UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Pronto Pharmacy, LLC**	**Docket No. 19-42**

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

Mark M. Dowd
U.S. Administrative Law Judge

May 5, 2020

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for the Government

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The Acting Administrator, Drug Enforcement Administration (DEA), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO),[1] dated August 23, 2019, suspending and seeking to revoke the Respondent's Certificate of Registration (COR), number FP2302076, and to deny any pending applications for renewal or modification of such registration, or for additional DEA registrations, on the ground that the Respondent's registration would be inconsistent with the public interest, pursuant to 21 U.S.C. § 824(a)(4), and as defined in 21 U.S.C. § 823(f). The Respondent requested a hearing on September 18, 2019,[2] and prehearing proceedings were initiated.[3] A hearing was conducted in this matter on January 28-29, 2020, in Tampa, Florida.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this Recommended Decision, is whether the record as a whole establishes by a preponderance of the evidence that the DEA Certificate of Registration, No. FP2302076, issued to the Respondent should be revoked, and any pending applications for modification or renewal of the existing registration be denied, and any applications for additional registrations be denied, because its continued registration would be inconsistent with the public interest under 21 U.S.C. §§ 823(f) and 824(a)(4).

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

[1] ALJ Ex. 1.
[2] ALJ Ex. 3.
[3] ALJ Ex. 4.

THE ALLEGATIONS

1. The Respondent repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. ALJ Ex. 1 at ¶ 4. Specifically, from at least January 2018 through at least May 2019, the Respondent repeatedly filled prescriptions for Schedule II narcotics in the face of obvious red flags of drug abuse and diversion. *Id.* Filling these prescriptions violated federal and Florida law, including 21 C.F.R. §§ 1306.04(a) and 1306.06, and Fla. Admin. Code r. 64B16-27.810.
2. In addition, the Respondent engaged in the "manufacture" of controlled substances, as the Controlled Substances Act defines that term. ALJ Ex. 1 at ¶ 5. The Respondent is not registered with the DEA as a manufacturer. *Id.* Manufacturing controlled substances without the appropriate registration is a violation of federal law, including 21 U.S.C. § 841(a)(1) and 21 C.F.R. § 1301.13(e). *Id.*

pronto can only dispense on doctors order and dose not issue out prescriptions

IMPROPER DISPENSING

Between January 9, 2018, and May 7, 2019, the Respondent repeatedly issued prescriptions in violation of the minimum practice standards that govern the practice of pharmacy in Florida. ALJ Ex. 1 at ¶ 11. These prescriptions presented numerous red flags of drug abuse and diversion, including drug cocktails, early refills, excessive dispensing of high-strength controlled substances, travelling long distances, and cash payments. *Id.* at ¶¶ 12, 13, 14, 15, 18, 19. Filling these prescriptions violated federal and state law, including 21 U.S.C. § 842(a)(1), 21 C.F.R. § 1306.04(a), and Florida Administrative Code r. 64B16-27.810. *Id.* at ¶ 19. The OSC/ISO provided the following specific examples of prescriptions that raised these red flags:

Drug Cocktails

3. **Patient A.G.:** On at least nine occasions between January 25, 2018, and April 12, 2019, the Respondent filled prescriptions issued by the same prescriber for patient **A.G.** for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(a). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for A.G. on the following four occasions: January 25, 2018; March 1, 2018; April 12, 2018; and May 8, 2018. *Id*. The Respondent filled prescriptions for oxycodone and alprazolam for A.G. on the following five occasions: December 20, 2018; January 17, 2019; February 14, 2019; March 20, 2019; and April 12, 2019. *Id*.
4. **Patient B.S.:** On at least five occasions between January 29, 2018, and April 22, 2019, the Respondent filled prescriptions issued by the same prescriber for patient **B.S.** for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(b). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for B.S. on the following two occasions: January 29, 2018, and May 22, 2018. *Id*. The Respondent filled prescriptions for oxycodone and alprazolam for B.S. on the following three occasions: December 20, 2018; February 28, 2019; and March 26, 2019. *Id*.
5. **Patient N.B.:** On at least three occasions between September 14, 2018, and January 16, 2019, the Respondent filled prescriptions issued by the same prescriber for patient **N.B.** for alprazolam and oxycodone or hydromorphone on the same date. ALJ Ex. 1, ¶ 12(c). Specifically, the Respondent filled prescriptions for hydromorphone and alprazolam for N.B. on September 14, 2018. *Id*. The Respondent filled prescriptions for oxycodone and alprazolam for N.B. on the following two occasions: December 20, 2018, and January 16, 2019. *Id*.

6. **Patient C.R.:** On at least three occasions between March 6, 2018, and July 12, 2018, the Respondent filled prescriptions issued by the same prescriber for patient **C.R.** for alprazolam and oxycodone on the same date. ALJ. Ex. at ¶ 12(d). Specifically, the Respondent filled prescriptions for oxycodone and alprazolam for C.R. on March 6, 2018; April, 19, 2018; and July 12, 2018. *Id*.
7. **Patient J.M.:** On at least five occasions between January 25, 2018, and May 16, 2018, the Respondent filled prescriptions issued by the same prescriber for patient **J.M.** for alprazolam and oxycodone on the same date. *Id*. Specifically, the Respondent filled prescriptions for oxycodone and alprazolam for J.M. on January 25, 2018; March 1, 2018; April 4, 2018; April 19, 2018; and May 16, 2018. *Id*.

Early Refills

8. **Patient A.H.:** On January 22, 2019, the Respondent filled a prescription for patient **A.H.** for a 30-day supply of hydromorphone 8 mg tablets. ALJ Ex. 1, ¶ 13(a). The Respondent filled additional prescriptions for A.H. for 30-day supplies of hydromorphone 8 mg tablets on February 15, 2019 (six days early); February 27, 2019 (18 days early); and March 14, 2019 (15 days early). *Id*.
9. **Patient M.M.:** On January 3, 2019, the Respondent filled a prescription for patient **M.M.** for a 28-day supply of hydromorphone 8 mg tablets. ALJ Ex. 1, ¶ 13(b). The Respondent filled additional prescriptions for M.M. for 30-day supplies of hydromorphone 8 mg tablets on January 24, 2019 (seven days early); February 19, 2019 (four days early); and a 28-day supply on March 15, 2019 (six days early). *Id*.
10. **Patient J.D.:** On May 10, 2018, the Respondent filled a prescription for patient **J.D.** for a 30-day supply of hydromorphone HCL powder. ALJ Ex. 1, ¶ 13(c). The Respondent filled additional prescriptions for J.D. for 30-day

supplies of hydromorphone HCL powder on May 30, 2018 (10 days early); June 15, 2018 (14 days early); and June 30, 2018 (15 days early). *Id*.

11. **Patient R.G.:** On January 29, 2018, the Respondent filled prescriptions for patient **R.G.** for a 30-day supply of oxycodone HCL powder and a 30-day supply of alprazolam 2 mg tablets. ALJ Ex. 1, ¶ 13(d). The Respondent filled additional prescriptions for 30-day supplies of oxycodone HCL powder and alprazolam 2 mg tablets for R.G. on February 21, 2018 (seven days early); March 19, 2018 (four days early); April 17, 2018 (one day early); and May 8, 2018 (nine days early). *Id*.

12. **Patient R.L.:** On February 1, 2018, the Respondent filled a prescription for patient **R.L.** for a 30-day supply of hydromorphone HCL powder. ALJ Ex. 1, ¶ 13(e). The Respondent filled additional prescriptions for 30-day supplies of hydromorphone HCL powder for R.L. on February 26, 2018 (five days early); a 29-day supply on March 22, 2018 (six days early); a 30-day supply on April 17, 2018 (three days early); and a 30-day supply on May 11, 2018 (six days early). *Id*.

High-Strength Controlled Substances

13. During the relevant time period, virtually all of the prescriptions for oxycodone and hydrocodone that the Respondent "compounded" were for oxycodone 30 mg immediate release and hydromorphone 8 mg immediate release, the highest strengths of these controlled substances. ALJ Ex. 1, ¶ 14. Furthermore, between January 11, 2018, and July 17, 2018, 100 percent of the oxycodone tablet prescriptions and 87 percent of the hydromorphone tablet prescriptions (approximately 44 prescriptions total) issued by a particular prescriber were for the highest strength available for those controlled substances. *Id*.

Long Distances

14. Between September 10, 2018, and May 6, 2019, the Respondent filled:
    a. 86 prescriptions for patients with addresses in Cape Coral, Florida, which is approximately 140 miles from the Respondent;
    b. 145 prescriptions for patients with addresses in Fort Myers, Florida, which is approximately 130 miles from the Respondent;
    c. 41 prescriptions for patients with addresses in Lehigh Acres, Florida, which is approximately 140 miles from the Respondent;
    d. 15 prescriptions for patients with addresses in Immokalee, Florida, which is approximately 150 miles from the Respondent;
    e. 15 prescriptions for patients with addresses in Naples, Florida, which is approximately 170 miles from the Respondent;
    f. 11 prescriptions for patients with addresses in Opa-locka, Florida, which is approximately 270 miles from the Respondent. ALJ Ex. 1, ¶¶ 15(a)-(f).
15. In addition, between September 10, 2018, and May 6, 2019, over 75 percent of the prescriptions for controlled substances filled by the Respondent were issued by prescribers whose medical practices are located more than 150 miles away from the Respondent. ALJ Ex. 1, ¶ 16.

Cash Payments

16. During the relevant time period, over 90 percent of the Respondent's prescriptions for oxycodone 30 mg and hydromorphone 8 mg filled by the Respondent were paid for with cash. ALJ Ex. 1, ¶ 18. In contrast, in 2018 approximately 11 percent of all prescriptions filled by independently owned pharmacies were paid for in cash. *Id*.

ILLEGAL MANUFACTURING

17. Between January 2018 and May 2019, the Respondent was engaged in manufacturing controlled substances, as that term is defined in the CSA,

without a separate DEA registration authorizing it to manufacture controlled substances, in violation of 21 U.S.C. § 841(a)(1) and 21 C.F.R. § 1301.13(e). ALJ Ex. 1, ¶ 20-28.

THE HEARING

Government's Opening Statement

In its Opening Statement, Tr. 14-17, the Government stated that through its investigation of the Respondent, the DEA obtained the Respondent's dispensing records and patient profiles, a pharmacy expert reviewed those records, and that review revealed suspicious patterns. Tr. 14. Those suspicious patterns included the fact that 99 percent of the Respondent's prescriptions were paid for in cash; over 90 percent of the Respondent's patients travelled more than 100 miles to fill their prescriptions; and that the Respondent dispensed a disproportionately high volume of opioids. *Id*. The DEA's expert reviewed the Respondent's records related to 11 specific patients and found that the prescriptions filled by these patients presented numerous red flags that could not have been resolved by a pharmacist acting in the usual course of professional practice. Tr. 14-15. The expert further opined that based on his review of the Respondent's records, the Respondent made no attempt to resolve the red flags presented by these prescriptions. *Id*.

In addition, the Government previewed that its evidence will show that the Respondent unlawfully manufactured controlled substances, specifically oxycodone and hydromorphone, without a manufacturer's registration. Tr. 15-17. To support this allegation, the Government intended to show that in May 2012 the Respondent's owner, Mr. Norman J. Clement, Sr., told DEA investigators that he compounded oxycodone and hydromorphone because it was cheaper than obtaining them from distributors. Tr. 14-15. In conclusion, the Government requested that the Respondent's registration be revoked and any pending applications be denied

because its continued registration presents a threat to the public. Tr. 17.

Respondent's Opening Statement

In the Respondent's opening statement, Tr. 503-06, the Respondent stated that the DEA initiated this case without objectively evaluating the evidence. Tr. 503. The DEA did not interview any patients identified in the OSC/ISO or the doctors who issued the prescriptions involved in this case. *Id*. The DEA also did not subpoena the medical records of the patients at issue. *Id*.

The Respondent argued that the Government's evidence will fail to show that any patients involved in this case suffered adverse consequences from the prescriptions filled by the Respondent. Tr. 504. Furthermore, the Respondent argued that the Government's evidence will fail to meet its burden to revoke the Respondent's registration. *Id*. In the Respondent's view, the Government's case is based on the faulty assumption that the patients must have been drug abusers because they received treatment for chronic pain. *Id*. The Respondent characterized this assumption as "inherently unfair and inappropriate." *Id*.

The Government's assumption ignores the Respondent's combined 90-years of pharmacy experience possessed by the Respondent's pharmacists as well as their professional education and training. Tr. 505. The Respondent's evidence is expected to prove that its pharmacists exercised appropriate professional judgment and resolved red flags. *Id*. The Respondent highlighted that the Government's evidence on red flags comes from a witness who has never practiced in Florida. *Id*. Furthermore, the Respondent's evidence will show that its pharmacists' professional judgment complied with the Florida standard of care, and that the Florida standard of care is established by state statutes rather than an "ivory tower aspirational goal." *Id*.

GOVERNMENT'S CASE-IN-CHIEF

The Government presented its case-in-chief through the testimony of three witnesses. First, the Government presented the testimony of Diversion Investigator Richard Albert. Tr. 24-180. Secondly, the Government presented the testimony of Task Force Officer Jeffrey Shearer. Tr. 181-94. Finally, the Government presented the testimony of its expert, Dr. Donald Sullivan. Tr. 195-502.

Diversion Investigator (DI) Richard J. Albert, Jr.

DI Albert has been a Diversion Investigator for more than seven years. Tr. 24-25. He is currently stationed in Tampa, Florida. Previously, he was stationed in Nashville, Tennessee. Tr. 24. To become a Diversion Investigator, DI Albert received training at the 12-week basic diversion school in Quantico, Virginia. Tr. 25.

DI Albert became involved in the investigation of the Respondent in May 2017, when he received a call from the Department of Health regarding a pharmacy that was compounding hydromorphone and oxycodone. Tr. 26. DI Albert and his supervisor then met with the Health Department investigator at the subject pharmacy. *Id*. The Respondent's owner, Mr. Norman J. Clement, Sr., was not present at the pharmacy, but his daughter and wife were present. Tr. 26-27. The investigators presented a Notice of Inspection to Mr. Clement, Sr.'s, daughter, who allowed the investigators to inspect the pharmacy. *Id*. Approximately 15-minutes into the inspection, Mrs. Clement asked the investigators to leave. *Id*. The investigators complied. Tr. 27.

In September 2017, the DEA served a subpoena on the Respondent requesting Schedule II controlled substance prescriptions, receiving records, and batch records. Tr. 27. Government Exhibit 2 is a receiving record sent from Auburn

Pharmaceutical to the Respondent. Tr. 28; GX 2. The DEA received this document in response to the September 2017 subpoena. *Id*.

Government Exhibit 3 is a receiving record for hydromorphone[4] sent from B&B Pharmaceuticals to the Respondent. Tr. 29; GX 3. The DEA received this document in response to the September 2017 subpoena. *Id*.

Government Exhibit 4 is a receiving record for oxycodone sent from Fagron, Inc., to the Respondent. Tr. 31; GX 4. The DEA received this document in response to the September 2017 subpoena. Tr. 32.

Government Exhibit 5 contains batch records for hydromorphone 8 mg. Tr. 32-33; GX 5. A batch record documents the production of a controlled substance and lists the ingredients in the controlled substance. Tr. 33. The batch record is created by the person who makes the substance. *Id*. The batch records indicate how many capsules were used in the production of a particular batch. Tr. 38, 40-41. Government Exhibit 5 documents the production of hydromorphone 8 mg. Tr. 33. The initials "N.C.," who DI Albert presumed to be the Respondent's owner, Norman J. Clement, Sr., appear in the columns labelled "Manufactured By," "Checked By," and "Final Product Checked By."[5] Tr. 35-37.

Government Exhibit 6 contains batch records for oxycodone 30 mg. Tr. 38-39; GX 6. The DEA received this document in response to the September 2017 subpoena. Tr. 39.

Upon reviewing the batch records received in response to the September 2017 subpoena, DI Albert noticed that the records listed lactose as the only non-controlled substance ingredient. Tr. 42-43. When he reviewed the prescriptions received in

[4] Hydromorphone is a Schedule II controlled substance. Tr. 29.

[5] During cross-examination, the Respondent's counsel directed DI Albert's attention to page 7 and 11 of Government Exhibit 6, which shows illegible initials in the "Manufactured By" column (page 7) and the "Checked By" column (page 11). Tr. 150; GX 6, pp. 7, 11. DI Albert was also unable to identify the signature on page 13 of Government Exhibit 6. Tr. 151; GX 6, p. 13.

response to the subpoena, he noticed that patients were travelling long distances to the pharmacy. Tr. 43, 129-30.

Government Exhibit 10 is a printout of the prescription drug monitoring program ("PDMP") for the Respondent's dispensing from September 2016 to June 2018. Tr. 46, 159, 162; GX 10, pp. 1, 20. This document represents the total number of controlled substance prescriptions that the Respondent dispensed during that 21-month time period. Tr. 162-63. The document lists 2,360 prescriptions. Tr. 162-63. DI Albert reviewed the Respondent's PDMP records during his investigation. Tr. 43-44. Government Exhibits 8 and 9 also contain PDMP printouts of the Respondent's dispensing. Tr. 49-52; GX 8-9.

DI Albert returned to the subject pharmacy in September 2018 to serve an administrative inspection warrant ("AIW") and subpoena. Tr. 52. Government Exhibit 67 is the subpoena, dated September 5, 2018, that DI Albert served on the Respondent's counsel at the time of executing the AIW. Tr. 52-53; GX 67. The second page of the subpoena is a list of patient names. Tr. 53; GX 67, p. 2. DI Albert did not speak with any patients who presented at the pharmacy while the AIW was being executed. Tr. 168. He also did not speak with any of the Respondent's staff, including Mr. Norman J. Clement, Sr., who was instructed by counsel to not answer any questions. Tr. 168, 173, 177.

During service of the AIW, digital forensic specialists captured mirror images of the Respondent's computer system. Tr. 54, 62, 91, 93, 134. The Respondent used Rx30 pharmacy software. Tr. 135. DI Albert received the information that was captured from the Respondent's system in Excel format, but he did not know the process that the digital forensic team used to convert that information into the format he received. Tr. 136. DI Albert was unable to determine whether errors were made in converting the captured images of the Respondent's system into Excel. Tr. 136-37.

During execution of the AIW, DI Albert observed Mr. Clement, Sr., conduct a closing inventory of the controlled substances that the Respondent had on-hand at the time. Tr. 54, 56, 165-66. Mr. Clement, Sr., signed the closing inventory. Tr. 56, 58; GX 7. The closing inventory lists 470 tablets of hydromorphone 8mg, 3,546 capsules of hydromorphone 8 mg, hydromorphone powder, 204 tablets of oxycodone 30 mg, 574 capsules of oxycodone 30 mg, and oxycodone powder. Tr. 59, 61; GX 7. Medications from distributors are in the form of tablets. When medications are compounded from powder in batch at a pharmacy, the dosage units are contained in capsules. Tr. 60.

Government Exhibit 11 is saved on a DVD. Tr. 63-64; GX 11. Government Exhibit 11 contains records electronically downloaded from the Respondent's computer system during execution of the AIW. Tr. 63.

Government Exhibit 12 is a report of the Respondent's dispensing over a three-month period. Tr. 68; GX 12. It covers November 2015 through January 2016. *Id*. This document was obtained electronically during execution of the AIW in September 2018. Tr. 69. Government Exhibit 13 was also obtained during service of the AIW. Tr. 70; GX 13.

Government Exhibit 14 is a PDMP dispensing record for patient A.G. Tr. 71-72; GX 14. Government Exhibit 15 is a record kept by the Respondent for patient A.G. with information about the patient as well as notes. Tr. 73-74; GX 15. It was electronically downloaded from the Respondent's computer system during the AIW search. Tr. 75. The DEA also obtained Government Exhibits 16 and 17 during the AIW search. Tr. 76-81, 140; GX 16-17. Government Exhibits 16 and 17 are dispensing records for patient A.G. maintained by the Respondent and obtained from the pharmacy. *Id*.

