests that it is an indicator of an elevated risk of diversion, or what, if any, steps are required prior to dispensing when a red flag is present.'' *Id.* at 17 (citing Tr. 865). As a threshold matter, how Professor Doering, or any other expert, defines a red flag is irrelevant. It is the Agency, not an expert, that must decide whether facts in a particular case demonstrate that a pharmacist knowingly filled a prescription that was not issued for a legitimate medical purpose pursuant to 21 CFR 1306.04(a). In this context, the role of the expert is merely to render an opinion of whether a pharmacist's decision to fill a particular prescription given the facts of the case satisfied the state's standard of pharmacy practice—one of several factors the Agency can consider in determining whether a pharmacy violated its corresponding responsibility. And as already noted, the CALJ chose not to make *any* recommended fact findings related to the Government's charges that Trinity II violated its corresponding responsibility.

In any event, the CALJ's characterization of Professor Doering's definition of red flags is at odds with Professor Doering's actual testimony. As noted *supra,* Professor Doering testified that a red flag is ''a term that's come to be used to give examples to pharmacies of things that might indicate or suggest that prescriptions were filled outside the usual course of pharmacy practice.'' Tr. 864. He also testified that a red flag ''could be indicative of abuse or misuse,'' ''over or under compliance,'' ''drug-drug interactions,'' or a ''forged'' or ''altered'' prescription. *Id.* at 869. All of these indicators reflect what the CALJ described as ''an elevated risk of diversion.'' Indeed, Professor Doering's testimony about red flags of diversion that pharmacists must look for was consistent with what the relevant Florida Administrative Rule requires pharmacists to look for as part of their prospective drug use review. *See* Florida Administrative Code Rule 64B16–27.810. In one example, he testified that red flags indicating ''over-utilization'' of a controlled substance ''touches upon some of the other issues, which means clinical use or abuse, or diversion to some other use.'' Tr. 885–86. ''Over[-]utilization'' ''might be distributing it to other persons'' (*i.e.,* diversion to others) or ''taking too much of it.'' *Id.* at 872. Thus, Professor Doering testified that the red flags can indicate both an increased risk of diversion to others, but also a risk of clinical abuse. As I noted *supra,* he testified about many examples of red flags of diversion in a wide variety of contexts, including those set forth in Rule 64B16–27.810. *See* Gov. Except. at 18–23.

Also, as already noted, and contrary to the CALJ's characterization, Professor Doering repeatedly testified about what pharmacists should do when a red flag is present. For example, he testified that, ''before filling any prescription'' as part of the ''prospective drug utilization review, or prospective drug use review,'' pharmacists must resolve the red flags and document such resolution ''on the face of the prescription, on the rear of the prescription, or in the patient profile.'' *E.g., id.* at 882, 870–73, 881–83, 958–59.[54] Most importantly, this

agency regulations.'' 66 FR at 41041 (citing *Klinestiver* v. *Drug Enforcement Administration,* 606 F.2d 1128, 1130 (D.C. Cir. 1979) (holding that ''nothing in 21 CFR 1316.59(a) requires DEA to limit admissible testimony to that which would be acceptable in a jury trial or under the Federal Rules of Evidence'')). If the CALJ wished to deny admission of Professor Doering's testimony and exclude it from evidence, the APA only authorizes exclusion of evidence that is ''irrelevant, immaterial, or unduly repetitious.'' 5 U.S.C. 556(d); *Klinestiver,* 606 F.2d at 1130 (''The history of [21 CFR 1316.59] convinces us that DEA never intended to bind itself to a higher standard of admissibility than that prescribed by . . . 5 U.S.C. 556(d)''); *Cropper,* 66 FR at 41041 (same) (''The sections governing these proceedings found in 21 Code of Federal Regulations contain no references to the FRE; and 21 CFR 1316.59 . . . requires only that admitted evidence be 'competent, relevant, material, and not unduly repetitious.'').

Although Rule 702 does use the words ''expert'' and ''reliable,'' that does not make the rule applicable here, even as guidance, to determine how much weight to give expert testimony. The CALJ concedes that Rule 702 only provides conditions for ''the admission of expert opinion testimony.'' R.D. at 15. Indeed, Rule 702 says nothing about how much weight to give an expert's opinion once it has been admitted. For this reason, the Agency adopted the CALJ's evidentiary recommendation in *Howard N. Robinson, M.D.,* 79 FR 19356, 19361 n.39 (2014), to overrule the Government's objection based on Rule 702 to receiving an expert witness because ''the nature of the objection was framed entirely as an argument as to weight and raised no appreciable issue regarding the qualifications of the witness to present expert testimony.'' Here, and as already noted, the CALJ properly accepted admission of Professor Doering's expert opinion (Tr. 843–44) but gave it no weight because it was, in the CALJ's view, insufficiently reliable. Thus, Rule 702 has no bearing, and provides no guidance, on the question of how much weight the expert's testimony should receive.

[52] ''The term *presiding officer* means an administrative law judge qualified and appointed as provided in the'' APA. 21 CFR 1316.42(f) (citing 5 U.S.C. 556). The APA, in turn, characterizes an ALJ as a ''presiding or participating employee'' of the Agency. 5 U.S.C. 556(b). In this case, the presiding officer or employee of the Agency was the CALJ.

[53] After reviewing prescription evidence and patient profiles for over 20 of Respondents' customers and testifying that he saw no notes or comments resolving red flags of diversion with respect to those customers, Professor Doering was asked ''How many more did you need to be able to see to determine whether or not [Respondents] kept the notes and comments?'' Tr. 2217. He responded: ''Well, technically speaking I'd have to look at each and every one to be sure that they exist. I think the logical conclusion is these profiles typically don't have such a section.'' *Id.* On this basis, the Government argues that a reasonable inference could be made that Trinity II never documented resolution of red flags of diversion—even for customers for whom patient profiles were not produced. Govt. Except. at 17 & n.5. I need not make this inference here because, as set forth *infra,* the prescription evidence and patient profiles that are already part of the record in this case are more than sufficient to establish by a preponderance of the evidence that Trinity II violated its corresponding responsibility pursuant to 21 CFR 1306.04(a).

[54] As the Government notes in its Exceptions, Professor Doering testified at length about the steps that a pharmacist must follow before filling a

Continued

testimony is consistent with the Florida Administrative Rules that also require resolving red flags and documenting resolution of red flags, which Professor Doering also discussed at length. *See* Florida Administrative Code Rule 64B16–27.800; Tr. 870–71, 873–75, 881–82, 887–89, 891, 895–96, 953–55, 957–59, 1015–16, 1169–70, 1353, 1419–20. The fact that his testimony closely tracks the Florida Administrative Rules supports, rather than undermines, the reliability of his expert opinion. As a result, I reject the CALJ's belief that (1) the expert's definition of a red flag is relevant and (2) in any event, that the expert failed to define a red flag as an indicator of an elevated risk of diversion and set forth the steps a pharmacist must follow prior to filling or dispensing.

Third, the CALJ stated that Professor Doering was unreliable because the CALJ believed that Professor Doering stated that ''it is the (presumably subjective) judgment of each individual pharmacist that governs whether a red flag is adequately resolved.'' R.D. at 17. Aside from the fact that the transcript fails to reflect Professor Doering making this statement,[55] the CALJ confuses the question of whose judgment should be used in filling a prescription with the question of whether Trinity II's pharmacists' decisions to fill certain prescriptions satisfied their corresponding responsibility.[56] The notion that pharmacists must use their professional judgement when filling prescriptions is neither new nor remarkable. Agency precedent, federal law, and Florida law uniformly require pharmacists to use their professional judgment in deciding whether to fill a prescription and dispense controlled substances.[57] Accordingly, I reject the CALJ's view that Professor Doering's testimony was unreliable simply because he testified that pharmacists must use their professional judgment—a statement that is consistent with Agency precedent.[58]

Fourth, the CALJ stated his belief that ''Professor Doering's reliance upon the subjective judgment of individual pharmacists as a Florida state standard'' undermined the reliability of his testimony. R.D. at 19. The CALJ contended that Professor Doering ''conceded that pharmacists in Florida can and do disagree on whether particular red flags are resolvable,[59] when a refill constitutes an 'early refill,' when duplicative therapy is present, and whether a particular combination of medications constitutes a 'drug cocktail.' '' *Id.* (citing Tr. 1828–29, 1967). This largely academic testimony (during cross-examination) about how reasonable pharmacists may differ on where to draw the line regarding certain red flags in the abstract is interesting but not relevant to the question that Professor Doering was actually called on as an expert to answer: Whether prescriptions like the ones *in this case* presented red flags of diversion.

And regarding prescriptions like those *in this case,* Professor Doering's testimony about what the standard of practice for Florida pharmacists was regarding early fills, duplicative therapy, and ''drug cocktails'' was clear. For example, Professor Doering testified that ''early fills'' or ''early refills'' are red flags of over-utilization, and that when there is a fill or refill was more than 2–3 days early, that ''early fill'' or ''early refill'' would be a red flag. *See* Tr. 989–991, 992 (''when there is a pattern of early refills, it makes one very concerned that there is over-utilization''), 1009. Although reasonable pharmacists in Florida may disagree whether the line should be drawn at two or three days, those are not the early fills in this case. In this vein, Professor Doering testified that pharmacists would not disagree that prescriptions filled or refilled eight to 17 days early, as the prescription evidence shows Trinity II routinely did, were red flags of diversion that pharmacists in Florida must resolve before filling. *E.g.,* Tr. 1004–05, 2106–2110.