Government Exhibit 19 is a PDMP dispensing record for patient A.H. Tr. 81-82; GX 19. The Government moved for the admission of Exhibits 19 through 43

and 46 through 52 as a group. Tr. 85-87. These exhibits were either obtained from the Respondent during the AIW search in September 2018 or printed from the PDMP. *Id*. They relate to the specific patients identified in the OSC/ISO. *Id*.

After executing the AIW at the pharmacy in September 2018, DI Albert sent the records he obtained to a pharmacy expert, Dr. Donald Sullivan, for review. Tr. 88. DI Albert served another subpoena on the Respondent in May 2019. Tr. 88-89; GX 68. Attached to the subpoena is a list of seven patients. Tr. 89; GX 68, p. 2. This subpoena requested that the Respondent produce five categories of documents, to include (1) patient profiles for the patients identified in the attachment; (2) other records maintained pursuant to the Florida Administrative Code; (3) original prescriptions and fill stickers of all prescriptions filled for patients listed in the attachment from September 10, 2018, to May 10, 2019; (4) any notes documenting the resolution of red flags; (5) and any other documentation related to the specific patients identified, such as dispensing records, billing records, PDMP records, and medical records. Tr. 89-90.

DI Albert received additional documents from the Respondent in response to the May 2019 subpoena. Tr. 94. The documents that DI Albert received related to patients A.G. and R.B. and are contained in Government Exhibits 18 and 44. Tr. 94-98; GX 18; GX 44. DI Albert sent the documents that he received in response to the May 2019 subpoena to the expert witness for review. Tr. 118. He then began preparing the OSC/ISO. Tr. 118-19.

In his investigation of the Respondent, DI Albert calculated the approximate distances from the cities where patients lived to the Respondent pharmacy. Tr. 99-105, 130. DI Albert made these calculations by using Google Maps to determine the distance from the cities of residence to the Respondent's address. Tr. 99-101. The

approximate distances on Google Maps are contained in Government Exhibit 54.[6] Tr. 99; GX 54.

DI Albert also searched for specific addresses in Google Maps. Tr. 105-12. Each of the specific addresses that DI Albert searched relate to a specific patient. Tr. 106, 108-09, 111-12. The one-way distances from those addresses to the Respondent are in Government Exhibits 55 through 60 and 62 through 65. Tr. 105-12; GX 55-60; GX 62-65.

Government Exhibit 55 shows a distance of 131 miles.[7] Tr. 106; GX 55, p. 1. Government Exhibit 56 shows a distance of 132 miles. Tr. 109; GX 56, p. 1. Government Exhibit 57 shows a distance of 148 miles. Tr. 110; GX 57, p. 1. Government Exhibit 58 shows a distance of 134 miles. GX 58, p. 1. Government Exhibit 59 shows a distance of 130 miles. GX 59, p. 1. Government Exhibit 60 shows a distance of 144 miles. GX 60, p. 1.

Government Exhibit 62 shows a distance of 137 miles. GX 62, p. 1. Government Exhibit 63 shows a distance of 138 miles. GX 63, p. 1. Government Exhibit 64 shows a distance of 131 miles. GX 64, p. 1. Government Exhibit 65 shows a distance of 138 miles. GX 65, p. 1.

Government Exhibit 61 shows the roundtrip distance from patient M.M.'s home, to the doctor's office, to the Respondent, and then back home. Tr. 112-18, 131, 172; GX 61. The total roundtrip distance from M.M.'s home to the doctor's office and the Respondent, and then back home, is 327 miles. Tr. 117, 131; GX 61, p. 1. Although DI Albert searched for the roundtrip distance between M.M.'s home, doctor's office, and the Respondent, he did not check to see whether M.M. filled any prescriptions at the Respondent in Tampa on the same day that he obtained them

[6] Although Google Maps includes estimated travel times as well as mileage, due to the high variability of travel times, only the mileage is being considered herein.

[7] The Google Maps printouts list three routes with different distances and travel times. When speaking of the distances between patients' homes and the Respondent, I will refer to the route with the shortest mileage.

from the doctor in Fort Myers. Tr. 133, 171. DI Albert is therefore not sure whether M.M. ever made the roundtrip drive that is depicted in Government Exhibit 61. *Id*. If M.M. had travelled from her home to the doctor's office and the Respondent on separate days, however, the total travel distance would be similar to the roundtrip distance travelled on one day.[8] Tr. 173.

DI Albert was candid in conceding there were matters and facts of which he was unaware. For example, during his investigation, DI Albert readily conceded he did not talk to any of the 11 patients named in the OSC/ISO. Tr. 123-24, 155. He also conceded that he did not contact the subject prescribing doctors. Tr. 125-26, 128, 173-74, 178-80. DI Albert also conceded that he was unfamiliar with the FDA guidelines on compounding and that he did not receive training on compounding during DI training. Tr. 152. He also admitted that he did not familiarize himself with the Florida laws governing pharmacies, and that he only applied federal law in his investigation. Tr. 152-53. DI Albert also candidly acknowledged that he did not know the significance of the citations to Florida law in the subpoenas that he served. Tr. 153-54. In addition, DI Albert acknowledged that he had not done a comparison of the Respondent's daily, weekly, and monthly dispensing volume to other nearby pharmacies. Tr. 167-68.

DI Albert's willingness to concede these points, excepting in these areas, bolsters his credibility. DI Albert's testimony focused primarily on identifying exhibits and describing his investigation. Based on my close observation of

[8] The distance from M.M.'s home to her doctor's office is 134 miles. GX 61, p. 3. Thus, the total distance travelled if M.M. went to the doctor and returned home on the same day would be 268 miles. The distance from M.M.'s home to the Respondent is 38 miles. Tr. 134; GX 61, p. 6. Thus, the total distance travelled if M.M. went to the Respondent and returned home on the same day would be 76 miles. Added together, these distances total 344 miles. Thus, if M.M. travelled to her doctor's office to obtain a prescription on one day and returned home, and then travelled to the Respondent on another day to fill the prescription and returned home, the total distance travelled to obtain and fill that prescription would be slightly higher (344 miles) than if she had made the roundtrip drive from home, to the doctor's office, to the pharmacy, and back home, all in one day (327 miles). However, during the hearing, counsel for the Government conceded, and Dr. Sullivan confirmed, it was the distance from the patient's home to her physician's office which represented the red flag of long distance. Tr. 294.

DI Albert at the hearing, my careful review of his testimony in the transcript, and in conjunction with other credible evidence, I find DI Albert to be a credible witness. DI Albert presented as an impartial investigator with no direct stake in the outcome of the case, and his testimony was straightforward, professional, and candid. Furthermore, his testimony was also detailed and internally consistent. For these reasons, I fully credit DI Albert's testimony and find that his testimony merits considerable weight in this Recommended Decision.

Task Force Officer (TFO) Jeffrey Shearer

TFO Shearer has been running a private investigation business for the past five years. Tr. 182. Before that, he was a police officer with the Tampa Police Department for 16 years. *Id*. He spent the last five-and-a-half years of his career with the Tampa Police Department as a task force officer working out of the DEA's Tampa District Office. Tr. 182-83. As a TFO, Mr. Shearer worked with the DEA in the Tactical Diversion Squad on investigations related to the diversion of controlled substances. Tr. 182.

TFO Shearer worked on an investigation of the Respondent. Tr. 183. In May 2012, during execution of an AIW at the Respondent pharmacy, TFO Shearer interviewed Mr. Clement, Sr., the Respondent's owner. *Id*. Mr. Clement, Sr., was cooperative during execution of the AIW. Tr. 192. Mr. Clement, Sr., was not in custody at the time and was free to leave. Tr. 183. In the interview, Mr. Clement, Sr., told TFO Shearer about his process for manufacturing oxycodone and hydromorphone in capsules. Tr. 183-84. Mr. Clement, Sr., told TFO Shearer that he could buy a 100 gram bottle of oxycodone powder for $1,100, enough to manufacture about 6,000 dosage units. Tr. 185. Tablets of oxycodone purchased from commercial distributors cost roughly $2-$10 per pill. *Id*. Mr. Clement, Sr., told TFO Shearer that he manufactured thousands of capsules per batch because it

was cost effective.[9] Tr. 184-85. The batch records that TFO Shearer reviewed in 2012 documented that Mr. Clement, Sr., produced thousands of pills in each batch. *Id*. Mr. Clement, Sr., was not charged with a crime. Tr. 190.

Based on listening to him testify at the hearing, and reviewing the transcript of his testimony, I find TFO Shearer to be a credible witness who testified in a candid, professional, and straightforward manner. TFO Shearer testified regarding events that had occurred approximately seven years prior to the hearing. He seemed fully capable of recalling the majority of those events with ease, but it is not surprising that some of his answers lacked detail. Any lack of detail, however, did not detract from his credibility or the usefulness of his testimony. He was honest about what he could not recall and he presented as an impartial individual without a direct stake in the outcome of the case. For these reasons, TFO Shearer's testimony is credible and merits significant weight in this Recommended Decision.

[9] Dr. Sullivan conceded a pharmacist is obligated to provide the least expensive medication available, and noted the price to the patient for oxycodone 30 mg in capsule form was $3.00 less than the cost for the same dosage in tablet form. Tr. 431-32, 477.

Dr. Donald L. Sullivan[10]

Dr. Sullivan is presently employed as a professor of Clinical Pharmacy at Ohio State University College of Pharmacy, and has been for five years. Tr. 196. *See* GX 53. Previously, he was employed at Ohio Northern University for 17 years. He obtained his Bachelor's degree in 1990. In 1991, he obtained his Master's in pharmacy administration, and his doctorate in pharmacy administration in 1996. Tr. 198. At Ohio State, in addition to performing research, he teaches pharmacy practice law to all four years of students. He teaches two courses on pharmacy operations, financial analysis, marketing, and human resource issues. Tr. 197. His courses cover professional standards for pharmacy personnel, including:

[10] The Respondent objected to the Government's leading questions to its own expert witness. It is my practice to permit the parties to ask leading questions to their own experts during direct examination. Tr. 498. The proscription of leading questions is designed to ensure a witness offers his own accurate testimony and is not manipulated by sponsoring counsel. It is designed to avoid suggested memory, and suggested conclusions. In short, to prevent the attorney from testifying through a pliable witness. The danger of leading questions on direct examination is the potential for their suggestibility on the witness, and the susceptibility of the witness to seek to please the questioner; essentially permitting the attorney to testify. Although the subject hearings are not strictly governed by the Federal Rules of Evidence, *see* Fed. R. Evid. 611, they may provide guidance consistent with relevant statutory and regulatory provisions. Regulations provide further guidance. Herein, the ALJ shall conduct the hearing in "an informal but orderly manner." *See* 21 C.F.R. § 1316.52. The ALJ shall "conduct a fair hearing, to avoid delay, and to maintain order." The ALJ "shall have all powers necessary to these ends, including . . . receive, rule on, exclude or rule on or limit evidence"; and take any other action as permitted by the Administrative Procedure Act (APA).

I don't find the dangers traditionally inherent in leading questions applicable to expert witnesses providing expert opinion in these hearings. They are not in the nature of traditional fact witnesses. They are not eye-witnesses. They are not offering testimony to establish the underlying facts or events. They do not rely on memory of distant events. They are called to provide interpretation of the underlying facts and to apply that interpretation to the various standards of care according to their expertise. They typically observe significant portions of the hearing, if not the entire hearing. I must presume sponsoring counsel has previewed their expert's prospective testimony prior to the commencement of the hearing. The direct testimony of expert witnesses in these hearings are typically thoroughly prepared presentations. Presumably, the direct expert testimony is typically rehearsed, and not improperly so. By the commencement of the hearing, sponsoring counsel has had abundant opportunity to "influence" their expert witness. The expert witnesses called in these matters typically display impressive credentials, are typically published in their fields and have previously offered expert testimony. Their subject opinions are rarely aired for the first time during the hearing. A summary of their testimony is provided to opposing counsel well before the hearing, enabling opposing counsel the opportunity to confront the subject opinion testimony with the expert's testimony summary, historic writings, statements, and prior testimony. Typically, an expert's subject opinions are confronted by an expert engaged by opposing counsel. Heretofore, I have not viewed these experts as susceptible to undue influence or manipulation by sponsoring counsel. Further, the nature of the issues justifying expert testimony in these matters is often complex and often requires exploration of subtle details and nuanced opinions. Restricting sponsoring counsel from leading questions often challenges counsel's ability to expeditiously probe the subject's complexities. Whereas a leading question can more readily direct the expert's attention to the issue at hand. If I were to see abuse of this practice, I have the discretion to suspend this practice.

dispensing; record keeping; documentation; drug utilization review; patient education and counseling; compounding from a pharmacy practice perspective, as well as state and federal statutes governing the practice of pharmacy. The study of federal law comprises about 50-percent of the legal curriculum. Tr. 197-98, 203.

He's lectured to independent pharmacies on behalf of wholesalers, including Cardinal Health, AmerisourceBergen, HD Smith, as well as several pharmacy organizations. Tr. 199. For the past four years, he's presented a two-hour Continuing Education program to Florida pharmacists on controlled substance dispensing. Tr. 199. Within the past two-to-three years, Florida has increased the professional requirements for pharmacists, to include validating controlled substance prescriptions, understanding different types of diversion, red flags for diversion, how to resolve red flags, naloxone availability, and state and federal laws governing dispensing controlled substances and related record keeping. Tr. 200. Dr. Sullivan has authored five publications, consumer drug reference books, as well as several peer-reviewed publications. Tr. 200. He's completed a research study into community pharmacists, the resources they use in identifying red flags, and their willingness to identify red flags of diversion. Tr. 202. He presents training for government investigators and attorneys. Tr. 203. He's been qualified as an expert in a California criminal trial and in four DEA show cause hearings similar to the instant hearing. Tr. 201, 354-55, 359.

He's a registered pharmacist in Ohio and in Florida. He's worked as a pharmacist in Ohio, but not in Florida. Tr. 198. However, he has not worked in retail pharmacy for 20 years. Tr. 414. His background is primarily in community pharmacy, which relates to typical private pharmacies and chain pharmacies. Tr. 199. He's also had experience at a pharmacy located within a mental health clinic, and in a mail order pharmacy. *Id*.

Dr. Sullivan described a recent problematic trend in medication reimbursement in which the pharmacies are sometimes being reimbursed less than their actual costs to purchase the medications. Tr. 430-31. This trend has caused small independent pharmacies to seek niche markets. Tr. 431.

Through his education, training, and experience, Dr. Sullivan is familiar with compounding in retail pharmacy, as well as issues related to abuse and diversion of controlled substances, and with the responsibilities of a retail pharmacist in the detection and prevention of such abuse and diversion. Tr. 203. Dr. Sullivan is also familiar with a pharmacist's corresponding responsibility under federal law, and the standard of care and professional obligations of a pharmacist in the state of Florida. Tr. 204. Dr. Sullivan was qualified as an expert in the field of pharmacy and the standard of care for the practice of pharmacy in the state of Florida. Tr. 204-05, 490.

Dr. Sullivan described the duties of a pharmacist in filling a controlled substance prescription. Tr. 206. First, the pharmacist must ensure the prescription is a "valid prescription for a legitimate medical purpose." *Id*. That is, the pharmacist must determine if it is issued "in the normal course of professional practice," that the pharmacist believes the patient can safely take it, that the medication is for an actual medical purpose, and is not being abused, misused, or diverted. *Id*. These requirements are codified in both federal and Florida law. Fla. Admin. Code r. 64B16-27.800, .810, and .831.

In reviewing a prescription, a pharmacist must first determine if the prescription appears legal on its face; that all the information necessary appears on the face of the prescription. Tr. 208. Then, applying clinical expertise, the pharmacist must consider possible over-utilization and under-utilization, where the patient is taking more or less medication than prescribed; consider possible abuse or misuse; whether it's serving a legitimate medical purpose; and whether it exposes the patient to potential undue risk of side-effects, adverse effects, or overdose.

Tr. 208-09. The Florida standard of care requires pharmacists to document their resolution of any potential issues discovered in the pharmacist's review of a prescription. Tr. 210, 437, 489.

Dr. Sullivan was unaware that Florida had codified "standard of care" for healthcare workers. Tr. 438; § 766.102, Fla. Stat.[11] He was unaware of the Florida Patient Bill of Rights. Tr. 462. Dr. Sullivan initially conceded there was no federal or Florida regulation mandating where or how the resolution of red flags must be documented. Tr. 435-37. In particular, Florida Administrative Code r. 64B16-27.831, Standards of Practice for the Filling of Controlled Substance Prescriptions, is silent as to whether a pharmacist must document the steps a pharmacist takes to validate a prescription. Tr. 449-50, 453-54. *But see* Tr. 488-89.

In conjunction with the precautionary evaluation described, the pharmacist is required to maintain a "patient profile" for each patient, which includes: the patient's full name, address and telephone number, age or date of birth, gender, a list of all new and refilled prescriptions obtained by the patient at the pharmacy, and any notes or comments by the pharmacist particular to that patient, such as drug allergies or contraindications. Tr. 209-10.

Dr. Sullivan explained the pharmacist's "corresponding responsibility" with that of the prescribing physician. Under federal law, the pharmacist has a corresponding responsibility, an equal responsibility with the prescribing physician, to determine if a prescription has been written for a legitimate medical purpose. Tr. 210-11. That a prescription is written by a physician does not absolve the pharmacist from ensuring that it is for a legitimate medical purpose. Tr. 211. Common potential concerns for a pharmacist are referred to as "red flags." Red flags

[11] The "prevailing professional standard of care," which under Florida law is defined as "that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate for reasonably prudent similar heath care providers." § 766.102, Fla. Stat.

include potential for diversion or abuse, patients traveling long distances to see their physicians, or to the pharmacy[12],[13] "drug cocktails commonly abused, large dosage units, payment in cash for all or part of a patient's prescriptions,[14] over-prescribing of immediate release pain killers, and patients traveling in groups. Tr. 213-15, 240-41[15], 473-76. Traveling long distances to a pharmacy creates the suspicion that pharmacies closer to the patient have declined to fill that particular prescription. Tr. 220. Drug cocktails, or drug combinations known for abuse, such as the combination opioid/benzodiazepine, represent a "red flag." Tr. 220-21; GX 66. Indeed, the FDA has issued a "black box" warning in August 2016, highlighting the potential danger to the patient of this combination of medications. Tr. 221-23. Cash payment for medications is a red flag as medications are typically expensive and normally patients will defer those costs to their health insurance. Tr. 224-25. Early refills, or early fills of new prescriptions, are suspicious as it may suggest the patient is not taking the medication as prescribed. Tr. 224-25. Florida initiated annual CME four years previously involving "validation and appropriate use of controlled substances." Tr. 235. Florida pharmacists are taught to identify the above red flags, to resolve them, and to document the resolution. Tr. 235-36.

[12] Dr. Sullivan noted 90% of prescriptions filled at the Respondent involved patients living more than 100 miles from the pharmacy. Tr. 235.

[13] Dr. Sullivan conceded he was not aware of any federal or Florida regulation limiting the distance traveled to fill a prescription. Tr. 462.

[14] Dr. Sullivan conceded no federal or Florida law prohibits pharmacies from accepting cash as payment for prescriptions. Tr. 444.

[15] The Government offered various statistical evidence regarding average national prices for controlled substances, average miles driven to the pharmacy by patients nationally, a high percentage of Respondent's patients traveling long distances to the Respondent's pharmacy, the relatively high percentage of the Respondent's patients paying by cash, the high percentage of the Respondent's controlled substance dispensations versus non-controlled, the extremely high percentage of compounded hydromorphone 8 mg dispensed versus the commercially available hydromorphone 8 mg tablet dispensed by the Respondent, the extremely high percentage of oxycodone 30 mg, and Alprazolam 2 mg (the highest dosage units commercially produced) prescriptions issued as compared with lower dosage units dispensed, that the Respondent dispensed almost twice as many oxycodone 30 mg capsules as tablets. Tr. 235-38, 241, 244-46, 250-51. This evidence was admitted as it related to the prompting and evaluation of various red flags. It was not admitted, and will not be considered, as probative evidence that specific prescriptions were filled contrary to the standard of care in Florida, which determination requires individualized proof and individualized analysis.