Professor Doering also testified that there would be no disagreement among reasonable pharmacists that when a patient simultaneously presents prescriptions for the ''drug cocktail'' of an opioid, a benzodiazepine, and a muscle relaxant, then this is a red flag that a Florida pharmacist must resolve. *Id.* at 2111. Likewise, he testified that when the same customer simultaneously presents two prescriptions for different immediate-release opioids with the same or similar instructions, this too is a red flag of duplicative therapy that a pharmacist must resolve before filling. *Id.* Notably, Professor Doering's testimony is consistent with the same standard of care requirements set forth in Florida Administrative Rule 64B16–27.810—a fact that bolsters the reliability of his expert opinion. *See* ALJ Ex. 38. Accordingly, I reject the CALJ's belief that Professor Doering's testimony about the prescriptions in this case was unreliable.

Fifth, the CALJ found Professor Doering's testimony unreliable because he failed to take into account the ''E–

controlled substance prescription presenting a red flag of diversion. Govt. Except. at 25–26. He testified that resolving the red flag during ''[d]rug utilization review means using the knowledge, skill, judgment, and experience of the pharmacist to evaluate all the information that might be in front of them regarding the use of this particular prescription, under this particular prescription, in this particular patient.'' Tr. 870–71. He testified that this review ''would mean consulting the patient profile, which might have a list of other drugs that a patient may be on[,] . . . a list of allergies or other adverse effects that patients may have had from the drug. It may have other idiosyncrasies[,] . . . [it] might have important demographic information, such as [an] address . . . information indicating other doctors, who may have or are seeing this very patient. It would also have information on dates of fills or refills, looking for . . . perhaps over[-]utilization of the medication.'' *Id.* at 871. He also testified that pharmacists should resolve red flags by reviewing the notes and comments field of the patient profile, consulting with the patient and/or the prescribing physician, and consulting Florida's Prescription Drug Monitoring Program, ''E-FORCSE.'' *Id.* at 873–74, 887–89, 895–96, 953–55, 957, 1015–16, 1419–20.

[55] As the Government states, ''[t]he Presiding Officer simply read the word 'subjective' into Professor Doering's testimony when it did not exist.'' Govt. Except. at 27.

[56] On the latter question, the CALJ also expressed confusion about whether Professor Doering was ''speaking from the shoes of the pharmacists'' or from his view of ''looking from the shoes of the expert'' in determining what the Florida standard of practice should be in resolving red flags. R.D. at 17 (quoting Tr. 881). However, the record is clear that Professor Doering testified that his opinion was that Florida law applicable to all pharmacists governs whether a pharmacist adequately resolved a red flag before filling a prescription. *See, e.g.,* Tr. 868–79.

[57] *See, e.g., Ralph J. Bertolino,* 55 FR 4,729, 4,730 (1990) (''The statutory scheme plainly requires that pharmacists use common sense and professional judgment. Where [pharmacists'] suspicions are aroused as reasonable professionals . . . pharmacists are called upon to obey the law and refuse to dispense.''); *id.* (''When [pharmacists'] suspicions are aroused as reasonable professionals,'' they must at least verify the prescription's propriety, and if not satisfied by the answer they must ''refuse to dispense''); *Medicine Shoppe-Jonesborough,* 300 Fed. Appx. 409, 412 (6th Cir. 2008) (same) (quoting *Bertolino*); *United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979) (''What is required by [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice''); Florida Bd. of Pharm. R. 64B16–27.810 (requiring a pharmacist ''upon recognizing any of the [issues]'' to ''take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber'').

[58] In its Exceptions, the Government also notes that ''the Presiding Officer's finding is largely immaterial in this case because the evidence established that Respondents' pharmacists did not exercise any judgment at all with respect to the prescriptions containing red flag(s).'' Govt. Except. at 29. Given that I have already found facts establishing that Trinity II failed to document or otherwise establish that its pharmacists resolved red flags of diversion before filling prescriptions, *see infra,* the Government's point is well-taken.

[59] *See also* R.D. at 26–27. The CALJ's concern regarding Professor Doering's testimony about ''whether particular red flags are resolvable'' is particularly irrelevant where, as here, I have limited my fact findings to customers where the Government established by a preponderance of the evidence that Trinity II failed to document that it resolved *any* red flags of diversion.

FORSCE'' printouts that the DIs had provided to him before rendering his opinions. R.D. at 22 (''although he testified that checking E–FORSCE is a necessary step in the process for the pharmacist, he rendered his opinions without taking into consideration any E–FORSCE printouts that were provided to him'' and would ''arguably have been relevant in reaching a determination as whether a bona fide red flag was actually present''). While the CALJ contends that E–FORSCE printouts for specific Trinity II customers would have ''arguably'' been relevant in identifying a red flag,[60] the CALJ failed to identify any prescription *in this case* where it would have been relevant to identifying a red flag.[61]

Moreover, the Government noted in its Exceptions that the CALJ failed to point out that Professor Doering never received E–FORSCE printouts for specific Trinity II customers—the printouts the CALJ opined would have been relevant to his opinions. Gov. Except. at 39; Tr. 553 (DI testified that he ''did not run a specific [E–FORSCE] query for each patient''). Instead, the DIs only provided Professor Doering with E–FORSCE printouts of the prescriptions filled by Trinity II, which was already reflected in (and hence redundant to) Trinity II's own prescriptions, dispensing reports, and patient profile. *See* Tr. 605 (DI testifying that ''[w]e try not to use E–FORSCE, we prefer to use the dispensing report because it's a more accurate reflection of the pharmacies. Because it's their records. It's what they have in their system.''). Thus, I reject the CALJ's belief that Professor Doering's failure to take into account the E–FORSCE printouts of the prescriptions filled by Trinity II made his testimony unreliable. He correctly based his opinions, instead, on the prescriptions, dispensing reports, and patient profiles on which those E–FORSCE printouts depend.

Sixth, the Government objected to the CALJ's belief that Professor Doering was unreliable because ''he was consistently unable to accurately calculate the number of days between two filled prescriptions, even though supplied on the witness stand with a calendar, a pad, a pencil, as much time as he needed, and repeated prompting and re-prompting by the Government.'' R.D. at 23. Even assuming, *arguendo,* that the CALJ's belief is correct, the CALJ failed to explain why it has any bearing on whether Professor Doering's expert opinions are reliable. Professor Doering testified that his trouble in making these calculation by hand, on the stand, stems from the fact that today's pharmacists rely on a computer to make them automatically. Tr. 1368.[62] More importantly, the calculation of ''the number of days between two filled prescriptions'' is a question of fact, not of expert opinion.[63] Thus, even if Professor Doering had little trouble making these calculations, it would not have obviated the Agency's independent requirement to make or to verify them as fact. *Cf.* Gov. Except. at 40 (''the Administrator does not even need Professor Doering's calculations to ascertain whether the prescriptions were early''). As already noted, the CALJ failed to make any recommended fact findings regarding the early fill allegations in this case, much less findings that conflicted with those made by Professor Doering. Thus, I reject the CALJ's belief that Professor Doering was unreliable based on his early fill calculations at the hearing.

Finally, Trinity II contends that if the Agency were to find Professor Doering unreliable in this case, then it would call into question the CALJ's previous finding in *Holiday CVS* that his consistent expert testimony there *was* reliable and accorded evidentiary weight. *E.g.,* ALJ Ex. 41, at 20 (''*Holiday CVS* and its progeny all find their basis in the testimony of Doering.''), 20 n.5 (''[I]n the event the Court finds Doering's testimony to be not credible or appropriate to rely upon, it likewise calls into question the validity of *Holiday CVS* due to its reliance on his testimony. The effect would be akin to removing a bottom floor card in a house of cards.'').[64] In response, the CALJ states that the ''Agency's legal conclusions in its prior final orders stand unaffected by a decision regarding the weight that should be accorded expert testimony in this matter; likewise, expert testimony reflected in prior final orders has no place in an evaluation of the evidence in this matter.'' R.D. at 15–16 n.51. Insofar as the Agency's legal conclusions in prior final orders depend on expert testimony that is inconsistent with Professor Doering's testimony in this case, I agree with the CALJ that the legal conclusions in those cases are not called into question.

However, I disagree with the CALJ's claim that expert testimony accepted in prior final orders has no place in evaluating the weight to be given to expert testimony in this matter. Where Professor Doering's testimony in this case is consistent with expert testimony previously found reliable by the Agency, then I do find that prior consistent testimony relevant to an evaluation of the reliability of Professor Doering's testimony in this case. Here, for example, the Government contends that his ''testimony about the drug

[60] The CALJ concedes that ''this aspect of the case certainly has no impact on whether the pharmacists' attempts at red flag resolution were adequately documented.'' R.D. at 22. In that vein, the Government observed that ''the issue the Presiding Officer should have focused on was the fact that Respondents' pharmacists were not checking E–FORSCE to resolve the red flags that were seen in the prescriptions themselves (as well as the patient profiles and dispensing reports), as evidenced by the lack of any documentation on the prescriptions and the patient profiles of E–FORSCE queries.'' Govt. Except. at 40 n.9.

[61] Indeed, even if Professor Doering had received E–FORSCE printouts for specific Trinity II customers, they would not have rendered red flags presented by the actual prescriptions less suspicious. On the contrary, if anything, they may have shown additional red flags—such as doctor-shopping—that may not have been presented by the prescription evidence already in the case.

[62] The following exchange at the hearing makes this point clear:

Judge Mulrooney: . . . Would you say that it's difficult to count up these days as a pharmacist, particularly if you're in a busy retail pharmacy?

[Professor Doering]: It's not difficult at all. Number 1, the computer does it for you. Number 2, they're not under the bright lights, under the stress of what I am. Although I may appear to be calm and cool, this is a stressful thing for me.

Tr. 1368. At this point, Professor Doering had already been testifying continuously for almost two days.

In addition to the pressure of testifying on the stand, Professor Doering appeared to suffer from witness fatigue, having testified for several days in a row in response to a similar pattern of questions during direct examination over and over again. For this reason, it is not surprising that this fatigue caused him to misstate whether he had certain documents in one instance, and to respond in ''automatic mode'' in another instance. *See* R.D. at 30–33. It is not uncommon for a witness who testifies for most of 5 days (as reflected in more than 1,400 pages of an almost 2,400-page transcript) to make an accidental misstatement. While the CALJ could reasonably find particular erroneous testimony unreliable based on such mistakes, it would not be reasonable to find the entirety of Professor Doering's testimony unreliable under the APA on this basis.

[63] In its Exceptions, the Government further noted that the fact that Professor Doering needed more than one attempt to make a particular calculation in the examples cited by the CALJ (R.D. at 23–24) does not change the Government's allegation that the prescriptions at issue ''were extremely early, in most instances anywhere from 8 to 15 days early, and Professor Doering reliably testified that they were each early.'' Govt. Except. at 40. I agree, and as I note *infra,* what is important is the fact that most (if not all) of the relevant fills and refills are so early that Trinity II should have resolved these red flags before filling the prescriptions.

[64] Trinity II's argument implies that allowing the CALJ to find the same expert testimony reliable in one case (*Holiday CVS*), yet unreliable in this case, calls into question whether such findings are arbitrary and capricious. Although I agree with Trinity II and the Government that some of Professor Doering's testimony in *Holiday CVS* is consistent with his testimony in this case, I do not consider whether the CALJ's inconsistent reliability findings are arbitrary and capricious because I find, consistent with the CALJ's finding in *Holiday CVS,* that Professor Doering's testimony in this case is reliable.

utilization review obligations of a pharmacist'' regarding early fills ''was consistent with the expert testimony that has been credited by [the] Agency in previous final decisions.'' ALJ Ex. 40a, at 73 (citing *Grider #1 & Grider #2* and *East Main Street Pharmacy*), 86 (Professor Doering's testimony regarding the early fills in this case ''was consistent with the testimony of other experts in Agency precedent'') (citing *Grider #1 & Grider #2* and *The Medicine Dropper*), 104 (Professor Doering's testimony regarding therapeutic duplication ''was again consistent with the testimony of another pharmacist expert that was credited by the Agency in a previous decision'') (citing *Grider #1 & Grider #2* and *Medicine Shoppe Jonesborough*). Given Trinity II's further claim that Professor Doering's testimony is consistent with his own accepted testimony in *Holiday CVS* ''and its progeny,'' the fact that Professor Doering's testimony in this case is consistent with accepted expert testimony in the Agency's prior decisions is not in dispute. I find that this undisputed fact bolsters the reliability of Professor Doering's expert testimony—further undermining the CALJ's determination that in this case his testimony is not reliable.

Accordingly, for all the foregoing reasons, I find that Professor Doering's expert testimony in this case was reliable under the APA.

The Public Interest Factors

Under the Controlled Substances Act (''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. § 823(f).

''[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.[65]

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.[66] I find that the record taken as a whole provides substantial evidence that Trinity II's pharmacists violated their corresponding responsibility pursuant to 21 CFR 1306.04(a) when they dispensed many of the prescriptions at issue. I also find that the Government has established by substantial evidence that Trinity II's pharmacists filled prescriptions outside the usual course of their professional practice in violation of 21 CFR 1306.06.

Accordingly, I conclude that the Government has established that Trinity II 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 Trinity II 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 Trinity II's misconduct is egregious, I will order that Trinity II'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 Allegations Pursuant to 21 CFR 1306.04(a)

''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, including . . . the packaging, labeling, or compounding necessary to prepare the substance for such delivery.'' *Id.* § 802(10). ''The terms 'deliver' or 'delivery' mean the actual, constructive, or attempted transfer of a controlled substance.'' *Id.* § 802(8). Thus, a pharmacy dispenses a controlled substance when it attempts to transfer a controlled substance to an ultimate user pursuant to a lawful

[65] 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, findings under a single factor can support the revocation of a registration or denial of an application. *See MacKay,* 664 F.3d at 821.

[66] 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 Trinity II, or taken any disciplinary action against it. *See* 21 U.S.C. 823(f)(1). However, even if true, 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 Trinity II'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 (DC Cir. 2008)).

As to factor three, there is no evidence that Respondent, its owner, its manager, or any of its pharmacists, has been convicted of an 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, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011).

The Government did allege, in the alternative in the Show Cause Order's eighth charge, misconduct with respect to factor five regarding Trinity II's filling and dispensing of a controlled substance in an amount that was at least five times the amount prescribed. Because I consider this evidence in evaluating factors two and four, I deem it unnecessary to separately address this misconduct under factor five.

prescription by packaging or labeling a controlled substance for such delivery.

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.* Thus, '' 'a practitioner is unauthorized to dispense a controlled substance if the prescription *either* lacks a legitimate purpose *or* is outside the usual course of professional practice.' '' *United States* v. *Bennett,* 874 F.3d 236, 245 (5th Cir. 2017) (quoting *United States* v. *Armstrong,* 550 F.3d 382, 397 (5th Cir. 2008), *overruled on other grounds by United States* v. *Balleza,* 613 F.3d 432, 433 n.1 (5th Cir. 2010)). 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.[67]

Id. (emphasis added). Thus, 1306.04(a) distinguishes between ''prescribing and dispensing'' and ''filling'' controlled substances, and who has responsibility for each function. Under this regulation, prescribing physicians are responsible for the ''proper prescribing and dispensing of controlled substances,'' and pharmacists bear a corresponding responsibility for ''filling'' only lawful prescriptions issued for a legitimate medical purpose.

As the Agency has made clear, to prove a violation of a pharmacist's corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter, *i.e.,* that the pharmacist ''knowingly'' filled a prescription that was not issued for a legitimate purpose. *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 the pharmacist filled a prescription (1) notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose, or (2) being willfully blind to (or deliberately ignorant of) 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)).[68]

Here, the Government makes no claim that any of Trinity II's 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 fills a controlled substance prescription (1) in the face of ''red flags'' or circumstances that do or should raise a reasonable suspicion as to the validity of a prescription and (2) without taking steps to resolve the red flag and ensure that the prescription is valid. ALJ Ex. 40a, at 66–68. In this case, the Government argues that Trinity II's pharmacists violated 21 CFR 1306.04(a) by filling prescriptions for drugs such as oxycodone and hydromorphone, even though Trinity II's pharmacists knew that these prescriptions presented various ''red flags'' of diversion which were never resolved. *Id.* at 68.

Notably, Florida law requires pharmacists to identify and resolve certain red flags for every prescription presented to them during a prospective drug use review. Florida Administrative Code Rule 64B–16–27.810, entitled ''Prospective Drug Use Review,'' requires pharmacists to ''review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness.'' ALJ Ex. 38 (Fla Admin Code r. 64B16–27.810(1)). This rule further requires that a pharmacist identify such issues as: ''[o]ver-utilization,'' ''[t]herapeutic duplication,'' ''[d]rug-drug interactions,'' ''[i]ncorrect drug dosage or duration of drug treatment,'' and ''[c]linical abuse/misuse.'' *Id.*

Importantly, ''[u]pon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.'' *Id.* at 64B16–27.810(2). Thus, Trinity II's pharmacists violate Florida law if they fail to identify and resolve the red flags that are part of the prospective drug use review set forth in Rule 64B16–27.810. And if they knowingly fill prescriptions without resolving these red flags during this review, then they violate their corresponding responsibility under 21 CFR 1306.04(a). *See, e.g., Grider Drug #1 & Grider Drug #2,* 77 FR at 44097–98, 44100 (pharmacies violated their corresponding responsibility because they ''did not do prospective DUR [drug utilization review] with respect to any of the six patients even though this is required by the Kentucky Board of Pharmacy's rules''); *East Main Street Pharmacy,* 75 FR at 66157 & n.31 (pharmacists required to recognize and consider red flags as part of the prospective drug utilization review ''before they dispense a prescription'').

Moreover, at all times relevant to this case, Florida law also required pharmacists to document resolution of a red flag. Rule 64B16–27.800[69] 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.'' *Id.* at 64B–16–27.800(1)(e).