To resolve red flags, a pharmacist should first discuss the matter with the patient, and attempt to get to know each patient. Tr. 239, 445-49; *see* Fla. Admin. Code r. 64B16-27.831. The next step would be to discuss the matter with the prescribing physician, which would provide another source of input for the pharmacist. However, the prescribing physician can never be the only source of information obtained. Tr. 229. Next, the pharmacist would review the patient's drug record, the PDMP, to determine other medications and the strengths of those medications, and conduct a "prospective drug utilization review," to make an independent clinical evaluation whether the subject prescription was written for a legitimate medical purpose. Tr. 211, 227. Once the pharmacist makes his independent clinical evaluation, the standard of care requires the pharmacist to document his evaluation. Tr. 228.

If a pharmacist is unable to resolve the red flags he should decline to fill the subject prescription. Tr. 228, 488. An example of an unresolvable red flag would be a prescription containing two immediate release narcotic pain killers in very high doses. Tr. 228-29. Dr. Sullivan later clarified that red flags should be evaluated in combination, that no single red flag was unresolvable. Tr. 480-86. Later, he corrected himself by explaining that a single red flag could be so egregious that it was unresolvable in isolation. Tr. 497-99.

Dr. Sullivan explained compounding, in which a pharmacist "makes a drug . . . from scratch . . . to meet the unique therapeutic needs of a patient." Tr. 230. Typical justification for compounding may include a patient's allergies to certain ingredients within commercially manufactured medications, or the unavailability of a particular medication, or strength of medication required for treatment among commercially available medications. Tr. 230-32, 336-38. Both oxycodone 30 mg, and hydromorphone 8 mg, are commercially available. Tr. 232.

By the fall of 2019, Dr. Sullivan had reviewed the materials sent to him by DI Albert. Tr. 233, 349, 405-06. These materials included the Respondent pharmacy prescription log covering approximately three months [GX 11], PDMP data over an 18-month period [GX 8-10], and the Respondent's Prehearing Statement, which included witness summaries. Tr. 341-43, 347-48. Dr. Sullivan did not speak with the subject patients. Tr. 407, 416-18. Dr. Sullivan did not review copies of the actual prescriptions. Tr. 348, 416, 500. Dr. Sullivan conceded the average 4-5 prescriptions filled at the Respondent's pharmacy per day were much fewer than the average community pharmacy of 190 prescriptions. Tr. 420.

Dr. Sullivan reviewed a list of prescriptions issued by Dr. Lemon. Tr. 251; ALJ Ex. 42[16], p. 8. Dr. Lemon's prescriptions for the highest strength available opioid was a potential red flag for diversion or abuse. Tr. 251-52. As to Dr. Purpora, whose prescribing history revealed he prescribed 65,000 doses of hydromorphone 8 mg to only 135 doses of hydromorphone 4mg, Dr. Sullivan opined that a prudent pharmacist would not fill Dr. Purpora's prescriptions for the highest dosage of hydromorphone. Tr. 253, 496. Similarly, Dr. Sullivan opined a reasonable pharmacist would not fill Dr. Purpora's prescriptions for oxycodone 30 mg, as Dr. Purpora prescribed over 24,000 dosage units of oxycodone 30 mg, to only 200 of the lower dosage units. Tr. 253-54.

Turning to specific patients, Dr. Sullivan opined the distance traveled by Patient A.G. from his home to the Respondent's pharmacy was a red flag. Tr. 254; GX 55; ALJ Ex. 42, p. 10. In reviewing A.G.'s prescription history, he was always prescribed the highest dose of hydromorphone and of oxycodone, and except for one instance, the highest dose of alprazolam. Tr. 254-55; GX 17; ALJ Ex. 42, p. 11. The combination of opioid and benzodiazepine, coming even after the FDA's black box

[16] The Government's demonstrative exhibit will be marked as ALJ Exhibit 42.

warning, represent unresolvable red flags and the potential for diversion and abuse. Tr. 255-56. A review of the PDMP report revealed the dangerous combination of the highest dosage unit of opioid along with a benzodiazepine, in addition to early fills on April 12, 2019, representing unresolvable red flags. Tr. 256-57, 267; GX 14; ALJ Ex. 42, p. 12.

A review of the patient profile in RX30, and of the subject prescriptions and fill stickers, failed to resolve the red flags noted or justify the compounding done. Tr. 259, 267; GX 17; ALJ Ex. 42, p. 11. In the patient memo, it simply stated, "Doctor okayed, received medication in compound capsule form," which is insufficient to justify compounding that medication, which requires an individualized therapeutic need. Tr. 257-58; GX 15; ALJ Ex. 42, p. 13. *See* 21 U.S.C. § 802(10), (15); *Wedgewood Village Pharm.*, 71 Fed. Reg. 16593, 16595 (2006). In addition, Dr. Sullivan noted that A.G. was prescribed both capsules and tablets of oxycodone 30 mg between November 8, 2017, and January 25, 2018, demonstrating there was no therapeutic need for compounding the oxycodone 30 mg. Tr. 256.

Dr. Sullivan was suspicious of the patient questionnaire used by the subject pharmacy. Tr. 259-60; GX 18. The questionnaire questioned whether the patient lived more than 100 miles from the pharmacy. Dr. Sullivan interpreted the questionnaire as cover for filling prescriptions for distant patients, rather than an effort to disclose or resolve red flags. Tr. 259-61; GX 18. A follow-up question to the distant traveling patients asked, "why do you travel this distance," and in this case, the patient responded, "quick and good service." Tr. 262. Dr. Sullivan opined that this reason was insufficient to resolve the red flags. The questionnaire contained a certification to be made by the patient, certifying that "I am taking all of my medication prescribed." Tr. 262. Dr. Sullivan deemed this certification ineffectual in resolving the red flags of early fills and of diversion. A further statement by the

patient that, "I am not selling any of my medication," did not alleviate any concerns that the patient may have been diverting his medication. Tr. 262. Indeed, Dr. Sullivan suspected the question exposed a subterfuge by the pharmacy, revealing the pharmacy believed patients were selling their medications, and the question was designed to relieve the pharmacy of any liability. Tr. 263. If a pharmacist believes a patient is selling his medications, the pharmacist should not fill any further prescriptions of that patient. Tr. 264.[17] Dr. Sullivan was directed to the "Pharmacy Comment" at the bottom of the prescriptions for A.G. Tr. 265-66; GX 18, p. 6. The notation, "non acute pain Uninsured Patient" suggested to Dr. Sullivan that whoever made the notations was trying to signal that this medication therapy was ongoing and to provide some justification for cash payment. Tr. 266.

As to Patient A.H., Dr. Sullivan opined the 132 miles from A.H.'s home to the Respondent pharmacy represented a red flag. Tr. 268; GX 56; ALJ Ex. 42, p. 14. The prescriptions from January to August, 2018 contained several red flags including, highest dosage of short acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine. Dr. Sullivan deemed these unresolvable red flags. Tr. 269. Later prescriptions for A.H. revealed significantly early fill dates for four consecutive months. Tr. 269-71; GX 19; ALJ Ex. 42, p. 16. Dr. Sullivan viewed this pattern of early fills as evidence of diversion or abuse, warranting action by the pharmacist such as refusing to fill these prescriptions. Tr. 271-72. The fact that the prescribing physician wrote the prescriptions early does not relieve the

[17] Dr. Sullivan also questioned the prescribing protocol for A.G., in that he was prescribed alternate monthly doses of 30 mg oxycodone and 10 mg of oxycodone. Tr. 264; GX 18, p. 6. However, I believe Dr. Sullivan misread the 30 mg oxycodone prescription of October 30, 2018, as a 10 mg dosage due to a poor copy. So, his conclusions in this regard will not be considered.

pharmacist's responsibility to resolve the red flag of early fills. Tr. 272. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to Patient A.H. Tr. 272-73. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist to decline filling the prescriptions for A.H. GX 19, 21; ALJ Ex. 42, p. 15-16.

As to Patient B.S., Dr. Sullivan opined the 132 mile distance from B.S.'s home to the Respondent pharmacy represented a red flag. Tr. 273; GX 57; ALJ Ex. 42, p. 18. The prescriptions from August 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine. Dr. Sullivan deemed these unresolvable red flags. Tr. 274, 276. Dr. Sullivan noted the anti-inflammatory ibuprofen 400 mg prescription, which he found inconsistent in combination with the high dose of pain medication. A once a day ibuprofen dose would have no effect in combination with such a high dose of pain medication. Dr. Sullivan interpreted the ibuprofen as an attempt to demonstrate that the doctor was trying an alternate therapy as opposed to prescribing controlled substances without a legitimate medical purpose, which Dr. Sullivan viewed as a red flag. Tr. 275. Later prescriptions for B.S. revealed significantly early fill dates. Tr. 275-76; GX 22; ALJ Ex. 42, p. 20. Dr. Sullivan viewed this pattern of early fills as evidence of diversion or abuse, warranting action by the pharmacist such as refusing to fill these prescriptions. Tr. 276-78. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient B.S. Tr. 277. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would

have caused a reasonable pharmacist to decline filling the prescriptions for B.S. GX 22, 24; ALJ Ex. 42, p. 19-20.

As to Patient C.R., Dr. Sullivan opined the 134 miles from B.S.'s home to the Respondent pharmacy represented a red flag. Tr. 279; GX 58; ALJ Ex. 42, p. 22. The prescriptions from July 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-reliever, oxycodone 30 mg, capsules of oxycodone 30 mg being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine, and the muscle relaxant tizanidine. A July 12, 2018 prescription for morphine sulphate 60 mg per day further heightened the danger to the patient. Tr. 280. Dr. Sullivan deemed these unresolvable red flags. Tr. 279-82; GX 27; ALJ Ex. 42, p. 23. A review of this patient's profile received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient C.R. Tr. 281. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist to decline filling the prescriptions for C.R. Tr. 281-83; GX 27; ALJ Ex. 42, p. 23.

As to Patient J.D., Dr. Sullivan opined the 130 miles from J.D.'s home to the Respondent pharmacy represented a red flag. Tr. 283; GX 59; ALJ Ex. 42, p. 23. The prescriptions from January 2018 to September 2019 contained several red flags including, highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; and the combination of two short-acting pain-relievers, hydromorphone and methadone 10 mg, resulting in an "extreme risk of overdose." Tr. 283-84, 468; GX 30; ALJ Ex. 42, p. 26. Dr. Sullivan deemed these red flags unresolvable. Tr. 284, 289. Several prescriptions filled in mid-2018 revealed unjustified early fills. Tr. 284-87; GX 30; ALJ Ex. 42, p. 27. The pharmacist noted in J.D.'s patient profile, "NEXT FILL DATE 7/5/18!!! WATCH FILL

DATES!!!!!!," demonstrating the Respondent knew of J.D.'s issues with early fills. Such note is insufficient to justify filling J.D.'s prescriptions early. Tr. 287-88; GX 29; ALJ Ex. 42, p. 28.

As to Patient J.M., Dr. Sullivan opined the 144 miles from J.M.'s home to the Respondent pharmacy represented a red flag. Tr. 289; GX 60; ALJ Ex. 42, p. 29. The prescriptions from June 2017 to September 2018 contained several red flags including, highest dosage of short-acting pain-relievers, hydromorphone 8 mg and oxycodone 30 mg, and of alprazolam 2 mg; capsules of oxycodone and hydromorphone being dispensed without required therapeutic justification; and the combination of short-acting opioids with a benzodiazepine, and a muscle relaxer. Dr. Sullivan deemed these unresolvable red flags. Tr. 290-91. Dr. Sullivan noted that J.M. was prescribed both capsules and tablets of oxycodone 30 mg between April 2018 and May 2018 demonstrating there was no therapeutic need for compounding the oxycodone 30 mg. Tr. 290. A review of this patient's file received by Dr. Sullivan failed to reveal any effort by the Respondent to resolve the red flags relating to patient J.M. *Id*. Dr. Sullivan opined that, for the reasons discussed above, the relevant standard of care would have caused a reasonable pharmacist to decline to fill the prescriptions for J.M. Tr. 291; GX 33; ALJ Ex. 42, p. 30.

As to Patient M.M., Dr. Sullivan opined the distance between M.M.'s home and the prescribing physician's office, south of Ft. Myers, Florida, represented a red flag. Tr. 294; ALJ Ex. 42, p. 32. In reviewing M.M.'s dispensing log, Dr. Sullivan identified many of the same red flags as revealed by the other patient's records: high-strength hydromorphone prescribed and dispensed; and capsules of hydromorphone dispensed without individualized therapeutic justification. Tr. 295; GX 36; ALJ Ex. 42, p. 33. Dr. Sullivan was also suspicious of the .4 mg of folic acid, which he suspected was intended to mask the opioid prescriptions. Tr. 295-96. In reviewing the prescriptions filled from January 2019 to April 2019, Dr. Sullivan

noted that the Respondent filled both capsules and tablets of hydromorphone, thus negating any prospect that the patient had an individualized therapeutic need for compounded medication. Tr. 297-98; GX 34; ALJ Ex. 42, p. 34. Dr. Sullivan was also concerned regarding a significant break in therapy, from July 18, 2018, and January 3, 2019. Tr. 297. Despite an almost six-month lapse in opioid therapy, the Respondent filled a prescription for hydromorphone 8 mg, the highest commercially available dosage. Tr. 298. If the patient had become opioid naïve during this lapse, there is a heightened risk of overdose. Tr. 298. Dr. Sullivan also recognized some red flags in the form of early fills. Tr. 299; GX 34; ALJ Ex. 42, p. 34. Dr. Sullivan deemed the above red flags unresolvable, and that no reasonable pharmacist would have filled the subject prescriptions. Tr. 299-300. *But see* Tr. 480-86.

As to Patient N.B., Dr. Sullivan opined the 137 miles from N.B.'s home to the Respondent pharmacy represented a red flag. Tr. 301; GX 62; ALJ Ex. 42, p. 36. The prescriptions from June 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; two separate prescriptions for alprazolam with two separate dosage units; and the combination of an opioid and benzodiazepine. Dr. Sullivan noted the anti-inflammatory ibuprofen 400 mg prescription, which he found inconsistent in combination with the high dose of pain medication. A once a day low ibuprofen dose would have no effect in combination with such a high dose of pain medication. Dr. Sullivan found these red flags unresolvable. Tr. 302-03, 305-06; GX 39; ALJ Ex. 42, p. 37. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 303-04; GX 37; ALJ Ex. 42, p. 38. Dr. Sullivan found no evidence of an attempt to resolve these red flags. Tr. 306-07; GX 37, 39; ALJ Ex. 42, pp. 38-39. Dr. Sullivan was concerned by the two-month gap in opioid treatment from September 14, 2018, and December 20, 2018, potentially producing opioid naïveté

in the patient. Tr. 304. In the patient memo, it simply stated, "Doctor ok patient to receive medication in compound capsule form," which is insufficient to justify compounding that medication, which requires an individualized therapeutic need. Tr. 306, 471; GX 38; ALJ Ex. 42, p. 39.

As to Patient R.B., Dr. Sullivan opined the 138 miles from N.B.'s home to the Respondent pharmacy represented a red flag. Tr. 307; GX 63; ALJ Ex. 42, p. 40. Dr. Sullivan further asserted that the number of patients traveling from the Ft. Myers area to the Respondent's pharmacy represented a red flag itself. Tr. 308. The coincidence of patients traveling over 100 miles to the Respondent's pharmacy from the same proximate area represents a pattern that the standard of care would require a pharmacist to notice and to investigate. Tr. 309-10.

The prescriptions from June 2017 to August 2018 contained several red flags including, highest dosage of short-acting pain-reliever, hydromorphone 8 mg, capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; prescriptions for alprazolam at the highest dosage strength; and the combination of an opioid and benzodiazepine. Dr. Sullivan found these unresolved red flags inconsistent with the standard of care in Florida. Tr. 311, 321; GX 43; ALJ Ex. 42, p. 41. The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 311-12; GX 40; ALJ Ex. 42, p. 42. Dr. Sullivan was concerned by the two-month gap in opioid treatment from September 12, 2018, to January 22, 2019, potentially producing opioid naïveté in the patient. Tr. 312, 471. Dr. Sullivan found no evidence of an attempt to resolve these red flags. Tr. 313; GX 41; ALJ Ex. 42, p. 41. In R.B.'s Patient Questionnaire, R.B. gave conflicting information as to the year of her injury. Tr. 313-14. Furthermore, R.B.'s justification for traveling more than 100 miles to the Respondent's pharmacy, "it's cheaper and they're good people," does not resolve the red flag of long-distance travel. Tr. 315; GX 44. Nor does R.B.'s declaration that she's not selling her medications resolve concerns of

diversion. Tr. 315. Patient R.B.'s PDMP report reveals she filled prescriptions at five different pharmacies, including the Respondent's pharmacy. Tr. 316-17; GX 44, p. 5. Dr. Sullivan views this as clear evidence of pharmacy shopping. Another suspicious entry in the PDMP record is the payment source for an April 6, 2016 prescription for oxycodone acetaminophen, and two August 22, 2017 prescriptions for hydrocodone, which were paid for using commercial insurance. Tr. 317-18; GX 44, p. 4. A patient alternately paying cash and using commercial insurance is a red flag of diversion or abuse. Tr. 318-19.

Dr. Sullivan noted prescriptions for R.B. in which it appeared the pharmacist, by permission of the prescribing physician, changed the prescribed "tablet" form of medication to compounded capsule. Tr. 319-20; GX 44, pp. 6, 8. As the "tablet" form was initially prescribed, changing to compounded capsule does not appear to have been done on the basis of an individualized therapeutic purpose. Tr. 321.

As to Patient R.G., Dr. Sullivan opined the 131 miles from R.G.'s home to the Respondent pharmacy represented a red flag. Tr. 322; GX 64; ALJ Ex. 42, p. 44. The prescriptions from June 2017 to September 2018 contained several red flags including, highest dosage of short-acting pain-reliever, capsules of oxycodone 30 mg being dispensed without required therapeutic justification; the highest strength for alprazolam; and the combination of an opioid and benzodiazepine. Dr. Sullivan noted the ongoing prescribing at the highest opioid dosage suggested a red flag for the lack of individualized treatment, with patients consistently receiving the highest dosage. Tr. 322-24, 329-30. A further indication that there was no therapeutic justification for the compounded capsules of oxycodone 30 mg was the two fills on August 10, 2018, for oxycodone. Tr. 324; GX 49; ALJ Ex. 42, p. 45. R.G. was dispensed 68 tablets and 70 capsules on that same day. Tr. 324-26. Dr. Sullivan found these red flags unresolvable. Tr. 322-23, 326; GX 49; ALJ Ex. 42, p. 45. The PDMP data revealed several prescriptions filled unjustifiably early.

Tr. 326-28; GX 49; ALJ Ex. 42, p. 46. The pharmacist noted in R.G.'s patient profile, "WATCH FILL DATES!!!!!!," demonstrating the Respondent knew of R.G.'s issues with early fills. Such note is insufficient to justify filling R.G.'s prescriptions early. Tr. 328; GX 47; ALJ Ex. 42, p. 47. Dr. Sullivan found no evidence of the resolution of these red flags. Tr. 329; GX 49; ALJ Ex. 42, p. 45.