Most significantly, the rule required that the record include the

[67] 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)).

[68] Courts have long held that when prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby deliberately avoid actual knowledge of the real purpose of the prescription, thereby filling them with impunity. *See United States* v. *Kershman,* 555 F.2d 198 (8th Cir. 1977). *See also United States* v. *Lawson,* 682 F.2d 480 (4th Cir. 1982) (''The key element of knowledge may be shown by proof that the defendant deliberately closed his eyes to the true nature of the prescription'').

[69] Because the prescriptions at issue in this case are dated from February 2012–February 2014, I apply the version of Rule 64B16–27.800 that applied prior to its amendment on March 18, 2015.

''[p]harmacist['s] comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' *Id.* at 64B–16–27.800(1)(f). 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.* at 64B–16–27.800(2), which is the ''prospective drug use review'' for red flags required by 64B–16–27.810. Finally, the rule required that ''[t]he pharmacist . . . record any related information indicated by a licensed health care practitioner.'' *Id.* at 64B–16–27.800(2). All of these ''patient record[s]'' must be ''maintained for a period of not less than two years from the date of the last entry in the profile record.'' *Id.* at 64B–16–27.800(4).

Thus, Florida's laws specifically require a pharmacist to 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 in the patient's ''profile record.'' Although such patient records provide relevant evidence in assessing whether a pharmacist resolved the suspicion created by the prescriptions at issue here, the Government only obtained and introduced patient profiles related to the 23 Trinity II customers identified in its December 4, 2014 subpoena. GX 98.[70] As noted *supra,* the Government established by a preponderance of the evidence that Trinity II's pharmacists failed to resolve red flags regarding these patients because the prescriptions, dispensing logs, and patient profiles contained no documentation that Trinity II resolved the red flags of diversion presented by these customers' prescriptions. As a result, I further find that the Government established by a preponderance of the evidence that Trinity II's pharmacists filled at least some of the prescriptions knowing that they lacked a legitimate medical purpose.

For example, the evidence shows that Trinity II knowingly filled controlled substances prescriptions well before the customer should have exhausted the supply obtained from a previous prescription filled by Trinity II. For one customer, J.T., Trinity II filled prescriptions for oxycodone 30 mg 14–16 days early on nine occasions in each of nine consecutive months—resulting in a cumulative effect of Trinity II filling and delivering[71] 135 extra days of oxycodone 30 mg (the equivalent of 1,080 extra tablets) for J.T. from March 2012–November 2012. While it is conceivable that a single early fill of a customer's prescription could be an unwitting mistake (albeit, at 16 days, a significant one) by one of Trinity II's pharmacists, it is not remotely credible that Trinity II could innocently repeat the same mistake nine times in nine consecutive months without knowing that the prescriptions lacked a legitimate medical purpose. Trinity II's pharmacists made no notes or comments on the front or back of these prescriptions, in the dispensing log, or in the patient profile explaining why J.T. should receive 135 extra days of oxycodone 30 mg. This lack of any explanation further highlights Trinity II's willingness to ignore the fact that J.T.'s early prescriptions lacked a legitimate medical purpose. This evidence of diversion of 135 extra days of a schedule II drug like oxycodone is so egregious that I find that it is more than sufficient to establish by a preponderance of the evidence that Trinity II's pharmacists were willfully blind[72] to the fact that J.T.'s prescriptions lacked a legitimate medical purpose when its pharmacists filled them 14–16 days early in each of nine consecutive months. On this basis alone, I find that Trinity II violated its corresponding responsibility under 21 CFR 1306.04(a). Indeed, the Agency has previously found violations of the corresponding responsibility when pharmacists knowingly filled prescriptions less than 15 days early.[73]

Trinity II's pattern of early fills and refills was not limited to one customer. The evidence establishes that Trinity II filled prescriptions for customer M.A. for hydromorphone 8 mg six to seven days early on eight occasions in eight consecutive months—resulting in the cumulative effect of Trinity II filling and providing 50 extra days of hydromorphone 8 mg for M.A. from May 2013-December 2013. Trinity II also filled a prescription for customer J.G. for lorazepam 2 mg nine days early on May 28, 2013. In addition, Trinity II filled and refilled J.G.'s prescriptions for Xanax 2 mg early on six occasions between October 10, 2012 and June 12, 2013—five days early, six days early, eight days early, 10 days early (twice), and 17 days early. The evidence also establishes that Trinity II filled prescriptions for customer L.H. for hydromorphone 8 mg eight days early on June 28, 2012 and nine days early on July 3, 2012.[74] As with customer J.T., Trinity II's failure to document anywhere on the relevant prescriptions, dispensing logs, or patient profiles why M.A., J.G., or L.H. should receive early fills and refills of these controlled substances further underscores Trinity II's pharmacists' knowledge that they were filling illegitimate prescriptions and violating their corresponding responsibility under 21 CFR 1306.04(a).

In his Recommended Decision, the CALJ declined to find that Trinity II violated its corresponding responsibility under § 1306.04(a) based on these early fills because of his belief that the determination of when a fill occurred must be based on ''the date when the customer picked up their medications,'' not when Trinity II filled the prescriptions. R.D. at 25. ''An early refill only logically bears upon this consideration [of over-utilization or under-utilization] at the moment the medication is being dispensed to the patient, not when a [fill] sticker is prepared by the pharmacy.'' *Id.* The CALJ offered the following explanation:

> While there may be some logical appeal to the principle that some or most of the steps required in a valid prospective drug use review should (and generally will) be completed prior to the preparation of the pharmacy fill sticker, no shred of that rationale could logically be applied to justify deeming the fill sticker preparation date as

[70] 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. 81 FR 31310 (2016).

[71] Given that J.T. came back on a monthly basis, it is a reasonable inference that the drugs were actually delivered to him.

[72] Moreover, this evidence would likely be sufficient to show that Trinity II had actual knowledge that these prescriptions lacked a legitimate medical purpose. However, the Government did not allege that Trinity II had such actual knowledge, making such a finding unnecessary.

[73] *E.g., Grider Drug #1 and Grider Drug #2,* 77 FR at 44098 (finding a violation of the corresponding responsibility where the refills for one patient were ''more than five days early, and some as much as nine to twelve days early''); *East Main Street Pharmacy,* 75 FR 66149, 66159 (2010) (accepting expert opinion that a refill of controlled substance ''two weeks early'' is a ''blatant example[ ] of abuse and diversion''); *cf. Jeri Hassman,* 75 FR 8194, 8201, 8229, 8231 (2010) (finding prescriptions were not for a legitimate medical purpose where approximately half of the controlled substance ''prescriptions were refilled five days early, with some being refilled as early as eight or nine days before the previous prescription would have run out'').

[74] These are only the most egregious examples of early filling of controlled substances by Trinity II in violation of its corresponding responsibility under § 1306.04(a). As I described in my fact findings, Trinity II also filled a prescription for Dilaudid 8 mg nine days early for customer D.E. without explanation.

equivalent to the date that a medication was dispensed (delivered/transferred) to a patient for early refill purposes.

Id. The CALJ cites to no authority (and I am aware of none) for the proposition that the date when the customer actually receives the controlled substance should be used to determine whether a pharmacy's early fill of a prescription violates its corresponding responsibility under 21 CFR 1306.04(a).[75]

Most importantly, the notion that the fill date is equivalent to the pick-up date is belied by § 1306.04(a)'s plain language, which states in pertinent part:

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

Id. (emphasis added). Section 1306.04(a) expressly *requires* pharmacists to identify and resolve suspicions that a prescription is illegitimate (like a prescription presented too early) before ''knowingly filling such a purported prescription.'' It does not allow a pharmacist to delay completing a prospective drug use review to confirm a suspicious prescription's legitimacy until ''a medication was dispensed (delivered/transferred) to a patient''—an event that necessarily occurs after the pharmacist has ''filled'' the prescription and which may even occur without the pharmacist's involvement at all. *See* R.D. at 25.[76] Such a rule would lead to the nonsensical result of allowing pharmacists to knowingly fill controlled substance prescriptions lacking a legitimate purpose so long as the pharmacist had not yet actually delivered them to the customer—directly contradicting § 1306.04(a)'s express prohibition.

And to the extent the CALJ's view is based on the notion that ''fill'' means ''dispense,'' or that the two terms are otherwise interchangeable, § 1306.04(a)'s plain language precludes that notion as well. Specifically, § 1306.04(a) distinguishes a prescribing practitioner's ''responsibility for the proper *prescribing and dispensing* of controlled substances'' only for a legitimate medical purpose from the pharmacist's corresponding responsibility not to ''knowingly *fill*[ ]'' prescriptions that lack a legitimate medical purpose. Filling constitutes part of the process of dispensing, but the CALJ cites to no decision of the Agency (and I am aware of none) holding that filling encompasses every part of the dispensing process, including the actual delivery to the ultimate user. If ''dispensing'' and ''filling'' shared the same meaning, then the Agency would not have used two different terms in the same regulation to describe prescribing practitioners' and pharmacists' respective responsibilities. Instead, the Agency would have simply used the term ''dispense'' to apply to both practitioners and pharmacists throughout the regulation. Thus, I reject the notion that under § 1306.04(a), the term ''fill'' is coextensive with the term ''dispense,'' which includes the delivery of a controlled substance.

Just as the operative date for determining whether a prescribing practitioner has met his/her responsibility under § 1306.04(a) is when the physician ''prescribe[s] and dispens[es]'' a controlled substance, the operative date for determining whether a pharmacist has met his/her corresponding responsibility is when the pharmacist ''fills the prescription.'' [77] And as noted *supra,* the record establishes by a preponderance of the evidence that the date on Trinity II's fill stickers represent the date when Trinity II's pharmacists filled the prescriptions at issue in this case. Accordingly, § 1306.04(a) required Trinity II to identify and to resolve any suspicions that a particular prescription lacked a legitimate medical purpose *before knowingly filling* the prescription.

As noted *supra,* the evidence of Trinity II's improper early fills alone is sufficient to prove that Trinity II knowingly filled illegitimate prescriptions in violation of its corresponding responsibility under § 1306.04(a). However, there are other

[75] Likewise, Trinity II contends that the date ''when the prescription was actually dispensed to the patient . . . and not the fill date, is the operative evidence of whether there was an improper dispensing event.'' Resp. Except. at 4; ALJ Ex. 41 at 16–17 (''Doering was basing his often incorrect counting on the date the prescription was filled, without having any knowledge as to when the customer actually picked up the prescription''). Trinity II claims that its ''electronic records included patient signature logs for when the prescription was actually dispensed to the patient,'' Resp. Except. at 4, and as a result of this claim, the CALJ averred that the Government's expert ''could not determine the date the patients picked up their medications because he had never been provided with the pharmacy's disbursement log.'' R.D. at 25. In fact, neither the CALJ nor Trinity II cite to any authority (and I am aware of none) supporting their position that the date when the customer actually receives the controlled substance should be used to measure whether a pharmacy lawfully filled a prescription early under 21 CFR 1306.04(a). To the extent that the CALJ and Trinity II rely on the definition of dispense, I discuss *infra* why such reliance is misplaced.

[76] The CALJ surmised that, unless the pharmacist's corresponding responsibility is delayed until ''the moment the medication is being dispensed to the patient,'' then ''any ethical Florida pharmacist who works ahead and prepares medications in advance of their eligibility to be picked up by the patient due to staffing or some other benign business-related issue would stand in unavoidable conflict with the standard of pharmacy practice in Florida merely by virtue of the date on the fill sticker.'' R.D. at 25. Aside from the fact that the record does not show that Trinity II routinely filled prescriptions ''in advance of their eligibility to be picked up,'' no Agency precedent supports the CALJ's hypothetical as some kind of exception to a pharmacist's corresponding responsibility. In fact, § 1306.04(a) precludes the CALJ's hypothetical by imposing a corresponding responsibility on the pharmacist at the time of ''filling,'' not at some point after filling the prescription. Thus, to fulfill their corresponding responsibility under § 1306.04(a), pharmacists must identify and resolve any red flags of diversion presented by controlled substance prescriptions (*e.g.,* by completing the prospective drug use review that Florida law required Trinity II to do) *before* filling them in order to avoid ''knowingly filling'' illegitimate prescriptions.

[77] Furthermore, even if § 1306.04(a) did impose on pharmacists a corresponding responsibility not to ''knowingly dispense'' an illegitimate prescription (rather than prohibiting them from ''knowingly filling such a purported prescription''), the calculation of an ''early fill'' would be the same. Under the CSA, '' 'dispense' means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner, including . . . the packaging, labeling, or compounding necessary to prepare the substance for such delivery.'' 21 U.S.C. 802(10). ''The terms 'deliver' or 'delivery' mean the actual, constructive, or attempted transfer of a controlled substance.'' *Id.* § 802(8). Thus, the situations in which a pharmacy ''dispenses'' a controlled substance includes when the pharmacy attempts to transfer a controlled substance to an ultimate user pursuant to a lawful prescription ''by packaging or labeling a controlled substance for such delivery''—*i.e.,* before a customer actually receives the prescribed controlled substance. As the Government points out in its Exceptions, even under Florida's definition, ''dispensing'' occurs before the customer receives the prescription. Gov. Except. at 46 (noting that Florida's 'dispense' definition in Ch. 465.003(6) unequivocally states that ''the actual sales transaction and delivery of such drug shall *not* be considered dispensing'') (quoting Fla. Stat. § 465.003(6)). In this case, when Trinity II filled a bottle with a prescribed controlled substance and then affixed a fill label or sticker to the bottle or ''packaging'' containing the controlled substance, Trinity II ''dispensed'' the prescription under the CSA (and arguably Florida law) by ''labeling . . . the substance for'' ''delivery to an ultimate user.'' The record reflects that the date on the fill sticker represents the date when Trinity II packaged or labeled a prescribed controlled substance. And as the CALJ concedes, ''the date on the fill sticker'' is also what the Government used to calculate the date when Trinity II ''filled'' the prescriptions at issue in the case. *See* R.D. at 25. Accordingly, even under the theory that ''fill'' in § 1306.04(a) really means ''dispense,'' the date on the fill sticker in this case reflects both the ''fill'' date and the ''dispense'' date.

examples of suspicious prescriptions nonetheless filled by Trinity II that further prove that Trinity II knowingly filled prescriptions lacking a legitimate medical purpose. For instance, the evidence established that on December 2, 2013, Trinity II knowingly filled two therapeutically duplicative prescriptions for customer R.H.—one for 120 tablets of hydromorphone 8 mg and a second for 120 tablets of oxycodone 30 mg. Each immediate-release opiate prescription had the same dosage instruction to take one tablet every six hours. The Agency has previously found that therapeutically duplicative prescriptions raise a strong suspicion of diversion, and a pharmacist who fails to resolve this suspicion before knowingly filling the prescription violates his/her corresponding responsibility under § 1306.04(a). *See The Medicine Shoppe,* 79 FR 59504, 59507 & n. 10 (2014) (finding that prescriptions for ''duplicative narcotics'' is evidence of diversion, and knowingly filling such prescriptions without resolving this strong suspicion violates § 1306.04(a)). Here, Trinity II's pharmacists offered no notes or comments on the front or back of these prescriptions, the dispensing log, or in the patient profile explaining why R.H. should have received these two therapeutically duplicative prescriptions. Thus, I find that Trinity II's pharmacist's decision to fill R.H.'s therapeutically duplicative prescriptions without explanation, combined with the early fill evidence already described, also shows that Trinity II knowingly filled prescriptions that lacked a legitimate medical purpose.

In addition, the evidence shows that Trinity II knowingly and routinely filled controlled substance prescriptions presented by customers who had traveled great distances to fill them, even though the Agency has previously held that prescriptions by such customers should cause pharmacists to suspect that the prescriptions are not legitimate.[78] For example, on June 5, 2013, customer S.S. traveled across the entire state of Florida—and approximately 397 miles roundtrip—to obtain from his physician in Tampa and to fill at Trinity II in Clearwater his prescription for 150 tablets of hydromorphone 8 mg. On May 10, 2012, customer C.V. traveled from his home in Port Charlotte, Florida—an approximately 224 miles roundtrip—to obtain from his physician in Tampa and to fill at Trinity II his prescription for 120 tablets of hydromorphone 8 mg. On June 13, 2013 and on July 3, 2013, customer D.E. traveled from his home in Brooksville, Florida—an approximately 119 miles roundtrip—to obtain from his physician in Tampa and to fill at Trinity II identical prescriptions for hydromorphone 8 mg. As already noted, Trinity II also filled the July 3, 2013 prescription nine days early—adding to the suspiciousness of this particular prescription's legitimacy. Nevertheless, even though Trinity II knew the addresses of S.S.,[79] C.V., D.E., and their respective physicians, the evidence shows that Trinity II failed to document why it nonetheless filled the schedule II controlled substance prescriptions for these customers.

The travel of customer D.W. deserves special mention. He traveled all the way from Wellborn, Florida—an approximately 404 miles roundtrip—to obtain from his physician in Tampa and to fill at Trinity II controlled substance prescriptions for oxycodone 30 mg with ginger and carisoprodol 350 mg on three separate occasions in March, April, and May of 2012. Moreover, D.W. endured the added inconvenience of traveling on different dates to fill his second and third prescriptions of each of these controlled substances—filling two prescriptions for oxycodone with ginger on April 5, 2012 and on May 3, 2012, and two prescriptions of carisoprodol on April 19, 2012 and on May 11, 2012. The fact that D.W. was willing to travel these distances so frequently, and inefficiently, just to fill these controlled substances prescriptions at Trinity II should have highlighted for its pharmacists just how unlikely it was that these prescriptions were filled for a legitimate medical purpose. Nevertheless, even though Trinity II knew how far away D.W. lived, Trinity II failed to document why it still filled D.W.'s highly suspicious controlled substance prescriptions.

Accordingly, Trinity II's pharmacists' knowledge of the great distances traveled by these customers, combined with their failure to document why their prescriptions should nonetheless be filled, shows that Trinity II's pharmacists knew that these prescriptions lacked a legitimate medical purpose.