As to Patient R.L., Dr. Sullivan opined the 138 miles from R.L.'s home to the Respondent pharmacy represented a red flag. Tr. 330; GX 65; ALJ Ex. 42, p. 48. The prescriptions from June 2017 to September 2018 contained several red flags including, highest dosage of short-acting pain-relievers, hydrocodone 8 mg and oxycodone 30 mg; capsules of hydromorphone 8 mg being dispensed without required therapeutic justification; the highest strength of alprazolam; and the combination of an opioid and benzodiazepine. Dr. Sullivan was concerned by the promethazine 25 mg prescription, as it acts as a muscle relaxant with sedative qualities, thus increasing potential side effects in combination with the opioid and benzodiazepine medications. Dr. Sullivan noted the ongoing prescribing at the highest opioid dosage suggested a red flag for the lack of individualized treatment, with patients consistently receiving the highest dosage. Tr. 331-32, 329-30. Dr. Sullivan found these red flags unresolvable. Tr. 332; GX 52; ALJ Ex. 42, p. 49.

The PDMP data revealed several prescriptions filled unjustifiably early. Tr. 333-35; GX 52; ALJ Ex. 42, p. 51. The pharmacist noted in R.L.'s patient profile, "NEXT FILL 6/10/18-10 DAYS EARLY MARCH & APRIL-TOLD HIM THIS 5/11/18GD," demonstrating the Respondent knew of R.L.'s issues with early fills. Such note is insufficient to justify filling R.L.'s prescriptions early. Tr. 334-35; GX 51; ALJ Ex. 42, p. 52. Dr. Sullivan found no evidence of the resolution of these red flags. Tr. 335-36; GX 50, 52; ALJ Ex. 42, pp. 49-52.

Finally, Dr. Sullivan opined that the compounding done in this case was not legitimate, as it was outside the standard of practice. Tr. 336-38. Dr. Sullivan

explained that the FDA wants pharmacists to have the ability to compound to address the rare cases of patients with special needs, such as allergies. Tr. 337-38. However, compounding is also the subject of licensing and regulation. Tr. 339-40. *See* 21 U.S.C. § 353a; Fla. Admin. Code r. 64B16-27.700, .797. Manufacturing is not permitted under a standard community retail pharmacy license. Tr. 340. It requires specific licensing. *Id*.

Dr. Sullivan noted that 95 or 96 percent of the subject hydromorphone medication was compounded. Dr. Sullivan concluded the extreme volume alone as proof positive that the Respondent's compounding was not limited to patients with individualized therapeutic needs. Tr. 337. Although the Patient Profiles reviewed contained a category for "allergy," no allergies were documented, either within the Patient Profiles or in any of the other records reviewed. Tr. 339; *see* Fla. Admin. Code r. 64B16-27.800(2). Dr. Sullivan found no evidence that any of the subject patients receiving compounded medications were subject to medication allergies. Tr. 339.

EXPERT OPINION

Although these proceedings are not bound by the Federal Rules of Evidence, they are often instructive in the evaluation of the admissibility of evidence herein. Rule 702 states as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The tribunal should ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. *Daubert v. Merrell Dow*

Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993). The subject of an expert's testimony must be scientific, technical, or other specialized knowledge. *Id.* at 589-90. This requirement "establishes a standard of evidentiary reliability." *Id.* at 590; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999) (noting it is the word "knowledge" in Rule 702 that establishes a standard of evidentiary reliability). "Knowledge connotes more than subjective belief or unsupported speculation," although the subject of the testimony need not be known to a certainty. *Id.*; *see also United States v. Garcia*, 919 F.3d 489, 496 (7th Cir. 2019) (ruling that without corroborating evidence agent's opinion testimony consisted of "educated speculation" rather than sufficient proof); *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000) (reciting rule that if expert bases his or her opinion on "assumed facts," the record must support those assumptions); *Viterbo v. Dow Chemical Co.*, 826 F.2d 420, 422 (5th Cir. 1987) (articulating general rule that questionable factual bases underlying an expert's opinion negatively impact the opinion's weight).

In order to be "scientific knowledge," an assertion or inference must be derived by the scientific method. *Id.* "Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Id.* Expert evidence is unreliable, and thus inadmissible, "if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case." *United States v. Bailey*, 571 F.3d 791, 803 (8th Cir.2009); *see also United States v. Two Elk*, 536 F.3d 890, 904 (8th Cir. 2008).

Faced with a proffer of expert scientific testimony, then, the judge should determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. *Daubert*, 509 U.S. at 592. "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is

scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93.

Regardless of what factors are evaluated, the main inquiry is whether the proffered expert's testimony is sufficiently reliable. *Id.* at 574 (citing *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005) ("There is no single requirement for admissibility as long as the proffer indicates that the expert evidence is reliable and relevant.")). Rule 702 requires a flexible approach. *Daubert*, 509 U.S. at 594. The focus of Rule 702 "must be solely on principles and methodology, not on the conclusions that they generate." *Id.* at 595. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* at 596; *see also Two Elk*, 536 F.3d at 903 (a district court "'must exclude expert testimony *if it is so fundamentally unreliable that it can offer no assistance to the jury,* otherwise, the factual basis of the testimony goes to the weight of the evidence.'" (emphasis in original) (quoting *Larson v. Kempker*, 414 F.3d 936, 940-41 (8th Cir. 2005))).

Here, Dr. Sullivan was qualified as an expert in the field of pharmacy and the standard of care for the practice of pharmacy in the state of Florida. He gave his opinion regarding the relevant standards of care in Florida for the practice of pharmacy, including the existence of red flags, or generally suspicious circumstances. He also gave his opinion regarding the parameters of lawful pharmacy compounding in light of federal statutes and regulations governing compounding and manufacturing. The relevant standard of care may be established by an expert witness through his experience in the field, and through his reliance upon and application of state and federal professional standards.

As the Supreme Court noted in *Kumho Tire*, 526 U.S. at 142, expert opinion, "whether based upon professional studies or personal experience, employs in the

courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id*. at 152. The district court's role is especially significant since the expert's opinion "can be both powerful and quite misleading because of the difficulty in evaluating it." *Daubert*, 509 U.S. at 595 (quoting Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991)).

> The Committee Note to the 2000 Amendments of Rule 702 also explains that "[n]othing in this amendment is intended to suggest that experience alone ... may not provide a sufficient foundation for expert testimony." Fed. R. Evid. 702 advisory committee's note (2000 amends.). Of course, the unremarkable observation that an expert may be qualified by experience does not mean that experience, standing alone, is a sufficient foundation rendering reliable *any* conceivable opinion the expert may express. As we observed in *Quiet Technology*, "while an expert's overwhelming qualifications may bear on the reliability of his proffered testimony, they are by no means a guarantor of reliability . . . . [O]ur caselaw plainly establishes that one may be considered an expert but still offer unreliable testimony." 326 F.3d at 1341-42. Quite simply, under Rule 702, the *reliability* criterion remains a discrete, independent, and important requirement for admissibility. Indeed, the Committee Note to the 2000 Amendments of Rule 702 expressly says that, "[i]f the witness is relying solely or primarily on experience, then the witness must explain *how* that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Fed. R. Evid. 702 advisory committee's note (2000 amends.) (emphasis added); *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.* (on remand), 43 F.3d 1311, 1316 (9th Cir.1995) (observing that the gatekeeping role requires a district court to make a reliability inquiry, and

> that "the expert's bald assurance of validity is not enough"). If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.

United States v. Frazier, 387 F.3d 1244, 1261 (11th Cir. 2004).

Dr. Sullivan demonstrated a commanding grasp of pharmacy practice and of the distinctions between pharmacy compounding and manufacturing. However, there were several matters for which he had diminished credibility. For one, he was unaware that Florida had codified the standard of care for medical personnel. Although I later determined the statute in question did not apply to pharmacists, it was somewhat surprising he was unaware of it, as he teaches Florida pharmacy law.[18] More problematically, he quickly agreed that it was consistent with his understanding of the standard of care for pharmacists in Florida, which was somewhat surprising, as the standard of care for medical personnel is a highly generalized standard, a prudent healthcare provider standard, while the standard of care for pharmacists in Florida, as set out in the relevant Florida regulations, is highly specific in listing particular responsibilities and duties.[19] He arguably conceded an alternate generalized standard of care for pharmacists in Florida, which is not consistent with Florida law or regulation. *See* Fla. Admin. Code r. 64B16-27.800,

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[18] However, under Florida Statute § 766.102, pharmacists are not considered "healthcare providers." This Florida law defines "healthcare providers" as:

> . . . any hospital or ambulatory surgical center as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

§ 766.202(4), Fla. Stat. Pharmacists are administered under chapter 465.

[19] The "prevailing professional standard of care," which under Florida law is defined as "that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate for reasonably prudent similar heath care providers." § 766.102, Fla. Stat. (emphasis added).

.810, and .831.

Secondly, he gave inconsistent testimony regarding unresolvable red flags. He described several red flags as unresolvable, that no explanation could warrant the filling of the subject prescription. Later, he conceded that those same red flags could be resolved. At one point he suggested no single red flag was unresolvable, rather it was the combination of red flags which made them unresolvable. Accordingly, because of these inconsistencies, in the absence of a reliable principle or method employed by Dr. Sullivan, I reject his conclusions regarding his claim that certain red flags were unresolvable. For each of the red flags he testified were "unresolvable," I accept his alternate opinion that each of those red flags went unresolved in this matter, a finding clearly supported by the evidence.

Dr. Sullivan deemed the questionnaire used by the Respondent as essentially a subterfuge, designed not to reveal red flags and enable the Respondent to assess them, but as cover for red flags already known to exist by the Respondent. This conclusion was developed on the basis of Dr. Sullivan's experience in reviewing pharmacies, which were found to be operating in violation of pharmacy standards. It seemed more in the nature of an observation of coincident patterns. This conclusion assumes the questionnaires were never intended to assist the Respondent in assessing red flags versus being a good faith effort to identify red flags, which was never fullfilled. If the questionnaires were designed to provide cover to the Respondent's illegal behavior, they fail to do so. I didn't see the questionnaires as providing any cover to the Respondent's improper filling of prescriptions. If anything, the completed questionnaires highlighted and documented red flags of long-distance travel. The completed questionnaires are damning not exculpatory. Although not dispositive of this issue, the Government has not alleged intentional diversion. I find Dr. Sullivan's subject conclusion more in the nature of speculation. I don't believe the record provides sufficient factual foundation to support this expert

opinion.[20] I also find it inconsistent with the facts of the case. Accordingly, on the basis of the instant record, I find Dr. Sullivan's subject conclusion unjustified.

Dr. Sullivan made a similar conclusion regarding the prescribing of non-controlled substances and of controlled substances not subject to abuse or diversion. Again, he deemed such prescriptions as an apparent subterfuge on the part of the prescriber, designed to mask the improper prescribing of controlled substances highly subject to abuse and diversion, and creating a red flag, which went unaddressed by the Respondent. I question the sufficiency of the factual foundation for Dr. Sullivan's expert opinion that the above prescriptions were an apparent attempt to mask scores of improper opioid prescriptions. The relevant medical records were not reviewed, the prescriber's justification for the prescriptions were not considered by Dr. Sullivan, nor was the patient's input as to the subject prescriptions considered. I find Dr. Sullivan's subject opinion, on the basis of this record, to be improperly speculative and unjustified as an expert opinion.[21] This finding does not affect the probity of Dr. Sullivan's opinions as to the therapeutic effect of the subject medications, their contraindication with other prescribed medications, or the justification of their prescription.

The Respondent made the point that Dr. Sullivan did not confer with the subject patients or with their prescribing physicians. Dr. Sullivan conceded that a diligent pharmacist would, as circumstances require, attempt to resolve any red flags by discussing them with the patient and with the prescribing physician. The Respondent argues that the fact Dr. Sullivan did not discuss any red flags with the patients or with the prescribers renders Dr. Sullivan's conclusions regarding red flags questionable as Dr. Sullivan did not attempt to resolve the subject red flags.

Although certainly the extent of Dr. Sullivan's review of relevant material is

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[20] *Daubert*, 509 U.S. at 592-93; *Garcia*, 919 F.3d at 496.

[21] This finding is based on principles governing expert witnesses. *See Garcia*, 919 F.3d at 496.

critical to the conclusions he draws, the focus of Dr. Sullivan's opinions relate to whether the Respondent complied with his corresponding responsibility to resolve red flags prior to dispensing the subject medications, and to documenting any resolution within the file. It is neither here nor there that Dr. Sullivan could have resolved his own concerns regarding the subject red flags by speaking to the patients and prescribers years later. Nor is it dispositive that Dr. Sullivan could have determined that the subject red flags were resolvable at the time they were dispensed, if the Respondent failed to satisfy his corresponding responsibility to resolve them. So, with the exception of his opinion regarding the apparent red flag created by the prescribing of non-controlled substances (discussed immediately above), I don't view the fact that Dr. Sullivan didn't speak with the subject patients or prescribers as diminishing the probity of his relevant opinions as to the Respondent's acts or omissions at all.

The Respondent makes the similar point regarding the fact that Dr. Sullivan did not review copies of the physical prescriptions, as there is evidence Respondent may have made notations relevant to resolving red flags directly onto the prescriptions. Dr. Sullivan freely conceded he had not been provided with copies of the prescriptions to review. Indeed, if Dr. Sullivan had been provided with the hard-copy prescriptions, presumably, he would have been able to provide an opinion as to those documents, and his other opinions and conclusions would have the benefit of that additional information. However, he was not asked to review the prescriptions by the Government. If an expert does not review all of the relevant evidence in the case, obviously the value or probity of his opinions and findings are limited accordingly. Here, he was provided sufficient materials to develop his opinions, which assist the factfinder to understand or to determine facts in issue. *Daubert*, 509 U.S. at 592.

RESPONDENT'S CASE-IN-CHIEF

The Respondent presented its case-in-chief through the testimony of a single witness, Norman L. Clement, Jr. Tr. 506-57.

Norman L. Clement, Jr.

Mr. Clement, Jr., is the son of Mr. Norman Clement, Sr., the Respondent's owner. Tr. 506-07. Mr. Clement, Jr., has held a pharmacy tech license in Florida since 2014. Tr. 507. He has worked for the Respondent since 2014. Tr. 507, 521. Mr. Clement, Jr., reported the Respondent employs approximately four pharmacists-in-charge. *Id*. He described the Respondent as a family operation. *Id*.

The Respondent gets few patient customers per day. Tr. 508. Typically, the pharmacy would only see two to three patients a day, sometimes none. *Id*. Four patients in one day would make for a busy day at the pharmacy. *Id*. The fact that the Respondent only saw a few patients per day meant that the staff could spend more time talking with the patients and getting to know them. *Id*.

Mr. Clement, Jr., testified that the Respondent's staff always recorded the information it collected from the patients. Tr. 509, 543. The types of information the Respondent collected from patients included "personal life information," how treatment was progressing, and dietary information. Tr. 509. The Respondent recorded this information in the patient's profile. Tr. 543. Sometimes it recorded the information on the hard-copy prescriptions. *Id*.

When a new patient presents at the pharmacy, the Respondent gathers information about the patient to assist the pharmacist in making a decision about whether to dispense to that patient. Tr. 509, 537-38, 540. The Respondent charges new patients $25 for an initial consultation. Tr. 542. As part of this information-gathering process, the Respondent asks patients to complete a questionnaire.

Tr. 511, 537-38, 542. The questionnaire solicits information regarding the reason the patient is visiting the Respondent, how the patient feels, and what caused the patient's ailment or injury. Tr. 511-12, 538, 540. Sometimes a patient has been rejected by three to six other pharmacies before visiting the Respondent. Tr. 538. The Respondent creates a patient profile for all new patients and places a copy of the questionnaire in the profile. Tr. 546-48. Notes regarding the resolution of red flags would be contained in the patient's profile. Tr. 553. Mr. Clement, Jr., testified that the Respondent "look[ed] at every aspect" of a prescription before filling it, and that if "everything checks out," the patient is cleared to fill the prescription. Tr. 540-41. The Respondent places a check mark on a prescription to verify it is cleared for dispensing. Tr. 554-55.

Mr. Clement, Jr., testified that the questionnaire asks the patients to provide details about their injury; simply claiming that "my back pain hurts" will not suffice. Tr. 512. The Respondent also makes a copy of the patient's driver's license. Tr. 513, 538. Mr. Clement, Jr., testified that the pharmacy checked the medical legitimacy of prescriptions[22] and called the prescribing doctor for all controlled substance prescriptions. Tr. 538-40, 542-43, 545. Initially, Mr. Clement, Jr., testified that the Respondent would write down what the doctor says in the patient's profile. Tr. 543-44. Government counsel later asked if the lack of notes about calling the doctor meant the doctor was never called. Tr. 550. Mr. Clement, Jr., responded, "Not necessarily," and explained that sometimes the Respondent would write those notes

[22] Mr. Clement, Jr.'s, testimony that the Respondent verified the medical legitimacy of the prescriptions it filled runs counter to Mr. Clement, Sr.'s, view, as written in his blog, that he is "not authorized or qualified to challenge a physician's diagnosis and treatment." Tr. 538, 566. If that is the case, it seems inconsistent that the Respondent would call a doctor's office at all, let alone to confirm a diagnosis. Tr. 551. Furthermore, it is difficult to understand how the Respondent ensured that prescriptions were medically legitimate if the Respondent believed it could not question a doctor's decision to prescribe a certain medication. Tr. 538, 566. The Respondent's vetting process, as described by Mr. Clement, Jr., seems superfluous if the Respondent's pharmacists are unable to question a diagnosis and treatment.

on the hard-copy prescription. Tr. 550-51. The Respondent would write, "M.D. okay" on the prescription to verify the doctor had been called. Tr. 550-52.

After reviewing the questionnaire, a staff member searches for the patient in the PDMP to see if the patient is visiting other pharmacies. Tr. 512-13, 538. Typically, the Respondent attaches a copy of the PDMP reports to the patient's file. Tr. 513. The software system that the Respondent used also produced a "Narx" score that informed the pharmacy about a patient's risk of addiction. Tr. 518-19. The Respondent and its staff used the "Narx" score feature when deciding whether to fill prescriptions. *Id*. Sometimes after conducting this process the Respondent has turned patients away. Tr. 512, 538, 542.

Mr. Clement, Jr.'s, primary duties at the Respondent are working with the computer system and records. Tr. 515, 522. The Respondent uses Rx30 software. Tr. 514. When the DEA served the OSC/ISO on the Respondent in August 2019, it also executed a search warrant and seized two of the Respondent's computers. Tr. 514-15, 530-31. The Respondent also kept files on a back-up system which was also seized by the DEA. Tr. 534-35. When the computers were eventually returned, they did not work and the scanned copies of prescriptions had been erased.[23] Tr. 514-15, 530-31. Mr. Clement, Jr., worked with an IT consultant and Rx30's technical support to try to recover the prescription image files from the computers seized by DEA. Tr. 517-18. Those recovery efforts were unsuccessful. *Id*.

The DEA also seized a touch-screen computer monitor. Tr. 516. When DEA returned the monitor, the screen had been shattered and it no longer worked.[24]

[23] Although Mr. Clement, Jr.'s, testimony about how files were backed-up was sometimes difficult to follow, Tr. 531-36, he seemed to indicate that the Respondent had the capability of retrieving lost files from Rx30's system. Tr. 535-36.

[24] I permitted the Respondent's counsel, over Government objection, to question Mr. Clement, Jr., on this topic to the extent it related to the issue of unfair, unequal, or uneven treatment, a defensive claim by the Respondent. Tr. 516-17. This claim is cognizable herein to the extent it may demonstrate the Respondent is treated unevenly vis-a-vis other like-situated respondents. The unexplained damage to computer equipment and deletion of files could be relevant to the issue of uneven treatment by the Agency. This evaluation will ultimately focus on the Administrator's

Tr. 516-17, 531. The DEA also seized most of the hard-copy prescriptions that were kept at the pharmacy.[25] Tr. 516.

In general, I found Mr. Clement, Jr.'s, testimony to be somewhat subjective. As essentially a party to the litigation, he had a clear personal and family interest in the outcome. The Respondent's position that the Agency has treated the Respondent unfairly was reflected in Mr. Clement, Jr.'s, testimony. His emotional description of the manner of the seizure of Respondent's equipment and records, and their destruction and loss in the hands of the Agency, manifests his partiality in this matter. However, having a personal interest in the litigation, or manifesting an emotional commitment to your cause, are not bars to credibility. They are simply factors to be considered. I had some concerns with aspects of his testimony, however, which detracted from his credibility on certain topics. For the most part, these concerns were situations where Mr. Clement, Jr., provided conclusory testimony, and then followed-up with more detail when pressed by counsel.

There were also instances of inconsistency. For example, Mr. Clement, Jr., initially testified that the Respondent's computer system worked normally after the

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disposition of this matter. *Chein v. DEA*, 533 F.3d 828, 836-37 (D.C. Cir. 2008). In *Morall v. DEA*, 412 F.3d 165 (D.C. Cir. 2005), DEA's revocation of a physician's registration was vacated because DEA had "consistently declined . . . to revoke the registration of any other physician in a comparable context, or even under significantly more troubling circumstances" and because DEA offered "no explanation" for the departure from its precedent. *Id.* at 181. Under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), the Administrator's choice of sanction is entitled to substantial deference and will be set aside only if his decision is "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* at 177 (quoting *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001) (quoting 5 U.S.C. § 706(2)(A))). Ordinarily, the "mere unevenness in the application of [a] sanction [will] not render its application in a particular case 'unwarranted in law.'" *Id.* at 183 (quoting *Butz v. Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)) (first alteration in *Morall).* If the revocation represents a "flagrant departure from DEA policy and practice," however, and if the departure is "not only unexplained, but entirely unrecognized in the [DA's] decision, the agency's sanction [cannot] withstand abuse of discretion review." *Id.* at 183. This issue is strictly governed by the above evaluation. As I noted during the hearing, equal protection issues are not cognizable herein. *See* 28 U.S.C. § 1331.

Additionally, no issues of spoliation were raised, and so will not be addressed. Even if spoliation had been alleged, the Respondent would have to show the Government acted in bad faith in the loss or destruction of evidence in their control. No such showing was made. *Managed Care Solutions, Inc. v. Essent Healthcare, Inc.*, 736 F. Supp. 2d 1317, 1322 (S.D. Fla. 2010).

[25] Mr. Clement, Jr., testified that the Respondent has not received back the hard-copy prescriptions seized by the DEA. Tr. 520. After testifying to this, the Respondent's counsel informed the Tribunal, on the record, that the DEA had provided copies of the prescriptions to counsel's office. *Id*.

DEA made mirror images of the Respondent's computer hard-drive. Tr. 522, 525. He then clarified that the Respondent's computers did not work normally. Tr. 525-26. The computer system started working normally again about 3-4 months after the DEA made mirror images of it. Tr. 527.

Another example concerns the Respondent's efforts to call patients' past pharmacies. At the beginning of direct examination, Mr. Clement, Jr., testified that as part of its intake process for new patients, the Respondent would call a new patient's past pharmacy only if the Respondent had questions of that pharmacy. Tr. 512. Government counsel later asked, "Sometimes you call their past pharmacist?" Tr. 546. He answered, "Yes." *Id*. Just moments later, Mr. Clement, Jr., testified that the Respondent always called pharmacies for every new patient. Tr. 547, 549. This testimony paints an unclear picture of whether the Respondent always called a patient's previous pharmacy or whether it only called in certain situations.

Another example concerned the extent to which the Respondent verified prescriptions' medical legitimacy. Mr. Clement, Jr., explained that neither he nor the Respondent's pharmacists were qualified to read an MRI report (or any other laboratory test). Tr. 539-40.[26] He said that some patients would provide a copy of their MRI report, but "no pharmacist needs to look at an MRI." *Id*. This testimony seems to conflict with his testimony that the Respondent got to know its new patients by looking into their history, background, "pain ailments, what they're going through, [and] sometimes treatment plans." Tr. 508. If the Respondent checked a patient's background, and confirmed medical legitimacy of the prescription, then it seems that the Respondent merely took the patient (and his or her doctor) at their

[26] Mr. Clement, Jr's., testimony would make sense if he was referring to the actual x-ray or MRI, which require special training to interpret, such as that of a radiologist, who reduces his findings to a written report, which would be appropriate for a pharmacist to review.

word, since checking commonly-procured objective medical findings, such as an MRI report, was outside the Respondent's scope of review. The fact that the Respondent may have merely taken doctors, patients, and pharmacies at their word is supported by Mr. Clement, Jr.'s, later testimony that a patient is cleared to receive controlled substances if the doctor says "yes" and the patient's previous pharmacy says the patient is "okay." Tr. 542.

There was another instance where Mr. Clement, Jr., came across as more of an advocate for the Respondent rather than an objective witness. In this instance, the Respondent's counsel asked Mr. Clement, Jr., whether the Respondent had developed a niche business in the types of patients it sees. Tr. 509-10. This seemed to be a straightforward, unambiguous question. Mr. Clement, Jr., responded, however, by describing, at length, the process of checking the patient's identification, and checking the PDMP and NarcFacts. Tr. 510-11. The Respondent's counsel then followed-up with a leading question, asking Mr. Clement, Jr., whether the Respondent "dispense[d] primarily to patients who are suffering from chronic non-malignant pain?" Tr. 511. Mr. Clement, Jr., answered in the affirmative. *Id*. Mr. Clement, Jr.'s, non-responsive answer demonstrated an eagerness to advocate the Respondent's safety measures for screening patients and preventing diversion, rather than answering the question about what types of clients the Respondent serviced.

Having listened to Mr. Clement, Jr.'s, testimony at the hearing, and having closely reviewed the transcript of his testimony, I find him to be generally credible, with the few exceptions noted above. He generally presented as a professional, knowledgeable, and honest witness. I will give his testimony weight to the extent it is internally consistent, and to the extent it is consistent with other evidence and testimony of record.

THE GOVERNMENT'S REBUTTAL CASE

After each party presented its case-in-chief, the Government presented the rebuttal testimony of DI Albert. Tr. 557-68.

DI Albert

The Government introduced DI Albert's rebuttal testimony to rebut Mr. Clement, Jr.'s, testimony about the resolution of red flags. Tr. 559-60, 563-64. DI Albert testified about a blog post authored by Mr. Clement, Sr.[27] Tr. 559, 561. DI Albert downloaded this blog post from the internet. Tr. 562. The blog post identifies its author as "Norman J. Clement, R.Ph, DDS." Tr. 563. DI Albert also downloaded an attachment from the blog post. Tr. 564-65. The attachment is a copy of the Government's prehearing statement in this case. Tr. 565. There are notes written on the prehearing statement, to include the following note on page 23:

> The question of the red flag issue is not an issue to [me] because I don't challenge the physician for diagnosing and writing prescriptions for the patients because I'm not authorized or qualified to challenge a physician's diagnosis and treatment of his or her patients. Therefore, on the red flag issues, the question is, are they challenging me for filling the prescription or are they challenging the physician who wrote the prescription?

Tr. 566. Neither the hard-copied blog post nor attachment were admitted into evidence; only the oral testimony of DI Albert reading the above-quoted paragraph. Tr. 567.

During this brief rebuttal testimony, DI Albert presented, as he did in the Government's case-in-chief, as an honest, professional, and impartial investigator who had no stake in the case's outcome. DI Albert presented his rebuttal testimony in a credible and reliable manner. Although I fully credit DI Albert's rebuttal

[27] Although the Government offered the title of the blog post, "DEA's Kourt of the Kangaroo," the title was only admitted for authentication purposes.

testimony, I will only consider his rebuttal testimony to the extent that the paragraph he read into the record rebuts Mr. Clement, Jr.'s, testimony that the Respondent resolved red flags.

THE FACTS

STIPULATIONS OF FACT

The Government and the Respondent did not agree to any stipulations of fact.

FINDINGS OF FACT

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me. The findings of fact are based primarily on those proposed by the Government in its post-hearing brief. I have also considered the findings of fact proposed by the Respondent and found that many of those proposed findings related to matters proposed by the Government or related to matters addressed elsewhere in this Recommended Decision. If a proposed finding of fact is not included in this section and is also not addressed elsewhere in this Decision, it is because that proposed finding was not relevant to deciding this case.

1. Respondent is registered with the DEA to handle controlled substances in Schedules II through V under Certificate of Registration No. FP2302076. Respondent's registered address is 1461 West Busch Boulevard, Tampa, Florida 33612. Respondent's DEA Certificate of Registration expires by its own terms on March 31, 2022. GX 1.
2. Oxycodone is a Schedule II controlled substance. 21 C.F.R. § 1308.12(b)(1).

3. Hydromorphone is a Schedule II controlled substance. 21 C.F.R. § 1308.12(b)(1).
4. Alprazolam is a Schedule IV controlled substance. 21 C.F.R. § 1308.14(c).
5. Morphine Sulfate is a Schedule II controlled substance. 21 C.F.R. § 1308.12(b)(1).
6. Methadone is a Schedule II controlled substance. 21 C.F.R. § 1308.12(c).
7. Hydromorphone 8 mg is a commercially available drug. Tr. 232. Hydromorphone 8 mg is the highest strength of hydromorphone that is commercially available. Tr. 248.
8. Oxycodone 30 mg is a commercially available drug. Tr. 232.

DEA's Investigation

9. After receiving a tip from the Florida Department of Health in May 2017, DEA investigators traveled to Respondent's registered address and presented a Notice of Inspection to the pharmacist present, who consented to the inspection. Approximately 10 to 15 minutes later, Respondent's owner, Norman Clement, Sr., indirectly asked the DEA investigators to leave, which they did. Tr. 26-27.
10. In September 2017, DEA investigators served an administrative subpoena on Respondent seeking, among other things, receiving records for hydromorphone and oxycodone powder used in Respondent's compounding as well as "batch records." Tr. 27. Government Exhibits 2 through 6 were produced by Respondent to DEA in response to the September 2017 subpoena and were admitted into evidence in this matter. Tr. at 27-34.
11. On September 10, 2018, DEA investigators executed an Administrative Inspection Warrant ("AIW") at Respondent's registered address. Tr. 52.
12. DI Albert and Respondent's owner conducted an inventory of the Schedule II controlled substances contained in the safe located at Respondent's address.

Tr. 56. On September 10, 2018, there were 3,546 compounded capsules of hydromorphone 8 mg; 460 commercially-produced tablets of hydromorphone 8 mg; 574 compounded capsules of oxycodone 30 mg; and 204 commercially-produced oxycodone 30 mg tablets in the safe. GX 7. There were also 155.2 grams of hydromorphone powder and 26 grams of oxycodone powder. *Id.* There were no other Schedule II controlled substances contained in the safe. Tr. 59.

13. During the AIW, DEA investigators attempted to inspect and copy certain records. Tr. 56. At the time, Respondent's owner was not able to tell the investigators where these records were located. Tr. 56-57. As a result, one of Respondent's owner's sons (Norman Clement, Jr.) was reached by video-teleconference on a series of mobile devices and was able to direct the investigators to the location of various records. Tr. 61-62; *see also* Tr. 521-23.

14. During the execution of the AIW, DEA investigators also served an administrative subpoena, seeking complete copies of the "patient record system" for certain specific patients. Tr. 53; GX 67.

15. During the execution of the AIW, a technician from DEA's Digital Evidence Laboratory (SFL-9) was able to obtain copies of electronic records from Respondent's system by "mirroring" the hard drive. Tr. 62. The records obtained by the SFL-9 investigator included information relating to patients not involved in this proceeding.[28] Tr. 90-93. The SFL-9 provided DI Albert

[28] I do not agree that DI Albert's testimony supports a finding that the SFL-9 investigator obtained a complete copy of the Respondent's electronic records, as the Government proposed in its post-hearing brief. Gov't PHB, p. 4, ¶ 16 (citing Tr. 90-93). DI Albert's testimony supports a finding that the information "mirrored" from the hard-drive included patients other than the eleven involved here, but his testimony does not support the conclusion that the information obtained was a "complete copy" of all of the Respondent's records. Tr. 90-93.

with electronic copies of the records obtained during the execution of the AIW. Tr. 62-63, 94.

16. Government Exhibit 11 is a complete and accurate copy of Respondent's dispensing log for June 1, 2017, to September 7, 2018, which was obtained during the execution of the AIW in September 2018. Tr. 63-66. Government Exhibits 12-13; 15-17; 20-21; 23-24; 26-27; 29-30; 32-33; 35-36; 38-39; 41-43; 47-49, and 51 are correct and accurate copies of documents that were obtained from Respondent's electronic record system by the SFL-9 technician during the execution of the AIW. Tr. 68-86.

17. During the course of the investigation, DI Albert queried the Florida Prescription Drug Monitoring Database (E-FORCSE or PDMP) and obtained information regarding Respondent's dispensing of controlled substance as it was reported to the State of Florida. Tr. 44. Government Exhibits 8-10 are accurate copies of the data obtained from the E-FORSCE database for the dates listed. Tr. 48-51. Government Exhibits 14, 19, 22, 25, 28, 31, 34, 37, 40, 46, and 50 are complete and accurate copies of E-FORSCE information for certain specific enumerated patients. Tr. 68-86. There is no evidence in the record to indicate that the information reported by Respondent to the E-FORSCE database is inaccurate or unreliable.

18. In May 2018, DI Albert served an additional subpoena on Respondent seeking the complete patient record system maintained by Respondent for certain specific patients, as well as any "other documentation kept by [Respondent] in connection with the filling of prescriptions . . . for these individuals." Tr. 88-89; GX 68.

19. Government Exhibit 18 includes all documents and information produced in response to the May 2018 subpoena regarding Patient A.G. Tr. 96; GX 18.

Government Exhibit 44 includes all documents and information produced in response to the May 2018 subpoena regarding Patient R.B. Tr. 97-98; GX 44.

20. The Respondent dispensed four to five prescriptions per day on average. Tr. 419.

The Standard of Professional Pharmacy Practice in Florida

21. The standard of care in Florida requires that a pharmacist make sure each prescription is valid and has been issued for a legitimate medical purpose prior to dispensing controlled substances. As part of this evaluation, a pharmacist must first determine whether the prescription is facially legitimate—whether it includes all of the required information. Then, the pharmacist must attempt to determine whether there is over-utilization or under-utilization; clinical abuse or misuse going on; whether the prescription was issued for a legitimate medical purpose; and whether the prescription puts the patient at "any potential undue risk of side effects, adverse effects, and/or potentially overdose situations." Tr. 207-08. Many of these issues are specifically enumerated in Florida Administrative Code r. 64B16-27.810. Florida law places a duty on a pharmacist to "take appropriate steps to avoid or resolve the potential problems." *Id*. If, during the course of the validation process, the concerns cannot be resolved, "the pharmacist shall refuse to fill or dispense the prescription." Fla. Admin. Code r. 64B16-27.931(2)(c); *see also* Tr. 228.

22. Florida law also requires that a pharmacy maintain a "patient profile" for its customers that includes a variety of information. Tr. 209; Fla. Admin. Code r. 64B16-27.800. Both Florida law and the standard of care require a pharmacist to document the steps that he took to resolve any areas of concern or potential problems in the patient profile. Fla. Admin. Code r. 64B16-27.800; Tr. 209-10, 489.

23. Dr. Sullivan testified that a "red flag" is a "warning sign" that "there's something potentially wrong with the prescription." Specifically, it is a sign that "the patient may either be abusing or diverting it." Dr. Sullivan testified that these "red flags" are well-documented in the pharmacy community and are known to pharmacists in the State of Florida. Tr. 211-14; 235-36.

24. Dr. Sullivan testified that some of these red flags include (1) patients travelling long distances to the pharmacy; (2) certain drug cocktails; (3) high dosages of immediate release pain killers; and (4) cash-paying customers. Tr. 214.

25. Dr. Sullivan testified that the prescribing of an opioid pain reliever and benzodiazepine at the same time is a significant red flag. Dr. Sullivan noted that the Food & Drug Administration had issued a warning in 2016 regarding the serious health risks posed by the combination of those two medications. Tr. 220-21; GX 66. Dr. Sullivan testified that a reasonable pharmacist acting within the usual course of professional practice in Florida would be "very very reluctant to dispense that combination of drugs" after the FDA safety warning. Tr. 223.

26. Dr. Sullivan testified that filling a controlled substance prescription early is a red flag. Tr. 225-27. He testified that the standard of care required a pharmacist not to fill a Schedule II controlled substance prescription until "the day or day before the medication from a previous prescription is supposed to run out." Tr. 270-71. While there may be legitimate reasons for a particular prescription to be filled early in "extreme" and "unusual" cases, there is no legitimate reason for a pharmacist to fill a Schedule II controlled substance prescription early in multiple consecutive months. Tr. 270-71.

27. When a pharmacist identifies one or more red flags, he must undertake an investigation into the prescription before he can fill it. Tr. 227. This may

include speaking with the patient and/or speaking with the prescriber. A pharmacist would also be expected to look at the patient profile as well as apply his clinical expertise to the drug, quantity, and strength prescribed. *Id*. The standard of care requires that the pharmacist document these conversations and analyses.[29] Tr. 227-28.

Respondent's Dispensing

Patient A.G.

28. At all times relevant to this matter, Patient A.G. resided at 411 NE 25th Ave, Cape Coral, Florida 33909. GX 15. Patient A.G.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 55.

29. All of the prescriptions filled by Patient A.G. at Respondent were paid for in cash. GX 14, 17.

30. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.G. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient A.G. was a "red flag," as was the fact that Patient A.G. was prescribed a "cocktail of benzodiazepine and opioid" at the highest strengths of both medications. Tr. 254-55. Dr. Sullivan also observed that Patient A.G. filled multiple prescriptions early. Tr. 257-59.

31. Between June 26, 2017, and August 30, 2018, Respondent filled 30 prescriptions for controlled substances for Patient A.G., including 10 prescriptions for hydromorphone 8 mg; 10 prescriptions for oxycodone 30 mg; 9 prescriptions for alprazolam 2mg; and 1 prescription for alprazolam 1mg. Information regarding the controlled substances dispensed to Patient A.G. is accurately set forth in Government Exhibit 17.

[29] For reasons explained elsewhere in this Recommended Decision, I am not accepting Dr. Sullivan's testimony that certain combinations of red flags are unresolvable, as proposed by the Government. Gov't PHB, p. 8, ¶ 34.

32. Between December 20, 2018, and April 12, 2019, Respondent filled 10 prescriptions for controlled substances for Patient A.G., including 5 prescriptions for oxycodone 30 mg and 5 prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient A.G. is accurately set forth in Government Exhibit 14.

33. Respondent maintained a patient profile for Patient A.G. The only pharmacist note in the profile for Patient A.G. stated: "Doctor OK to Receive Medication in Compound Capsule Form." Govt. Ex. 15.

34. Dr. Sullivan testified that the notes contained the Patient A.G.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 258.

35. Dr. Sullivan further testified that the answers provided on the Medical Questionnaire were not sufficient to resolve any of the specific red flags that he identified. Tr. 260-63.

Patient A.H.

36. At all times relevant to this matter, Patient A.H. resided at 1001 NE 6th Place, Cape Coral, Florida 33909. GX 20. Patient A.H.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 56.

37. All of the prescriptions filled by Patient A.H. at Respondent were paid for in cash. GX 19, 21.

38. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.H. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient was a "red flag," as was the fact that Patient A.G. was prescribed a "cocktail of benzodiazepine and opioid" at the highest strengths of both medications. Tr. 268-69.

39. Between January 4, 2018, and August 16, 2018, Respondent filled 11 prescriptions for controlled substances for Patient A.H., including six

prescriptions for hydromorphone 8 mg and five prescriptions for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient A.H. is accurately set forth in Government Exhibit 21.