The evidence further shows that Trinity II routinely filled ''cocktail prescriptions'' in which customers simultaneously presented multiple prescriptions that would provide the same customer an opioid, a benzodiazepine, and carisoprodol (a muscle relaxant). Trinity II routinely filled these ''cocktail prescriptions'' even though the Agency has 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 at 66157–58. Nevertheless, on June 27, 2013 and July 23, 2013, Trinity II filled for customer S.S. prescriptions for the same combination of controlled substances—an opioid (hydromorphone 8 mg), a benzodiazepine (alprazolam 2 mg), and carisoprodol 350 mg—on each date. This is also the same customer who had traveled across the entire state of Florida to obtain these prescriptions—further highlighting the suspicious nature of his prescriptions. *See supra.* Trinity II's pharmacists provided no notes or comments explaining why they knowingly filled these ''cocktail'' prescriptions. *Id.* Thus, I find that Trinity II's pharmacists' knowledge that these prescriptions reflected a well-established suspicious ''cocktail'' of controlled substances for a customer who they also knew had traveled across the entire state of Florida established that Trinity II's pharmacists knew that these prescriptions lacked a legitimate purpose.

Likewise, the record shows that on March 7, 2012, May 3, 2012, and May 31, 2012, Trinity II filled prescriptions for the same ''cocktail'' of controlled substances—an opioid (oxycodone 30 mg), a benzodiazepine (alprazolam 2 mg), and carisoprodol—issued by the same prescribing physician to customers J.Ha. and R.Ha. on each date. And yet,

[78] *E.g., East Main Street Pharmacy,* 75 FR 66,149, 66,153 & n. 16, 66,163–66,164 (2010) (finding that traveling nearly 100 miles to pharmacy ''provided further reason to know that the prescriptions were not legitimate'' and that customers traveling 90 miles from their residence to the pharmacy constituted ''travelling great distances to fill their prescriptions'' and concluding ''the fact that the patients were driving so far to get their prescriptions filled 'would be a major red flag for any pharmacist'").

[79] The fill sticker that Trinity II generated and attached to the back of the prescription, the dispensing log, and the patient profile all show S.S.'s address to be in Orange Park, Florida, which is a city located near Jacksonville, Florida. GX 44, at 1, 2, 9; Tr. 1680. However, as noted *supra,* the front of the prescription lacked S.S.'s address. As a result, the Government alleged that Trinity II's filling of this prescription constitutes an independent violation of 21 CFR 1306.05, which requires, *inter alia,* all prescriptions for controlled substances to bear the full name and address of the patient and imposes a corresponding liability ''upon the pharmacist . . . who fills a prescription not prepared in the form prescribed by DEA regulations.'' *Id.* at § 1306.05(a), (f). The CALJ also recommended that I find that Trinity II violated 21 CFR 1306.05. *See* R.D. at 46. At the time these prescriptions were issued, the Agency had made a public pronouncement that, if missing, pharmacists could add a patient's address if state law allowed it. *See Superior I and II,* 81 FR at 31336 n.58. Here, the Government has produced no evidence that Florida law, the Board of Pharmacy's regulations, or the Board's policy prohibited Trinity II's pharmacists from adding the patient's address to the prescriptions.

Trinity II's pharmacists never explained why they filled these highly suspicious prescriptions. The suspiciousness of these ''cocktail prescriptions'' was further compounded by the fact that these prescriptions also reflected ''pattern prescribing'' and a lack of individualized drug therapy. Specifically, Trinity II knew that J.Ha. and R.Ha. shared a last name and home address and that their prescriptions were issued (1) by the same prescribing physician, (2) on the same day, and (3) for the same drugs.[80] Trinity II's pharmacists provided no notes or comments explaining why they knowingly filled these prescriptions. *See supra.* Thus, I find that the fact that Trinity II's pharmacists' knew that these prescriptions reflected a well-established suspicious ''cocktail'' of controlled substances for two customers who also shared the same last name, address, and prescribing physician, established that Trinity II's pharmacists knew that these prescriptions lacked a legitimate purpose.

Accordingly, and in light of the very substantial weight of the evidence of diversion presented by the suspicious prescriptions in this case—early fills, therapeutic duplication, customers traveling great distances, ''cocktail prescriptions,'' and ''pattern prescribing''—I find that Trinity II's pharmacists violated their corresponding responsibility by knowingly filling prescriptions that lacked a legitimate medical purpose.

The Allegations Pursuant to 21 CFR 1306.06

Under 21 CFR 1306.06, ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' Pharmacists fill prescriptions for controlled substances in the usual course of their professional practice, for example, when pharmacists follow the prescribing physician's instructions for a prescription issued for a legitimate medical purpose. When pharmacists knowingly fail to follow such instructions in filling otherwise valid prescriptions, they are not ''acting in the usual course of [their] professional practice'' and therefore violate 21 CFR 1306.06.

Here, Trinity II filled prescriptions without following the prescribing physician's instructions with respect three of the Show Cause Order's charges. Specifically, in the third and fourth charges of the Show Cause Order, the Government charged Trinity II with twice filling prescriptions for customer D.G. for fentanyl patches on dates prior to the prescribing physician's explicit ''No Exceptions Do Not Fill Until'' instructions on each prescription. As noted *supra,* I have found that the Government proved these facts by a preponderance of the evidence.[81] Although he did not rely on 21 CFR 1306.06,[82] the CALJ recommended that I sustain the Government's third and fourth charges. I do sustain those charges, but only on the basis that Trinity II violated 21 CFR 1306.06[83] when it filled[84] these prescriptions

[80] *See East Main Street Pharmacy,* 75 FR at 66,157 (noting red flags such as ''lack of indivdua[liza]tion of therapy, certain patterns from physicians of seeing the same types of controlled substances over, and over, and over, again''). This is not the only example of Trinity II filling prescriptions presenting this type of ''pattern prescribing.'' On two occasions—November 20, 2013 and December 18, 2013—Trinity II filled prescriptions for customers M.W. and J.W. for the same controlled substance (oxycodone 30 mg with ginger), even though Trinity II knew that these customers shared the same last name, address and prescribing physician. Trinity II's pharmacists never explained why they nonetheless filled these prescriptions. As a result, I find that it is highly probable that Trinity II's pharmacists knew that these prescriptions also lacked a legitimate medical purpose.

[81] In addition, I find that there is no evidence establishing that the ''Do Not Fill'' prescriptions underlying the Show Cause Order's third and fourth charges were invalid under 21 CFR 1306.04(a) and 1306.11(a). For this reason, I deny the Government's allegation that Trinity II also (1) violated their corresponding responsibility under 21 CFR 1306.04(a) when they filled these two prescriptions and (2) filled a prescription without a valid prescription in violation of 21 CFR 1306.11(a) regarding these prescriptions. *See* ALJ Ex. 1b, at 14–15.

It is also for this reason that I disagree with the CALJ's statement that, ''[b]ecause the scrip[t] was not valid until the date articulated by the practitioner, . . . the Respondent filled these two prescriptions without a lawful order from a practitioner.'' R.D. at 49. As the CALJ himself noted in recommending that I reject the Government's claim of a § 1306.11(a) violation regarding the Show Cause Order's fifth charge, ''because there was a (seemingly) valid scrip[t] presented for each of these dispensing events,'' Trinity II's conduct should *not* be reviewed ''as if it were dispensed with *no* [valid] order from the practitioner.'' *Id.* at 49 n.116. I agree. In the Show Cause Order's third, fourth, and fifth charges, customers presented apparently valid prescriptions to Trinity II, but its pharmacists ignored (repeatedly) the same instructions when filling them. Thus, I agree with the CALJ's argument regarding the fifth charge, and I apply the same argument in rejecting his rationale regarding the third and fourth charges.

[82] The CALJ criticized the Government for not relying on 21 CFR 1306.12 and 21 CFR 1306.14 as a basis for the third and fourth charges. R.D. at 47 n.111 (''It is difficult to imagine why the Government did not cite to these regulatory sections, which speak directly to the violations at issue in OSC ¶¶ 9 and 10.''). However, the CALJ's own analysis supplies a good explanation for why the Government did not pursue charges on that basis. The CALJ conceded that ''those regulatory sections specifically pertain to the situation where a practitioner issues multiple prescriptions, presumably on the same date.'' *Id.* at 47. He further referenced DEA's ''notice of final rule implementing the regulation,'' in which ''DEA noted that the rule 'did not address whether a single prescription with ''Do not fill before [date]'' instructions is permissible' '' and that ''no 'existing provision of the CSA or DEA regulations address[es] this type of prescribing.' '' *Id.* at 47–48 (quoting ''Issuance of Multiple Prescriptions for Schedule II Controlled Substances,'' 72 FR 64,921–64,924 (2007)). Here, the ''Do Not Fill'' prescriptions underlying the Show Cause Order's third and fourth charges were not issued on the same date and hence are not ''multiple prescriptions'' on the same date within the meaning of 21 CFR 1306.12(b).