40. Between September 11, 2018, and April 18, 2019, Respondent filled at least seven prescriptions for controlled substances for Patient A.H., including seven prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient A.H. is accurately set forth in Government Exhibit 19.

41. Respondent maintained a patient profile for Patient A.H. The patient profile for Patient A.H. contained no pharmacist notes or comments. GX 20. In Dr. Sullivan's opinion, Patient A.H.'s patient profile was insufficient to resolve any of the red flags that he identified. Tr. 272.

Patient B.S.

42. At all times relevant to this matter, Patient B.S. resided at 117 Zobora Circle, Fort Myers, Florida 33913. GX 23. Patient B.S.'s residence is approximately 150 miles (one-way) from Respondent's registered address. GX 57.

43. All of the prescriptions filled by Patient B.S. at Respondent were paid for in cash. GX 22, 24.

44. Dr. Sullivan examined the dispensing data and the patient profile for Patient B.S. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient B.S. was a "red flag," as was the fact that Patient B.S. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 274-75.

45. Between August 22, 2017, and August 23, 2018, Respondent filled 19 prescriptions for controlled substances for Patient B.S., including 12 prescriptions for hydromorphone 8 mg; six prescriptions for alprazolam 2 mg; and one prescription for alprazolam 1 mg. Information regarding the

controlled substances dispensed to Patient B.S. is accurately set forth in Government Exhibit 24.

46. Between December 20, 2018, and April 22, 2019, Respondent filled at least nine prescriptions for controlled substances for Patient B.S., including two prescriptions for hydromorphone 8 mg, four prescriptions for oxycodone 30 mg, and three prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient B.S. is accurately set forth in Government Exhibit 22.

47. Respondent maintained a patient profile for Patient B.S. The patient profile for Patient B.S. contained no pharmacist notes or comments. GX 23.

48. Dr. Sullivan testified that the notes contained in Patient B.S.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 277.

Patient C.R.

49. At all times relevant to this matter, Patient C.R. resided at 2907 Jackson Street, Fort Myers, Florida 33901. GX 26. Patient C.R.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 58.

50. All of the prescriptions filled by Patient C.R. at Respondent were paid for in cash. GX 25, 27.

51. Dr. Sullivan examined the dispensing data and the patient profile for Patient C.R. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient C.R. was a "red flag," as was the fact that Patient C.R. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 279-80.

52. Between July 19, 2017, and August 30, 2018, Respondent filled 13 prescriptions for controlled substances for Patient C.R., including six prescriptions for oxycodone 30 mg, six prescriptions for alprazolam 1 mg, and

one prescription for morphine sulfate 30 mg. Information regarding the controlled substances dispensed to Patient C.R. is accurately set forth in Government Exhibit 27.

53. Respondent maintained a patient profile for Patient C.R. The only pharmacist note in the profile for Patient C.R. stated: "Script has wrong birthdate on it. Dr[.] has now update[.]" GX 26.

54. Dr. Sullivan testified that the notes contained the Patient C.R.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. at 281.

Patient J.D.

55. At all times relevant to this matter, Patient J.D. resided at 229 NW 15th Place, Cape Coral, Florida 33993. GX 29. Patient J.D.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 59.

56. All of the prescriptions filled by Patient J.D. at Respondent were paid for in cash. GX 28, 30.

57. Dr. Sullivan examined the dispensing data and the patient profile for Patient A.H. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient A.H. was a "red flag," as was the fact that Patient A.G. was prescribed the highest strengths of hydromorphone. Tr. 283.

58. Between January 15, 2018, and September 4, 2018, Respondent filled ten prescriptions for controlled substances for Patient J.D., including nine prescriptions for hydromorphone 8 mg and one prescription for methadone 10 mg. Information regarding the controlled substances dispensed to Patient J.D. is accurately set forth in Government Exhibit 30.

59. In addition, Dr. Sullivan noted that Respondent dispensed two immediate release narcotic pain relievers (hydromorphone 8 mg and methadone 10 mg)

to Patient J.D. on March 24, 2018. Dr. Sullivan testified that dispensing two immediate release narcotic pain relievers on the same day was "a red flag in and of itself." Tr. 283-84.

60. Respondent maintained a patient profile for Patient J.D. The only pharmacist note in the profile for Patient J.D. stated: "Next Fill 7/5/18!!! Watch fill dates!!!!!!" GX 29.

61. Dr. Sullivan testified that the notes contained in Patient J.D.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 287-88.

Patient J.M.

62. At all times relevant to this matter, Patient J.M. resided at 3004 30th Street SW, Lehigh Acres, Florida 22976. GX 32. Patient J.M.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 60.

63. All of the prescriptions filled by Patient J.M. at Respondent were paid for in cash. GX 31, 33.

64. Dr. Sullivan examined the dispensing data and the patient profile for Patient J.M. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient J.M. was a "red flag," as was the fact that Patient J.M. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 289-90.

65. Between June 22, 2017, and September 7, 2018, Respondent filled 23 prescriptions for controlled substances for Patient J.M., including eight prescriptions for oxycodone 30 mg; six prescriptions for hydromorphone 8 mg; and nine prescriptions for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient J.M. is accurately set forth in Government Exhibit 33.

66. Respondent maintained a patient profile for Patient J.M. The patient profile for Patient J.M. contained no pharmacist notes or comments. GX 32.

67. Dr. Sullivan testified that the notes contained the Patient J.M.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 290.

Patient M.M.

68. At all times relevant to this matter, Patient M.M. resided at 1145 W Walnut Street, Lakeland, Florida 22815. GX 35. The prescriptions that Patient M.M. filled at Respondent were issued by a practitioner located at 1670 San Carlos Blvd., Fort Myers Beach, Florida 22931. GX 36.

69. Patient M.M.'s residence is approximately 130 miles (one-way) from the prescriber's location. GX 61. All of the prescriptions filled by Patient M.M. at Respondent were paid for in cash. GX 34, 36.

70. Between June 6, 2017, and August 16, 2018, Respondent filled 14 prescriptions for controlled substances for Patient M.M., including 14 prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient M.M. is accurately set forth in Government Exhibit 36.

71. Between January 3, 2019, and April 16, 2019, Respondent filled at least 5 prescriptions for controlled substances for Patient M.M., including 5 prescriptions for hydromorphone 8 mg. Information regarding the controlled substances dispensed to Patient M.M. is accurately set forth in Government Exhibit 34.

72. Dr. Sullivan examined the dispensing data and the patient profile for Patient M.M. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient M.M. from her home to her

physician was a "red flag," as was the fact that Patient M.M. was prescribed the highest available strength of hydromorphone.[30] Tr. 292-95.

73. Respondent maintained a patient profile for Patient M.M. The patient profile for Patient M.M. contained no pharmacist notes or comments. GX 35.

74. Dr. Sullivan testified that the notes contained in Patient M.M.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 300.

Patient N.B.

75. At all times relevant to this matter, Patient N.B. resided at 2132 SE 5th Place, Cape Coral, Florida 33990. GX 38. Patient N.B.'s residence is approximately 135 miles (one-way) from Respondent's registered address. GX 62.

76. All of the prescriptions filled by Patient N.B. at Respondent were paid for in cash. GX 37, 39.

77. Between June 21, 2017, and August 14, 2018, Respondent filled 19 prescriptions for controlled substances for Patient N.B., including 12 prescriptions for hydromorphone 8 mg, four prescriptions for alprazolam 2 mg, and three prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient N.B. is accurately set forth in Government Exhibit 39.

78. Between September 14, 2018, and April 10, 2019, Respondent filled at least nine prescriptions for controlled substances for Patient N.B., including five prescriptions for oxycodone 30 mg, three prescriptions for alprazolam 1 mg, and one prescription for hydromorphone 8 mg. Information regarding the

[30] For reasons explained later in this Recommended Decision, I am not accepting Dr. Sullivan's opinion that the roundtrip distance from M.M.'s home to the prescriber's office, to the Respondent, and back home, is a red flag, as proposed by the Government. Gov't PHB, pp. 20-21, ¶ 101.

controlled substances dispensed to Patient N.B. is accurately set forth in Government Exhibit 37.

79. Dr. Sullivan examined the dispensing data and the patient profile for Patient N.B. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient N.B. was a "red flag," as was the fact that Patient N.B. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 301-02, 305.

80. Respondent maintained a patient profile for Patient N.B. The only pharmacist note in the profile for Patient N.B. stated: "Doctor OK Patient to Receive Medication in Compound Capsule Form." GX 38.

81. Dr. Sullivan testified that the notes contained in Patient N.B.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 306.

Patient R.B.

82. At all times relevant to this matter, Patient R.B. resided at 2512 Pauldo Street, Fort Myers, Florida 33916. GX 41. Patient R.B.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 63.

83. All of the prescriptions filled by Patient R.B. at Respondent were paid for in cash. GX 40, 43.

84. Between June 28, 2017, and August 16, 2018, Respondent filled 24 prescriptions for controlled substances for Patient R.B., including 12 prescriptions for hydromorphone 8 mg, 11 prescriptions for alprazolam 2 mg, and one prescription for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient R.B. is accurately set forth in Government Exhibit 43.

85. Between September 12, 2018, and April 15, 2019, Respondent filled at least 10 prescriptions for controlled substances for Patient R.B., including five

prescriptions for hydromorphone 8 mg and five prescriptions for alprazolam 1 mg. Information regarding the controlled substances dispensed to Patient R.B. is accurately set forth in Government Exhibit 40.

86. Respondent maintained a patient profile for Patient R.B. The patient profile for Patient R.B. contained no pharmacist notes or comments. GX 41.

87. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.B. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.B. was a "red flag," as was the fact that Patient R.B. was prescribed a cocktail of benzodiazepine and opioid with the opioid prescribed at the highest strength. Tr. 310-11.

88. Dr. Sullivan testified that the notes contained in Patient R.B.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 313.

Patient R.G.

89. At all times relevant to this matter, Patient R.G. resided at 1915 NE 5th Street, Cape Coral, Florida 33909. GX 47. Patient R.G.'s residence is approximately 130 miles (one-way) from Respondent's registered address. GX 64.

90. All of the prescriptions filled by Patient R.G. at Respondent were paid for in cash. GX 46, 49.

91. Between June 28, 2017, and September 7, 2018, Respondent filled 29 prescriptions for controlled substances for Patient R.G., including 17 prescriptions for oxycodone 30 mg, and 12 prescriptions for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient R.G. is accurately set forth in Government Exhibit 49.

92. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.G. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.G. was a "red flag," as was the fact

that Patient R.G. was prescribed a cocktail of benzodiazepine and opioid at the highest strengths of both medications. Tr. 322-23.

93. Respondent maintained a patient profile for Patient R.G. The only pharmacist note in the profile for Patient R.G. stated: "Watch Fill Dates!!!!!!!!!!!!" GX 47.

94. Dr. Sullivan testified that the notes contained in Patient R.G.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) any of the red flags that he identified. Tr. 328.

Patient R.L.

95. At all times relevant to this matter, Patient R.L. resided at 135 SW 29th Terrace, Cape Coral, Florida 33914. GX 51. Patient R.L.'s residence is approximately 140 miles (one-way) from Respondent's registered address. GX 65.

96. All of the prescriptions filled by Patient R.L. at Respondent were paid for in cash. GX 50, 52.

97. Between June 21, 2017, and September 4, 2018, Respondent filled 16 prescriptions for controlled substances for Patient R.L., including 14 prescriptions for hydromorphone 8 mg, one prescription for oxycodone 30 mg, and one prescription for alprazolam 2 mg. Information regarding the controlled substances dispensed to Patient R.L. is accurately set forth in Government Exhibit 52.

98. Between December 27, 2018, and April 16, 2019, Respondent filled at least five prescriptions for controlled substances for Patient R.L., including five prescriptions for oxycodone 30 mg. Information regarding the controlled substances dispensed to Patient R.L. is accurately set forth in Government Exhibit 50.

99. Dr. Sullivan examined the dispensing data and the patient profile for Patient R.L. and identified multiple "red flags." Specifically, Dr. Sullivan concluded that the distance travelled by Patient R.L. was a "red flag," as was the fact that Patient R.L. was prescribed opioids at the highest strengths available. Tr. 330-31.

100. Respondent maintained a patient profile for Patient R.L. The only pharmacist note in the profile for Patient R.L. stated: "Next Fill 6/10/18 - 10 Days Early March & April – Told Him This 5/11/18 GD[.]" GX 51.

101. Dr. Sullivan testified that the notes contained in Patient R.L.'s patient profile were insufficient to resolve (or to suggest an attempt to resolve) the red flags that he identified. Tr. 335.

Compounding

102. Respondent repeatedly dispensed both commercially-available tablet and compounded capsule forms of controlled substances to the same patients, indicating that those patients did not have a legitimate therapeutic need for the compounded form. *See, e.g.*, Tr. 256, 290, 297, 321, 325, 326.

103. In May 2012, then-TFO Jeffrey Shearer conducted an interview with Respondent's owner regarding the compounding that he doing at Respondent. Tr. 183.

104. Respondent's owner indicated that his formulary was designed to ensure that the compounded product was "essentially similar" to the commercially-produced product. Respondent's owner stressed that his compounded product had the same "bioavailability" as the commercially available product. Tr. 184-85.

105. TFO Shearer observed that Respondent's owner was compounding thousands of dosage units at one time. Respondent's owner explained that he did so

because it was "cost effective" to produce large volumes at the same time. Tr. 185.

106. Respondent's owner told TFO Shearer that some of his customers did not want the compounded capsules, but that Respondent's owner assured the patients that the capsules and the tablets were "the same, that they would have the same effect." Tr. 185-86.

ANALYSIS

FINDINGS AS TO ALLEGATIONS

The Government alleges that the Respondent's COR should be revoked because the Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes, and within the course of professional practice, in violation of its corresponding responsibility, and repeatedly filled prescriptions in the face of obvious red flags of diversion without documenting the resolution of those red flags, and its registration would be inconsistent with the public interest, as provided in 21 U.S.C. § 824(a)(4) and 21 U.S.C. § 823(f), and in violation of state law under the Florida Administrative Code, and state requirements for the minimum standard of care. The Government also alleges the Respondent engaged in a pattern of manufacturing controlled substances without proper registration.

In the adjudication of a revocation or suspension of a DEA COR, DEA has the burden of proving that the requirements for such revocation or suspension are satisfied. 21 C.F.R. § 1301.44(e). Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, to rebut the Government's *prima facie* case, a respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.*, 74 Fed. Reg. 20727, 20734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the "egregiousness of the violations and the [DEA's] interest in deterring similar

misconduct by [the] Respondent in the future as well as on the part of others." *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38364 (2013). Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008).

The Agency's conclusion that "past performance is the best predictor of future performance" has been sustained on review in the courts, *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie*, 419 F.3d at 482-83; *see also Ronald Lynch, M.D.*, 75 Fed. Reg. 78745, 78754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.*, 74 Fed. Reg. 17529, 17543 (2009) (finding that much of the respondent's testimony undermined his initial acceptance that he was "probably at fault" for some misconduct); *Krishna-Iyer*, 74 Fed. Reg. at 463 (noting, on remand, that despite the respondent having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Med. Shoppe–Jonesborough*, 73 Fed. Reg. at 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman v. SEC*, 450 U.S. 91, 100-01 (1981). The Acting Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie*, 419 F.3d at 481. The Supreme Court

has defined "substantial evidence" as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consol. Edison Co. of New York v. NLRB*, 305 U.S. 197, 229 (1938). While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Acting Administrator's ability to find facts on either side of the contested issues in the case, *Shatz v. U.S. Dep't of Justice*, 873 F.2d 1089, 1092 (8th Cir. 1989); *Trawick*, 861 F.2d at 77, all "important aspect[s] of the problem," such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Village Pharm. v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys v. DEA*, 96 F.3d 658, 663 (3rd Cir. 1996). The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman*, 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall*, 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein v. DEA*, 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz v. Glover Livestock Comm'n Co.*, 411 U.S. 182, 188 (1973)). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Acting Administrator's decision. *Morall*, 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Acting Administrator and do not limit the exercise

of his discretion. 5 U.S.C. § 557(b) (2006); *River Forest Pharmacy, Inc. v. DEA*, 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Analysis of Dispensing Allegations

The Government alleges that the Respondent filled numerous prescriptions for eleven patients that raised red flags of drug abuse and/or diversion, to include drug cocktails; early fills; traveling long distances; prescriptions for the highest strengths of oxycodone, hydromorphone, and alprazolam; paying in cash; and dispensing compounded capsules without therapeutic justification. ALJ Ex. 1, pp. 4-7. The Government further alleges that the Respondent failed to resolve these red flags. *Id*. The Government claims that by filling these eleven patients' controlled substance prescriptions and failing to resolve the red flags they presented, the Respondent violated its corresponding responsibility under 21 C.F.R. § 1306.04(a) and dispensed controlled substances outside the usual course of pharmacy practice in violation of 21 C.F.R. § 1306.06, in addition to Florida Administrative Code r. 64B16-27.831. *Id*. Furthermore, the Government claims that by failing to resolve red flags and to document that resolution in the patients' profiles, the Respondent violated Florida Administrative Code r. 64B16-27.800 and .810. *Id*.

With respect to each patient, the Government presented documentary evidence and testimony from its pharmacy expert, Dr. Sullivan, that the Respondent filled numerous controlled substance prescriptions that raised red flags including, drug cocktails, early fills, long distance, highest strengths, and cash payments. The Government further presented evidence that the Respondent failed to document any resolution of these red flags in the patients' profiles. Finally, the Government proved the Respondent compounded medication without therapeutic justification.

I will now turn to the evidence the Government presented for each patient. After examining the evidence for each patient, I will determine whether the

Government has presented a *prima facie* case that the Respondent filled these prescriptions in violation of federal and state law.

Patient A.G.

From January 2018 to April 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to A.G. on six occasions. GX 14. During the same time period, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to A.G. on three occasions. *Id*.

Dr. Sullivan testified that the Respondent filled several prescriptions for A.G. before his prior month's supply of medication ran out. Tr. 257. For example, the Respondent filled oxycodone and alprazolam prescriptions for A.G. on January 17, 2019, the 28th day after dispensing a 30-day supply of each drug to him on December 20, 2018 (2 days early). ALJ Ex. 42,[31] p. 12; GX 14. The Respondent filled an alprazolam prescription for A.G. on February 14, 2019, the 28th day after dispensing a 30-day supply on January 17, 2019 (2 days early). *Id*. The Respondent filled another oxycodone prescription for A.G. on April 12, 2019, the 23rd day after dispensing a 28-day supply on March 20, 2019 (5 days early). *Id*. The Respondent also filled an alprazolam prescription for A.G. on April 12, 2019, the 23rd day after dispensing a 30-day supply on March 20, 2019 (7 days early). *Id*. These prescriptions should not have been filled early unless the Respondent documented a good reason for doing so. Tr. 257.

[31] Because the Government structured its direct examination of Dr. Sullivan by using the demonstrative exhibit for ease of reference, I will cite to that document as well as the Government Exhibit from which the information is derived. I will mark the demonstrative exhibit as ALJ Exhibit 42. I will treat the demonstrative exhibit similar to a summary of voluminous records under Federal Rule of Evidence 1006. The demonstrative exhibit, however, was never introduced into evidence, so it is being used as a guide or aid for review of the record. Thus, the admitted evidence trumps the demonstrative exhibit with respect to any inconsistency between the two.

Patient A.G.'s home address was located about 131 miles from the Respondent. ALJ Ex. 42, p. 10; GX 55. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist.[32] Tr. 254.

From June 2017 to August 2018, the Respondent dispensed ten prescriptions each for oxycodone, hydromorphone, and alprazolam. ALJ Ex. 42, p. 11; GX 17. Each of these prescriptions, except for one alprazolam prescription, was written for the highest commercially available strength of the drug. *Id*.; Tr. 255. All of the oxycodone prescriptions dispensed during this time period were for 30 mg dosage units, the highest strength available of oxycodone. *Id*. All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength available of hydromorphone. *Id*. Nine of the ten alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength available of alprazolam. *Id*. Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 256.