[83] Federal courts have suggested that the identical phrase—''usual course of his professional practice''—found in 21 CFR 1306.04(a) essentially includes a knowingly requirement in criminal cases. *See, e.g., Bennett,* 874 F.3d at 245 (finding that a prescribing physician violates § 1306.04(a) when the practitioner ''knowingly distribut[es] prescriptions outside the usual course of professional practice'') (internal citations and quotations omitted). Assuming the ''knowingly'' scienter standard applies to the application of § 1306.06 to this administrative proceeding, I find that the Government has met its burden to prove it. The Government's burden of proof in this proceeding is ''preponderance of the evidence,'' not ''beyond a reasonable doubt.'' In that vein, while it is conceivable that a Trinity II pharmacist may mistakenly fail to follow ''Do Not Fill Until'' instructions in good faith once, it is less credible that Trinity II's pharmacists would fail to follow such instructions for the same customer two months in a row without doing so knowingly. The CALJ apparently agreed. R.D. at 48–49 (''Despite the clear indication of the practitioner's limitation on the scrip[t]s, Respondent's employees blatantly ignored the instruction and filled the prescriptions before the practitioner had authorized them to be filled.''). When this pattern is combined with the broader pattern of Trinity II's pharmacists knowingly filling prescriptions in violation of their corresponding responsibility, *see supra,* I have little trouble finding that the Government has established by a preponderance of the evidence that Trinity II's pharmacists knowingly failed to follow the ''Do Not Fill Until'' instructions in D.G.'s prescriptions and hence filled prescriptions outside the pharmacists' usual course of their professional practice under 21 CFR 1306.06.

In any event, even if the Government could not prove that this conduct violated § 1306.06 or otherwise met Factors Two or Four under 21 U.S.C. 823(f), I find that a pharmacist blatantly and knowingly ignoring a physician's instructions on an otherwise valid prescription would constitute ''[s]uch other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). *See* R.D. at 48 (''To allow a pharmacy to fill a prescription at any time before a date specified by the issuing practitioner would completely undermine the practitioner's decision to issue the scrip[t] in that manner.'').

[84] In its Exceptions, Trinity II offered its conclusory argument that the date ''when the prescription was actually dispensed to the patient . . . and not the fill date, is the operative evidence of whether there was an improper dispensing event. Because the Government never requested'' ''the pharmacy's electronic records [which] included patient signature logs,'' ''there was insufficient evidence to meet the Government's burden of proof for this allegation.'' Resp. Except. at 4. I reject this Exception for the same two reasons that I rejected the same argument *supra* in the context of Trinity II's violations of 21 CFR 1306.04(a). Like § 1306.04(a), 21 CFR 1306.06 expressly hinges on whether pharmacists ''filled'' controlled substance prescriptions in the usual course of their professional practice; it does not depend on ''when the prescription was actually dispensed to the patient'' as Trinity II claims. Thus, the ''operative evidence'' is the evidence of filling, and the CALJ properly reviewed the dates on the fill sticker, the

Continued

before the prescribing physician's ''Do Not Fill'' instructions.

In the Show Cause Order's fifth charge, the Government alleged, and as noted *supra* I have found, that Trinity II filled for customer J.T. seven consecutive prescriptions for a morphine sulfate solution that was at least five times, and sometimes 15 times, stronger than the dosages that the physician had prescribed. Although the Government charged that this conduct violated 21 CFR 1306.06 and 21 CFR 1306.11(a), I find that the conduct did not violate 21 CFR 1306.11(a) because I find that there is no proof that the prescriptions underlying the Show Cause Order's fifth charge were invalid. *See* R.D. at 49 n.116 (''there was a (seemingly) valid scrip[t] presented for each of these dispensing events''). For this reason, the CALJ recommended that I deny the Government's allegation that Trinity II filled prescriptions in the fifth charge without a valid prescription and in violation of 21 CFR 1306.11(a) regarding these prescriptions. *See id.*

Although he did not rely on 21 CFR 1306.06,[85] the CALJ nonetheless recommended that I sustain the Government's fifth charge. I do sustain this charge, but only on the basis that Trinity II violated 21 CFR 1306.06. As with D.G.'s prescriptions in the third and fourth charges, customer J.T. presented apparently valid prescriptions to Trinity II, but the Government proved the allegations in its fifth charge that Trinity II's pharmacists repeatedly ignored the prescriptions' instructions when filling them. While it is conceivable that a Trinity II pharmacist may have mistakenly failed to follow a prescription's dosage instructions in good faith once, it is not remotely credible that Trinity II's pharmacists would fail to follow such instructions for the same customer seven times in the span of six months without doing so knowingly. For this reason, I have little trouble finding that the Government has established by a preponderance of the evidence that Trinity II's pharmacists knowingly filled prescriptions with the incorrect dosage strength of a controlled substance seven times and hence filled prescriptions outside the pharmacists' usual course of their professional practice in violation of § 1306.06.

The Allegations Regarding Prescriptions Filled by Non-Pharmacists

In the Show Cause Order's final two charges, the Government alleged that Trinity II violated federal and Florida law when it allowed pharmacist interns to fill controlled substances prescriptions. Section 1306.06 provides that controlled substances prescriptions ''may only be filled by a pharmacist.'' Federal law states that a pharmacist ''means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (*e.g.,* pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.'' 21 CFR 1300.01(b).

In his Recommended Decision, the CALJ found that Florida law authorized pharmacy interns to dispense controlled substances. Specifically, the CALJ found that Florida defined a ''pharmacist'' as a person ''licensed pursuant to chapter 465 to practice the profession of pharmacy'' in Florida, and that Chapter 465 in turn defines the ''practice of the profession of pharmacy'' to include ''dispensing.'' R.D. at 44 (quoting Fla. Stat. §§ 893.02(18), 465.003(13)). The CALJ also found that Florida law states that a ''person other than a licensed pharmacist or pharmacy intern may not engage in the practice of pharmacy.'' R.D. at 44 (quoting Fla. Stat. § 465.014(1)). On this legal basis, the CALJ recommended that I find that ''both pharmacists and pharmacy interns are authorized under Florida law to 'practice the profession of pharmacy,' which includes dispensing. Therefore, it is acceptable for pharmacy interns to dispense controlled substances under Florida law and under the DEA regulations.'' R.D. at 44.

In its Exceptions, the Government took issue with the CALJ's characterization of Florida law and whether it authorized pharmacist interns to dispense controlled substances under the supervision of a licensed Florida pharmacist. The Government contended that § 893.04(1) of Chapter 893 of Florida law states that controlled substance prescriptions may only be dispensed by ''a pharmacist, in good faith and in the course of professional practice''—making no reference to pharmacy interns. Gov. Except. at 78. The Government also argued that pharmacy interns are not ''licensed pursuant to Chapter 465 to practice the profession of Pharmacy'' as required under § 893.02(18) but instead are ''registered with the'' state under § 465.03(12). Gov. Except. at 79. For these reasons, the Government asked me to reject the CALJ's recommendation and find that pharmacy interns are essentially never authorized to dispense controlled substances prescriptions in Florida. *Id.* at 80.

I find that both the CALJ and the Government have misinterpreted Florida law. Although Florida law is not as clear as federal law in this regard, Florida law neither permits all pharmacy interns to dispense controlled substances (as the CALJ recommended), nor prohibits all pharmacy interns from doing so (as the Government claims). Rather, Florida law permits pharmacy interns to dispense controlled substances only when they are under the statutorily prescribed supervision of a licensed pharmacist. For example, Florida statutes makes it unlawful for an intern registered in Florida to ''fill, compound, or dispense prescriptions or to dispense medicinal drugs'' *if* the intern is ''not acting under the direct and immediate personal supervision of a licensed pharmacist.'' Fla Stat. § 465.015(2)(b). Florida law also authorizes disciplinary actions against pharmacists ''permitting a registered intern who is *not* acting under the direct and immediate personal supervision of a licensed pharmacist, to fill, compound, or dispense any prescriptions in a pharmacy owned and operated by such pharmacists or in a pharmacy where such pharmacists are employed or on duty.'' *Id.* 465.016(1)(c) (emphasis added). In addition, Florida's Administrative Code states that ''[n]o intern shall perform any acts relating the filling, compounding, or dispensing of medicinal drugs *unless* it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy

front of the prescription, and the dispensing report to identify the fill date. Second, for the reasons I have already discussed *supra,* the dispensing date would ultimately have been the same as the fill date.

[85] The CALJ recommended that I find that Trinity II's conduct in the Show Cause Order's fifth charge violated Trinity II's corresponding responsibility under 21 CFR 1306.04(a) because ''the regulation's plain language imposes a corresponding responsibility on the pharmacist 'for the proper . . . dispensing' of the prescription. Dispensing a stronger concentration of a controlled substance than has been authorized by the practitioner is a violation of that corresponding responsibility.'' R.D. at 49.

The CALJ's interpretation of § 1306.04(a) is incorrect for at least two independent reasons. First, as noted *supra,* pharmacists violate their corresponding responsibility when they ''knowingly fill[ ]'' a prescription that lacks a legitimate purpose. The CALJ has already recommended that I find (and I have so found) that the underlying prescriptions at issue in the fifth charge were valid, R.D. at 49 n. 116 (''there was a (seemingly) valid scrip[t] presented for each of these dispensing events''), making impossible a finding that Trinity II's pharmacists knowingly filled illegitimate prescriptions in violation of § 1306.04(a). Second, also as noted *supra,* the plain language of § 1306.04(a) assigns'' [t]he responsibility for the proper prescribing and dispensing of controlled substances . . . upon the prescribing practitioner,'' not upon the pharmacists, whose corresponding responsibility expressly relates to filling, not dispensing. Indeed, it is likely for these reasons that the Government did not claim that Trinity II violated its corresponding responsibility in the Show Cause Order's fifth charge.

in this state.'' Fla. Admin. Code r. 64B16–26.400 (emphasis added). Thus, I find that it is lawful in Florida for a pharmacy intern, registered in Florida, to fill and to dispense prescriptions so long as it is under the statutorily prescribed supervision of a licensed Florida pharmacist.

Here, even assuming *arguendo* as true the Government's allegations that Mina A. Ghobrial was a pharmacy intern who worked at Trinity II and filled controlled substances prescriptions during the alleged time period, I have already found that the Government failed to establish that Ghobrial was not supervised by a licensed Florida pharmacist when Ghobrial did so. *See supra.* Accordingly, I agree with the CALJ's recommendation that I find (and I do so find) that the Government has failed to carry its burden that Ghobrial was not properly supervised under Florida law, and I agree with the CALJ's recommendation that I reject (and I do so reject) the Show Cause Order's sixth and seventh charges.

Summary of Factors Two and Four

As found above, Trinity II's pharmacists knowingly filled dozens of controlled substance prescriptions for more than a dozen patients even though those prescriptions lacked a legitimate medical purpose. 21 CFR 1306.04(a). Moreover, Trinity II's pharmacists knowingly and repeatedly ignored the instructions set forth in legitimate prescriptions issued to two of its customers and thereby failed to fill them in the usual course of their professional practice. 21 CFR 1306.06. Thus, I conclude that Trinity II has engaged in egregious misconduct which supports the revocation of its registration. *See Dewey C. MacKay,* 75 FR 49956, 49997 (2010); *Krishna-Iyer,* 74 FR at 463; *Alan H. Olefsky,* 57 FR 928, 928–29 (1992). I therefore hold that the Government has clearly established its *prima facie* case that Trinity II's registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

In its Exceptions, Trinity II argued that, ''[e]ven assuming that the DEA met its burden of proof, '' the CALJ ''erred in failing to balance the relatively *de minimis* problems that the ALJ found were supported by the preponderance of the evidence against the number of prescriptions during the [two-year] audit period in which there was no problem.'' Resp. Except. at 5 (citing *Iyer* v. *DEA,* 249 Fed. Appx. 159, 160 (11th Cir. 2007) (unpublished). Specifically, Trinity II claims that ''the sanction of revocation . . . is not supported'' because the CALJ found that ''approximately 0.07%'' of the prescriptions filled by Trinity II violated the law. *Id.* at 5–6.

Trinity II's challenge to the CALJ's recommendation of revocation on the basis of the *Iyer* decision and the existence of prescriptions it filled ''in which there is no problem'' is unavailing for at least three reasons. *First,* as a threshold matter, I have already found that the scope of Trinity II's violations of federal law—particularly regarding Trinity II's egregious violations of its corresponding responsibility—far exceed the number that even the CALJ identified. In other words, some of the very prescriptions that Trinity II filled and claims in its Exceptions were ''no problem,'' were, in fact, highly problematic and illegal. *Second,* Trinity II's arguments based on the unpublished 11th Circuit opinion *Iyer* v. *DEA* are identical to those already rejected by the Agency in multiple final opinions, such as *Wesley Pope, T.J. McNichol,* and *Dewey C. MacKay,* and I incorporate the relevant portions of those final opinions herein. *E.g., Wesley Pope,* 82 FR 14944, 14981–14984 (2017); *T.J. McNichol,* 77 FR 57133, 57144–57146 (2012); *Dewey C. MacKay,* 75 FR at 49977. As I have pointed out previously (and repeat here for emphasis), the 11th Circuit has never chosen to publish the *Iyer* decision, and by local rule it is therefore not binding precedent for this case or for any other case. 11th Cir. R. 36–2 (''Unpublished opinions are not considered binding precedent''). In addition, no subsequent 11th Circuit panel has chosen to adopt it; on the contrary, they have affirmatively declined multiple opportunities to do so. *See Pope,* 82 FR at 14983 (identifying cases in which respondents have raised *Iyer*-based arguments identical to Trinity II's, and the 11th Circuit has nonetheless denied the petitions of review and affirmed the Agency's sanction). Moreover, the 10th Circuit, in a published opinion, flatly rejected the same argument Trinity II has made here. *MacKay* v. *DEA,* 664 F.3d 808, 819 (10th Cir. 2011). *Third,* and most significantly, even assuming *arguendo* that Trinity II legally filled every other controlled substance prescription presented to it between February 2012 and February 2014, and I consider them consistent with *Iyer,* I nevertheless find that the violations identified by the CALJ are sufficiently egregious to outweigh the remaining (and presumptively non-problematic) prescriptions. Thus, I find that the CALJ did not err in his recommendation that revoking Trinity II's registration is in the public interest.

I therefore hold that the Government has established its prima facie case that Trinity II's registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

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 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 CALJ recommended that I find that Trinity II ''has not accepted responsibility'' and that, as a result, ''evidence of remedial steps is irrelevant.'' R.D. at 52 (citing *Hassman,* 75 FR at 8236). The CALJ further recommended that I find that, ''[i]n any event, the Respondent provided no evidence of remedial steps in this case.'' *Id.*

In its Exceptions, Trinity II claims that the CALJ ''failed to provide

Respondents' with the opportunity to present their evidence'' ''that it accepts responsibility for the established misconduct, and has taken appropriate steps to prevent such misconduct in the future.'' Resp. Except. at 4. Trinity II specifically claims that the CALJ did not consider as ''mitigating evidence'' that Trinity II allegedly ''voluntarily ceased dispensing schedule II controlled substances by March 1, 2014.'' *Id.* at 4–5.

I agree with the CALJ that Trinity II has not accepted responsibility for its misconduct nor presented sufficient mitigating evidence to assure me that Trinity II can be entrusted with the responsibility carried by a DEA registration. The CALJ observed:

> There was no aspect of the evidentiary rulings issued during the prehearing proceedings in this case that would have limited [Trinity II's] ability to do so in any way. . . . the Respondent elected to proceed on a peculiar course where it presented no defense to these allegations, accepted no responsibility for them, and never indicated that it would act differently in the future. The registrant is essentially saying, it did it, it liked it, and it will continue to do it. . . . it has left the Agency little choice but to revoke its registration to ensure the safety of the public.

R.D. at 54 n.124. Indeed, even in its Exceptions, Trinity II identifies no evidence of acceptance of responsibility, much less remorse, for its misconduct in this case. It did not even try to provide such evidence at the hearing. And it is difficult to overstate the significance of the misconduct that Trinity II has failed to accept. Trinity II's willingness to knowingly fill seemingly any prescription and any combination of prescriptions that its customers presented—no matter how obvious it was that the prescription lacked a legitimate purpose—is alarming. Trinity II was apparently equally ready to provide controlled substances to an unscrupulous customer earlier, or at dramatically greater dosages, than the prescribing physician had instructed on the face of the prescriptions.

I thus find that Trinity II 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 Trinity II knowingly diverted controlled substances, there is no need to consider its remedial efforts [86] 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 Trinity II'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, even with respect to valid prescriptions, Trinity II's pharmacists repeatedly and knowingly failed to fill them consistent with the prescribing physicians' instructions. *Cf. Medicine Shoppe-Jonesborough,* 300 Fed. Appx. 409, 411–412 (6th Cir. 2008) (rejecting '' 'human error' defense'' to dispensing ''the same drug in different concentrations'' because ''dispensing the right drug in the wrong strength 'can have serious consequences for the health of patients' '') (internal citations omitted).

I further find that the Agency's interest in deterring future misconduct both on the part of Trinity II as well as the community of pharmacy registrants supports revocation. As for the issue of specific deterrence, the revocation of Trinity II's registration is not a permanent bar. And regarding 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. This interest would be compelling even if it was not the case that the nation faces an epidemic of opioid abuse.

I therefore conclude that the revocation of Trinity II's registration is necessary to protect the public interest. And I will further order that any application of Trinity II to renew or modify its registration, or for any other 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 FT0531586 issued to Trinity Pharmacy II, Inc., be, and it hereby is, revoked. I further order that any application of Trinity Pharmacy II, Inc. to renew or modify its registration, or for any other registration, be, and it hereby is, denied. This order is effective immediately.

Dated: February 6, 2018.

Robert W. Patterson,

Acting Administrator.

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[86] Furthermore, the CALJ did not deny Trinity II, as it claims in its Exceptions, the opportunity to establish that it ceased dispensing schedule II controlled substances. Resp. Except. at 4–5. During the hearing, one of the DIs testified to his awareness that Trinity II stopped distributing schedule II controlled substances as of March 1, 2014. Tr. 527. However, Trinity II provided no evidence that this decision was intended to be remedial. More importantly, I have found that Trinity II's violation of its corresponding responsibility extended to other controlled substances, such as alprazolam, not regulated under schedule II. Thus, even if Trinity II had ceased distributing schedule II controlled substances as a remedial measure, it falls far short of what would have been necessary to mitigate Trinity II's misconduct.