In addition to these red flags, patient A.G. paid for all of his prescriptions in cash. GX 14; GX 17. Dr. Sullivan testified that paying in cash is a red flag.[33] Tr. 214.

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[32] Although we do not know if A.G., in fact, travelled 131 miles from his home to the Respondent each time he filled a prescription there, the Respondent knew he lived that far away, and was therefore on notice of a classic red flag of drug abuse and/or diversion. This is true of ten of the eleven patients. The fact that the patients lived over 100 miles away is a red flag even if the patients did not travel that distance each time they visited the pharmacy. The focus is on the information the Respondent knew, and the Respondent knew the patients lived over 100 miles away because it had their addresses on the prescriptions. This information should have aroused the Respondent's suspicion. The remaining patient (M.M.) lived approximately 134 miles from his prescriber's office, which represents its own red flag of long distance travel to obtain the prescription. Tr. 291-94.

[33] The Respondent argues that it did not view cash payments as suspicious because it did not accept insurance as a form of payment. Resp't PHB, at 19-20, 35. I am not convinced by this argument for two reasons. First, the Respondent did not provide any direct evidence that the only form of payment it accepted during the relevant time period was cash. Rather, it drove at this issue indirectly by asking hypothetical questions such as how would the Respondent get paid if it did not have contracts with insurance carriers or pharmacy benefit managers. Tr. 443-44. Second, even if the only form of payment that the Respondent accepted was cash, the fact that a patient was willing to pay in cash should still have aroused the Respondent's suspicion since it is a firmly-established red flag of drug abuse and/or diversion in DEA case law. In fact, the DEA has recognized for at least the past 10 years that paying in cash for controlled substances raises a red flag. *E. Main Street Pharm.*, 75 Fed. Reg. 66149, 66164 (2010). The fact

Although patient A.G. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 259, 267; GX 17; ALJ Ex. 42, p. 11. The patient profile that the Respondent kept for A.G. contains only one note: "Doctor OK to receive medication in compound capsule form." ALJ Ex. 42, p. 13; GX 15; Tr. 258-59. This single note fails to resolve the red flags raised by drug cocktails, early fills, long distance travelled, highest strengths, and cash payments. Tr. 259. Dr. Sullivan further explained that this note suggested that the Respondent called the doctor and requested to fill the prescription with capsules. Tr. 258.

Patient A.H.

From January 2018 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to A.H. on five occasions. ALJ Ex. 42, p. 15; GX 21.

The Respondent provided three early fills of hydromorphone prescriptions for A.H. from February to March 2019. Tr. 270-71; ALJ Ex. 42, p. 16; GX 19. The Respondent dispensed hydromorphone to A.H. on February 15, 2019, the 24th day after dispensing a 30-day supply on January 22, 2019 (6 days early). *Id*. The Respondent also dispensed hydromorphone to A.H. on February 27, 2019, the 12th day after dispensing a 30-day supply on February 15, 2019 (18 days early). *Id*. The Respondent then dispensed hydromorphone to A.H. on March 14, 2019, the 15th day after dispensing a 30 day-supply on February 27, 2019 (15 days early). *Id*.

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that the patients in this case were willing to pay in cash was even more concerning given the other red flags that they raised. In other words, while a pharmacy is free to run its business as it chooses, it does not change the fact that paying in cash for highly abused, commonly diverted opioids is recognized by the DEA as a classic red flag, especially when it occurs alongside the other red flags present in this case. *See Edge Pharm.*, 81 Fed. Reg. 72092, 72103, 72111-12 (2016) (noting that paying in cash or cash equivalent, such as by credit or debit card, is viewed in combination with other evidence of diversion). This conclusion is consistent with Dr. Sullivan's opinion that paying in cash for controlled substances remains suspicious when it occurs with the other red flags involved here, even if the pharmacy did not take insurance. Tr. 475-76.

Filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 271. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. *Id*.

Patient A.H.'s home address was located about 132 miles from the Respondent. ALJ Ex. 42, p. 14; GX 56; Tr. 268. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 268.

From January 2018 to August 2018, the Respondent dispensed six prescriptions of hydromorphone and five prescriptions of alprazolam. ALJ Ex. 42, p. 15; GX 21. Each of these prescriptions was written for the highest strength of the drug. *Id*.; Tr. 269. All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength available of hydromorphone. *Id*. All of the alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength available of alprazolam. *Id*. Dispensing these controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 269.

In addition to these red flags, patient A.H. paid for all of his prescriptions in cash. GX 19; GX 21. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient A.H. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 272; GX 20; ALJ Ex. 42, p. 17.

Patient B.S.

From August 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to B.S. on five occasions. ALJ Ex. 42, p. 19; GX 24; Tr. 274. From December 2018 to March 2019, the Respondent dispensed a

drug cocktail of alprazolam and oxycodone to B.S. on three occasions. ALJ Ex. 42, p. 20; GX 22; Tr. 276-77.

Dr. Sullivan also pointed out the duplicative therapy that the Respondent dispensed in January and February 2019. Tr. 276; ALJ Ex. 42, p. 20. After dispensing a 30-day supply of oxycodone to B.S. on January 31, 2019, only five days later the Respondent dispensed a 28-day supply of hydromorphone. *Id*. Then only two weeks later, the Respondent dispensed another 30-day supply of oxycodone to B.S. *Id*. Oxycodone and hydromorphone are potent immediate-release narcotic pain killers. Tr. 276. The fact that B.S. presented overlapping prescriptions for different immediate-release opioids with duplicative therapy was a red flag of abuse and/or diversion. *Id*.

Patient B.S.'s home address was located about 148 miles from the Respondent. ALJ Ex. 42, p. 18; GX 57; Tr. 273-74. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 273-74.

From August 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone and 7 prescriptions of alprazolam. ALJ Ex. 42, p. 19; GX 24; Tr. 274. All but one of these prescriptions was written for the highest commercially available dosage strength of the drug. *Id*. All of the hydromorphone prescriptions dispensed during this time period were for 8 mg dosage units, the highest strength of hydromorphone. *Id*. All but one of the alprazolam prescriptions dispensed during this time period were for 2 mg dosage units, the highest strength of alprazolam. *Id*. From December 2018 to April 2019, the Respondent dispensed four prescriptions of oxycodone and one prescription of hydromorphone. ALJ Ex. 42, p. 20; GX 22; Tr. 276. All four of the oxycodone prescriptions were written for 30 mg, the highest strength of oxycodone. *Id*. The hydromorphone prescription was written for 8 mg, the highest strength of hydromorphone. *Id*. Dispensing these

controlled substances at their highest strengths, especially in combination with each other, raised red flags that required resolution. Tr. 274, 276-77.

Dr. Sullivan also pointed out the additional red flag of ibuprofen 400 mg prescribed along with the highest-strength of hydromorphone. Tr. 274-75; ALJ Ex. 42, p. 19; GX 24. He compared 400 mg of ibuprofen to two tablets of over-the-counter Advil or ibuprofen. Tr. 275. In other words, 400 mg of ibuprofen is "an extremely low dose" that "doesn't make sense" to prescribe along with the highest strength of a potent opioid pain killer. *Id*. He opined that it is common for doctors who illegally prescribe controlled substances to also prescribe low doses of non-controlled medication to make their treatment appear legitimate.[34] *Id*.

In addition to these red flags, patient B.S. paid for all of his prescriptions in cash. GX 22; GX 24. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient B.S. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 277-78; GX 23; ALJ Ex. 42, p. 21.

Patient C.R.

From July 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to C.R. on five occasions. ALJ Ex. 42, p. 23; GX 27;

[34] While I am ordinarily inclined to accept the unrebutted testimony of an expert, Dr. Sullivan's opinion regarding the ibuprofen (or any other non-controlled medication) as a subterfuge by the prescriber is a bridge too far for me and without sufficient factual foundation. First, I am not convinced that doctors would believe that they could mask the ongoing prescribing of the highest dosage opioids by periodically mixing in some low-dose non-controlled drugs into a patient's medication regimen. Secondly, his opinion that doctors who prescribe low-dose non-controlled medication along with high-strength opioids are merely attempting to mask their illegal prescribing imputes motive without sufficient factual foundation. An expert, however, must base his knowledge on more than "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590 (discussing Federal Rule of Evidence 702). Without additional supporting evidence I am unable to rely on Dr. Sullivan's opinion regarding this red flag. *Id; Garcia*, 919 F.3d at 496. The same will be true with respect to the other patients as to whom he raised a similar red flag to this one. I will, however, accept his opinion that prescriptions for opioids and low-dose non-controlled drugs raises a red flag to the extent that a low-dose non-controlled medication "doesn't make sense" alongside a high-dose opioid. Tr. 275. In other words, I accept his testimony that low doses of non-controlled drugs are suspicious because they do not make medical sense when prescribed with high doses of opioids, but I do not accept his testimony that any doctor prescribed those non-controlled drugs with the intent to cover illegitimate treatment.

Tr. 280. On one of these occasions, the Respondent dispensed morphine tablets in addition to oxycodone and alprazolam. *Id*.

Patient C.R.'s home address was located about 134 miles from the Respondent. ALJ Ex. 42, p. 22; GX 58; Tr. 279. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 279.

From July 2017 to August 2018, the Respondent dispensed six prescriptions of oxycodone. ALJ Ex. 42, p. 23; GX 27; Tr. 279-80. Each of these six oxycodone prescriptions were for 30 mg dosage units, the highest strength available of oxycodone. *Id*.

In addition to these red flags, patient C.R. paid for all of her prescriptions in cash. GX 25; GX 27. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient C.R. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 281-82; GX 24; ALJ Ex. 42, p. 23. The patient profile that the Respondent kept for C.R. contains only one note: "Script has wrong birthdate on it. Dr has now update." ALJ Ex. 42, p. 24; GX 26. Dr. Sullivan opined that this note failed to resolve the red flags raised by C.R.'s prescription. Tr. 281-82. In fact, changing an incorrect birthdate on a prescription is of such minor consequence that it is not necessary to note it in the patient's profile. Tr. 283.

Patient J.D.

On one occasion the Respondent dispensed a drug cocktail of hydromorphone and methadone to J.D. Tr. 283-84; ALJ Ex. 42, p. 26; GX 30. Taking these two immediate-release narcotic pain killers at the same time put J.D. "at extreme risk of overdose." Tr. 284.

The Respondent provided three early fills of hydromorphone prescriptions for J.D. from May to June 2018. Tr. 284-87; ALJ Ex. 42, p. 27; GX 30. The Respondent

dispensed hydromorphone to J.D. on May 30, 2018, the 20th day after dispensing a 30-day supply on May 10, 2018 (10 days early). *Id*. The Respondent also dispensed hydromorphone to J.D. on June 15, 2018, the 16th day after dispensing a 30-day supply on May 30, 2018 (14 days early). *Id*. The Respondent then dispensed hydromorphone to J.D. on June 30, 2018, the 15th day after dispensing a 30 day-supply on June 15, 2018 (15 days early). *Id*. Filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 285. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271.

Patient J.D.'s home address was located about 130 miles from the Respondent. ALJ Ex. 42, p. 25; GX 59; Tr. 283. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 283.

From January 2018 to September 2018, the Respondent dispensed nine prescriptions of hydromorphone. ALJ Ex. 42, p. 26; GX 30; Tr. 283-84. Each of these nine hydromorphone prescriptions were for 8 mg dosage units, the highest strength available of hydromorphone. *Id*.

In addition to these red flags, patient J.D. paid for all of her prescriptions in cash. GX 28; GX 30. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient J.D. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 287-88; GX 29; ALJ Ex. 42, p. 28. The patient profile that the Respondent kept for J.D. contains only one note: "Next fill 7/5/18!!! Watch fill dates." ALJ Ex. 42, p. 28; GX 29. Dr. Sullivan opined that this note failed to resolve the red flags raised by J.D. requesting early fills of controlled substance prescriptions or the other red flags raised by his prescriptions. Tr. 287-88. This note is insufficient to resolve the red

flag of early fills because a pharmacist acting within the usual course of professional practice would have either refused to fill early prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. *Id*.

Patient J.M.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to J.M. on five occasions. ALJ Ex. 42, p. 30; GX 33; Tr. 289-90. During the same time period, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to J.M. on three occasions. *Id*.

Patient J.M.'s home address was located about 144 miles from the Respondent. ALJ Ex. 42, p. 29; GX 60; Tr. 289. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 289.

From June 2017 to September 2018, the Respondent dispensed nine prescriptions of alprazolam, eight prescriptions of oxycodone, and six prescriptions of hydromorphone. ALJ Ex. 42, p. 30; GX 33; Tr. 289-90. All of these prescriptions were for the highest strength available of the drug. All of the nine alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id*. All of the eight oxycodone prescriptions were for 30 mg dosage units, the highest strength of oxycodone. *Id*. All of the six hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id*.

In addition to these red flags, patient J.M. paid for all of her prescriptions in cash. GX 31; GX 33. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient J.M. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 290; GX 32; ALJ Ex. 42, p. 31.

Patient M.M.

The Respondent provided three early fills of hydromorphone prescriptions for M.M. from January to March 2019. Tr. 299-300; ALJ Ex. 42, p. 34; GX 34. The Respondent dispensed hydromorphone to M.M. on January 24, 2019, the 21st day after dispensing a 28-day supply on January 3, 2019 (7 days early). *Id*. The Respondent also dispensed hydromorphone to J.D. on February 19, 2019, the 26th day after dispensing a 30-day supply on January 24, 2019 (4 days early). *Id*. The Respondent then dispensed hydromorphone to J.D. on March 15, 2019, the 24th day after dispensing a 30-day supply on February 19, 2019 (6 days early). *Id*. Filling three consecutive hydromorphone prescriptions early is a red flag. Tr. 285, 300. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300.

Patient M.M.'s home address was located about 38 miles from the Respondent. GX 60, pp. 5-6; Tr. 292-93. The concern about the distance M.M. would have had to travel, however, was the distance from his home to the prescribing doctor's office. Tr. 293-94. Patient M.M.'s home was located about 134 miles from the doctor's office who issued him controlled substance prescriptions. GX 61, pp. 1-3. Dr. Sullivan opined that the distance from M.M.'s home to the doctor's office should have raised red flags to a reasonable pharmacist.[35] Tr. 292-94.

From June 2017 to August 2018, and from January to April 2019, the Respondent dispensed 14 and 5, respectively, hydromorphone prescriptions to

[35] I am not accepting Dr. Sullivan's testimony that the roundtrip distance from M.M.'s home to the doctor's office, and then to the Respondent, and then back home, is a red flag. Tr. 293. There was no evidence M.M. ever made that round trip. The 38 miles from M.M.'s home to the Respondent is not overly suspicious on its face. I believe the Government withdrew its allegation as to that distance. I will, however, accept Dr. Sullivan's testimony that the 134 miles from M.M.'s home to the doctor's office is a red flag. Tr. 294.

patient M.M. ALJ Ex. 42, p. 33-34; GX 34; GX 36; Tr. 295. All of these 19 prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id*.

Dr. Sullivan also pointed out the red flag raised by M.M.'s prescriptions for folic acid 0.4 mg. Tr. 295-96; ALJ Ex. 42, p. 33; GX 36. From June 2017 to August 2018, the Respondent dispensed folic acid 0.4 mg to M.M. on eight occasions. *Id*. Folic acid is a vitamin and 0.4 mg of folic acid is a dose that could be obtained over-the-counter without a prescription. Tr. 295. Dr. Sullivan opined that it is common for doctors who unlawfully prescribe controlled substances to add low doses of non-controlled medication to make their controlled substance prescribing appear legitimate. *Id*. For the same reasons I gave earlier with respect to B.S., however, I do not accept Dr. Sullivan's testimony in this regard. *Supra* p. 76.

Dr. Sullivan also observed a concerning lapse in M.M.'s opioid prescriptions from July 2018 to January 2019. Tr. 297-98; ALJ Ex. 42, p. 34; GX 34. After M.M. filled a hydromorphone prescription in July 2018, M.M. did not present another prescription until January 2019, when she presented a prescription for 8 mg dosage units of hydromorphone, the highest strength of that drug. *Id*. The seven-month lapse in hydromorphone prescriptions followed by a prescription for the highest strength of hydromorphone should have raised a red flag because returning abruptly to such a high dose after not taking it for seven months would have put M.M. at "heightened risk for overdose." *Id*.

In addition to these red flags, patient M.M. paid for all of her prescriptions in cash. GX 34; GX 36. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient M.M. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 300-01; GX 35; ALJ Ex. 42, p. 35.

Patient N.B.

From June 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to N.B. on six occasions. ALJ Ex. 42, p. 37; GX 39; Tr. 302. From September 2018 to January 2019, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to N.B. on two occasions, and a cocktail of alprazolam and hydromorphone on one occasion. ALJ Ex. 42, p. 38; GX 37; Tr. 305.

The Respondent provided two early fills of prescriptions for N.B. from January to March 2019. Tr. 303-04; ALJ Ex. 42, p. 38; GX 37. First, the Respondent dispensed oxycodone and alprazolam to N.B. on January 16, 2019, the 27th day after dispensing a 30-day supply of each drug on December 20, 2018 (3 days early). *Id*. Then, the Respondent dispensed oxycodone to N.B. on March 13, 2019, the 19th day after dispensing a 28-day supply on February 22, 2019 (9 days early). *Id*. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300, 304.

Patient N.B.'s home address was located about 137 miles from the Respondent. ALJ Ex. 42, p. 36; GX 62; Tr. 301. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 301.

From June 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone to N.B. ALJ Ex. 42, p. 37; GX 39; Tr. 302. All of these 12 hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id*. In addition, the Respondent also dispended four prescriptions of alprazolam in 2 mg dosage units, the highest strength of alprazolam. *Id*. Dr. Sullivan also pointed out that on one occasion the Respondent dispensed alprazolam to N.B. in 2 mg and 1 mg dosage units. *Id*. Taking the same controlled substance in two different strengths is a red flag. *Id*.

Dr. Sullivan also pointed out the additional red flag of prescriptions for 30 tablets of ibuprofen 400 mg along with prescriptions for the highest-strength of hydromorphone. Tr. 302-03; ALJ Ex. 42, p. 37; GX 39. He compared 400 mg of ibuprofen to two tablets of over-the-counter Advil or ibuprofen. Tr. 275, 302-03. In other words, 400 mg of ibuprofen is "an extremely low dose" that "doesn't make sense" to prescribe along with the highest strength of a potent opioid pain killer. *Id*. He explained that for patients whose pain is bad enough to warrant taking the highest strength of hydromorphone, it is normal to also prescribe 600-800 mg of ibuprofen to be taken 3-4 times per day (1800-3200 mg total per day). Tr. 302. The prescriptions that N.B. presented, however, were for 400 mg per day. ALJ Ex. 42, p. 37; GX 39. In Dr. Sullivan's view, prescribing ibuprofen at such a low strength along with the highest strength of hydromorphone raises a red flag. Tr. 302-03. He opined that it is common for doctors who illegally prescribe controlled substances to also prescribe low doses of non-controlled medication to make their treatment appear legitimate. Tr. 275. For the same reasons I gave earlier with respect to B.S. and M.M., however, I do not accept Dr. Sullivan's testimony in this regard. *Supra* pp. 76, 81.

Dr. Sullivan also observed a concerning two-month gap in N.B.'s opioid prescriptions in October and November 2018. Tr. 304-05; ALJ Ex. 42, p. 38; GX 37. N.B. presented a prescription for hydromorphone in September 2018 and then presented an oxycodone 30 mg prescription in December 2018, but did not present any opioid prescriptions to the Respondent in October and November. *Id*. Not taking opioids for two months and then starting up again on the highest strength of oxycodone is concerning and puts the patient at heightened risk of overdose. Tr. 297-98, 304-05. This lapse in filling opioid prescriptions raises a red flag. *Id*.

In addition to these red flags, patient N.B. paid for all of her prescriptions in cash. GX 37; GX 39. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient N.B. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 306-07; GX 38; ALJ Ex. 42, p. 39. The patient profile that the Respondent kept for N.B. contains only one note: "Doctor OK patient to receive medication in compound capsule form." ALJ Ex. 42, p. 39; GX 38. Dr. Sullivan opined that this note failed to resolve the red flags raised by N.B.'s prescriptions. *Id*.

Patient R.B.

From June 2017 to August 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to R.B. on twelve occasions. ALJ Ex. 42, p. 41; GX 43; Tr. 311.

The Respondent provided one early fill of hydromorphone to R.B. On February 18, 2019, the Respondent dispensed hydromorphone to R.B. on February 18, 2019, the 27th day after dispensing a 31-day supply of hydromorphone on January 22, 2019 (4 days early). ALJ Ex. 42, p. 42; GX 40; Tr. 312.

Patient R.B.'s home address was located about 138 miles from the Respondent. ALJ Ex. 42, p. 40; GX 63; Tr. 307. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 307.

From June 2017 to August 2018, the Respondent dispensed 12 prescriptions of hydromorphone and 12 prescriptions of alprazolam to R.B. ALJ Ex. 42, p. 41; GX 43; Tr. 311. All of the 12 hydromorphone prescriptions were for 8 mg dosage units, the highest commercially available strength of hydromorphone. *Id*. Eleven of the 12 alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id*.

As with patients M.M. and N.B., Dr. Sullivan also observed a concerning three-month gap in R.B.'s opioid prescriptions in October, November, and December 2018. Tr. 312; ALJ Ex. 42, p. 42; GX 40. R.B. presented a prescription

for hydromorphone in September 2018 and did not present another hydromorphone prescription to the Respondent until January 2019.[36] *Id*. A three-month lapse in opioid treatment renders the patient opioid naïve and puts the patient at heightened risk of overdose upon resumption of opioid treatment. Tr. 297-98, 304-05, 312. This lapse in filling opioid prescriptions raises a red flag. *Id*.

Dr. Sullivan also observed that R.B.'s PDMP report revealed evidence of pharmacy shopping. Tr. 316-17. The PDMP report showed that R.B. filled controlled substance prescriptions at five different pharmacies, to include the Respondent. Tr. 316-17; GX 44, p. 5.

In addition to these red flags, patient R.B. paid for all of her prescriptions that were filled by the Respondent in cash. GX 40; GX 43. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214. Although R.B. always paid in cash at the Respondent, she used insurance to purchase controlled substance prescriptions at other pharmacies on three occasions. GX 44, pp. 4-5; Tr. 317-19. Dr. Sullivan noted that a patient does not break the law by alternating between paying in cash and using insurance. Tr. 319. It is, however, another red flag that a pharmacist should resolve. Tr. 318-19. When a pharmacist evaluates the red flag raised by a patient paying in cash for controlled substances, it would be relevant to consider the fact that the patient was using insurance to fill prescriptions at another location. Tr. 318.

[36] Patient R.B.'s PDMP report indicates that the hydromorphone prescription he received from the Respondent in September 2018 was for a 120-day supply. GX 40; ALJ Ex. 42, p. 42. If that were true, the gap in opioid prescriptions from September 2018 to January 2019 would not raise any concern because the September 2018 prescription would have lasted four months. That number, however, must have been incorrectly reported to the PDMP. In fact, the September 2018 prescription was written for a 30-day supply, not 120-days as reported in the PDMP. This becomes evident by comparing the PDMP report to the actual prescription, which is one of the few hard-copy prescriptions in evidence. The PDMP report indicates that the Rx number for the September 2018 hydromorphone prescription (10th from the top) is 5011489 and was issued by Dr. Michael Lemon. GX 40. The corresponding prescription bearing the same Rx number on the fill sticker is located at Government Exhibit 44, pages 6-7 (prescription at top right corner). That prescription was written by Dr. Lemon for 120 tablets of hydromorphone 8 mg, to be taken one tablet every 6 hours (or 4 tablets per day). GX 44, p. 6. A 120-tablet prescription with these instructions would last one month, not four months. Thus, R.B.'s three month lapse in filling opioid prescriptions at the Respondent remains a concern that the Respondent should have addressed.

Although patient R.B. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 313; GX 41; ALJ Ex. 42, p. 43.

Patient R.G.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and oxycodone to R.G. on twelve occasions. ALJ Ex. 42, p. 45; GX 49; Tr. 322-24.

The Respondent provided multiple early fills of prescriptions for R.G. from February to May 2018. Tr. 326-28; ALJ Ex. 42, p. 46; GX 49. The Respondent dispensed alprazolam and oxycodone to R.G. on February 21, 2018, the 23rd day after dispensing a 30-day supply of each drug on January 29, 2018 (7 days early). *Id*. The Respondent again dispensed alprazolam and oxycodone to R.G. on March 19, 2018, the 26th day after dispensing a 30-day supply of each drug on February 21, 2018 (4 days early). *Id*. The Respondent then dispensed alprazolam to R.G. on April 17, 2018, even though the doctor instructed that the prescription should not be filled until April 20, 2018 (3 days early). *Id*. The Respondent dispensed oxycodone to R.G. on May 8, 2018, the 21st day after dispensing a 30-day supply of oxycodone on April 17, 2018 (9 days early). *Id*. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 271, 300, 304, 328.

Patient R.G.'s home address was located about 131 miles from the Respondent. ALJ Ex. 42, p. 44; GX 64; Tr. 322. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 322.

From June 2017 to September 2018, the Respondent dispensed 17 prescriptions of oxycodone and 12 prescriptions of alprazolam to R.G. Tr. 322-24;

ALJ Ex. 42, p. 45; GX 49. All of these 29 prescriptions were for the highest strength of the drug. *Id*. All of the 17 oxycodone prescriptions were for 30 mg dosage units, the highest strength of oxycodone. *Id*. All of the 12 alprazolam prescriptions were for 2 mg dosage units, the highest strength of alprazolam. *Id*.

In addition to these red flags, patient R.G. paid for all of his prescriptions in cash. GX 46; GX 49. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient R.G. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 328-29; GX 47; ALJ Ex. 42, p. 47. The profile that the Respondent kept for patient R.G. contains only one note: "Watch fill dates!!!!!!!!!!!!!!" *Id*. Dr. Sullivan opined that this note was insufficient to resolve the red flags raised by the multiple prescriptions that R.G. presented for early filling as well as the other red flags raised by his prescriptions. *Id*.

Patient R.L.

From June 2017 to September 2018, the Respondent dispensed a drug cocktail of alprazolam and hydromorphone to R.L. on one occasion. ALJ Ex. 42, p. 49; GX 52; Tr. 331.

The Respondent provided four early fills of hydromorphone to R.L. from February to May 2018. Tr. 333-34; ALJ Ex. 42, p. 51; GX 52. First, the Respondent dispensed hydromorphone to R.L. on February 26, 2018, the 25th day after dispensing a 30-day supply of hydromorphone on February 1, 2018 (5 days early). *Id*. The Respondent dispensed hydromorphone to R.L. again on March 22, 2018, the 24th day after dispensing a 30-day supply of hydromorphone on February 26, 2018 (six days early). *Id*. Then the Respondent dispensed hydromorphone to R.L. on April 17, 2018, the 26th day after dispensing a 30-day supply of hydromorphone on March 22, 2018 (4 days early). *Id*. The Respondent also dispensed

hydromorphone to R.L. on May 11, 2018, the 24th day after dispensing a 30-day supply of hydromorphone on April 17, 2018 (6 days early). *Id*. Filling four consecutive hydromorphone prescriptions early is a red flag. Tr. 271, 285, 300, 334. A pharmacist acting within the usual course of professional practice would have either refused to fill these prescriptions until at least the day before the prior month's supply would have run out or refused to fill future prescriptions of the same drug for the patient. Tr. 334.

Patient R.L.'s home address was located about 138 miles from the Respondent. ALJ Ex. 42, p. 48; GX 65; Tr. 330. Dr. Sullivan opined that this distance should have raised a red flag to a reasonable pharmacist. Tr. 330.

From June 2017 to September 2018, the Respondent dispensed 14 prescriptions of hydromorphone, one prescription of oxycodone, and one prescription of alprazolam to R.L. Tr. 331-32; ALJ Ex. 42, p. 49; GX 52. All of these 16 prescriptions were for the highest strength of the drug. *Id*. All of the 14 hydromorphone prescriptions were for 8 mg dosage units, the highest strength of hydromorphone. *Id*. The oxycodone prescription was for 30 mg dosage units, the highest strength of oxycodone. *Id*. The alprazolam prescription was for 2 mg dosage units, the highest strength of alprazolam. *Id*. From December 2018 to April 2019, the Respondent dispensed five prescriptions of oxycodone to R.L. in 30 mg dosage units, the highest strength of oxycodone. Tr. 331-32; ALJ Ex. 42, p. 50; GX 50.

In addition to these red flags, patient R.L. paid for all of his prescriptions in cash. GX 50; GX 52. Dr. Sullivan testified that paying in cash is a red flag. Tr. 214.

Although patient R.L. presented prescriptions to the Respondent that raised multiple red flags of drug abuse and/or diversion, the Respondent filled each prescription and never documented any resolution of these red flags. Tr. 334-36; GX 51; ALJ Ex. 42, p. 52. The profile that the Respondent kept for patient R.L. contains only one note: "Next fill 6/10/18-10 days early March & April-Told him

this 5/11/18[ ]GD." *Id*. Dr. Sullivan opined that this note failed to resolve the red flags raised by the multiple prescriptions that R.L. presented for early filling as well as the other red flags raised by his prescriptions. *Id*.

Analysis of Dispensing Evidence for All Eleven Patients

The preceding presentation of the Government's evidence shows that the Respondent filled numerous prescriptions of oxycodone, hydromorphone, and alprazolam for eleven patients that raised multiple red flags of drug abuse and/or diversion.[37] Not only did Dr. Sullivan opine that these red flags are recognized by Florida's standard of pharmacy practice, but all of these red flags are firmly-established indicators of drug abuse and/or diversion in DEA case law. Furthermore, the Government's evidence shows that the Respondent failed to document sufficient resolution of red flags in the patients' profiles. Although a few patients' profiles contain a single note regarding a single red flag, Dr. Sullivan credibly opined that those solitary notes fail to adequately resolve the concern. Tr. 258-59, 281-83, 287-88, 306, 328-29, 334-35.

With respect to red flags, a pharmacy's duty can be easily summarized as identify, resolve, and document. Florida law and the standard of practice in Florida require a pharmacist to conduct a prospective drug use review before dispensing a controlled substance. Tr. 211, 227-28; Fla. Admin. Code r. 64B16-27.810; *Trinity II*, 83 Fed. Reg. at 7329. The purpose of the prospective drug use review is to identify red flags that require resolution before dispensing a controlled substance.

[37] Dr. Sullivan also opined that some prescriptions for ten of the patients (A.G., A.H., B.S., C.R., J.M., M.M., N.B., R.B., R.G., and R.L.) raised the red flag of lacking therapeutic justification for compounded capsules. I am not accepting that opinion in this analysis of the Respondent's dispensing. There is no evidence that the patients requested their medication to be dispensed in compounded capsule form as opposed to tablets. Rather, the decision to compound seems to have been made by the Respondent and the Respondent alone. Thus, compounding without medical justification would not have been a suspicious behavior raised by the patient, the patient's prescription, or the prescriber. It is, instead, suspicious behavior raised by the pharmacy. The evidence that the Respondent compounded without individualized therapeutic justification is, therefore, more appropriate for the analysis of illegal manufacturing.

Tr. 207-08, 211. To resolve red flags, the pharmacy has a number of tools available, to include speaking with the prescriber and patient; reviewing the patient's PDMP; and reviewing the pharmacy's dispensing history to the patient. Tr. 227, 447-48; Fla. Admin. Code r. 64B16-27.831(2)-(3). Once a pharmacy identifies and resolves red flags (or decides the red flags cannot be resolved), Florida law and the standard of practice requires the pharmacy to document information that would enable the pharmacy to resolve the suspicion. Tr. 210, 228, 489; Fla. Admin. Code r. 64B16-27.800; *Trinity II*, 83 Fed. Reg. at 7330. As Dr. Sullivan stated, "if you don't document it you didn't do it." Tr. 228. Even if a pharmacy identified and resolved red flags, it would be outside the standard of practice in Florida for a pharmacy to dispense a controlled substance if the pharmacy failed to document what it did to resolve the red flags. *Id*.

Although the DEA does not require the pharmacy to document in a specific place, Florida law specifies that the pharmacy must document information relevant to the resolution of red flags in the patient's profile. Fla. Admin. Code r. 64B16-27.800; *Trinity II*, 83 Fed. Reg. at 7330. Initially, Dr. Sullivan testified that Florida law does not specify where a pharmacy must document resolution of red flags. Tr. 436-37, 449, 452. He also testified under cross-examination that a pharmacist could document resolution of red flags on the prescription itself. Tr. 410. I later questioned Dr. Sullivan about Florida Administrative Code r. 64B16-27.800, entitled "Requirement for Patient Records." Tr. 453-55. This regulation requires Florida pharmacies to maintain a patient record system or patient profile. Tr. 209; Fla. Admin. Code r. 64B16-27.800. Dr. Sullivan explained that the term "patient record system" in Florida Administrative Code r. 64B16-27.800 means the same thing as patient profile.[38] Tr. 209. He acknowledged that this regulation requires

[38] Because patient record system and patient profile mean the same thing, I will use the term patient profile throughout the remainder of this Recommended Decision.

pharmacies to document in the patient record system information related to "allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs" the patient is taking. Tr. 453; Fla. Admin. Code r. 64B16-27.800(2).

Dr. Sullivan also pointed out that this regulation requires pharmacies to document "any related information indicated by a licensed health care practitioner." *Id*. I asked Dr. Sullivan whether this regulation "would include the resolution of red flags," and he answered in the affirmative. Tr. 455. Red flags, in his opinion, would be "relevant patient information" covered by this regulation. *Id*. Later on redirect examination, Dr. Sullivan noted that the requirement of this regulation to document "comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug," would include information related to red flag resolution. Fla. Admin. Code r. 64B16-27.800(1)(f); Tr. 489. Thus, while Dr. Sullivan did not disagree with opposing counsel's statement that resolution could be documented on the hardcopy prescription, Tr. 410, he later acknowledged that Florida regulation requires Florida pharmacies to document information pertaining to red flag resolution in the patient profile. Tr. 453-55, 489. In other words, a pharmacist is not prohibited from taking notes on a prescription. *Id*. But in order to comply with Florida Administrative Code r. 64B16-27.800, the pharmacist must document information relevant for purposes of resolving red flags in the patient profile as well. *Id*.

Notwithstanding Dr. Sullivan's varied testimony, after reviewing the same regulation, the Agency concluded in *Trinity II* that patient records maintained pursuant to Florida Administrative Code r. 64B16-27.800 must contain information related to resolving red flags. 83 Fed. Reg. at 7330. The Agency reasoned, therefore, that under Florida law patient profiles "provide relevant evidence in assessing whether a pharmacist resolved" red flags of drug abuse and/or diversion. *Id*. Failure

to document information relevant for purposes of resolving red flags in accordance with this regulation would indicate that the pharmacy failed to resolve red flags. Tr. 453, 455, 489. Importantly, however, the Government's evidence in *Trinity II* included hardcopy prescriptions. 83 Fed. Reg. at 7330.

Here, the Government's evidence shows that despite receiving numerous prescriptions for controlled substances from eleven patients that raised the classic signs of drug abuse and/or diversion, the Respondent failed to document any resolution of the red flags in the patients' profiles. In fact, the profiles for five patients (A.H., B.S., J.M., M.M., and R.B.) contain no notes whatsoever, even though the prescriptions presented by these patients raised multiple red flags, as discussed above. GX 20; GX 23; GX 32; GX 35; GX 41; ALJ Ex. 42, pp. 17, 21, 31, 35, 43. The multiple red flags raised by these five patients triggered the Respondent's responsibility to identify, resolve, and document in the patients' profiles. Failure to have done so violates Florida law.

The profiles for the remaining six patients contain single notes that fail to dispel the suspicions aroused by the patients' prescriptions. Patient A.G.'s and N.B.'s profiles, for example, state that an unnamed doctor on an unknown date approved of A.G. and N.B. taking compounded capsules of an unknown medication for an unknown reason. ALJ Ex. 42, pp. 13, 39; GX 15; GX 38. These notes say nothing about the other red flags raised by A.G.'s and N.B.'s prescriptions, to include dangerous drug combinations, early fills, highest strengths of drugs, cash payments, and long distance travel. *Id*. Furthermore, the plain meaning of the notes suggest that the Respondent requested the doctors' approval to compound, rather than the doctor requesting a compounded medication for an individualized therapeutic reason. Tr. 258-59, 306. If A.G. and N.B. had legitimate medical reasons for compounded capsules, the doctors would have written their prescriptions that way. *Id*.

Patient C.R.'s profile states that a prescription had the wrong birthdate. ALJ Ex. 42, p. 24; GX 26. Changing an incorrect birthdate is of such minor significance that it does not merit a note in the patient's profile. Tr. 283. Yet, no other notes address the numerous red flags raised by C.R.'s prescriptions. Tr. 281-83.

The notes in J.D.'s, R.G.'s, and R.L.'s profiles relate to early fill dates. ALJ Ex. 42, pp. 28, 47, 52; GX 29; GX 47; GX 51. These notes, however, fail to address the numerous other red flags raised by these patients' prescriptions. Tr. 287-88, 328-29, 334-35. Furthermore, Dr. Sullivan explained that the proper action to take in response to a patient who requests an early fill is to wait until at least the day before the prior month's supply is set to run out or to refuse to fill the prescription. Tr. 271, 287-88, 300, 304, 328, 334. Even if a pharmacy documented a problem with early fills, filling a controlled substance several days early is outside the standard of care unless the patient has a very good reason. Tr. 270, 335. Although there are "extreme cases where patients need to fill prescriptions early," the profiles for these three patients do not document any "extremely good unusual reason" that would have justified the Respondent to fill their prescriptions early. Tr. 270. Thus, even if these patients had legitimate reasons for obtaining early fills, the Respondent did not document those reasons. ALJ Ex. 42, pp. 28, 47, 52; GX 29; GX 47; GX 51.

Neither the patient profiles, nor the questionnaires that the Respondent asked patients to fill out, resolve red flags. The record contains two such questionnaires. The questionnaire asks patients why they are receiving treatment; whether the patient lives farther than 100 miles from the pharmacy, and if yes, then why is the patient filling prescriptions at the Respondent; how did the patient's injury develop; and what happens if the patient does not take his/her medication.[39] GX 18, p. 1;

[39] Mr. Clement, Jr.'s, testimony about how the Respondent relied on the patient questionnaires is inconsistent with the answers given on the two questionnaires in evidence. Mr. Clement, Jr., testified that the questionnaire asks the patients to provide details about the injury; simply claiming that "my back pain hurts" will not work. Tr. 512. The answers given by A.G. and R.B., however, are not much better than "my back pain hurts." Patient A.G. wrote that his

GX 44, p. 1. The questionnaire also asks patients to certify that they are not selling their medication and that they are taking all of their medication. *Id*.

Patient A.G. disclosed on his questionnaire that he lived more than 100 miles from the Respondent. GX 18, p. 1. He stated on the questionnaire that his reason for filling prescriptions at the Respondent despite the significant distance was "quick and good service." *Id*. Patient A.G.'s statement that he chose the Respondent for its "quick and good service" does not alleviate the red flag raised by him living more than 100 miles from the Respondent. Tr. 262. The same is true of his certification that he was taking all of his medication and not selling it. *Id*. Dr. Sullivan explained that a pharmacist should assume the patient is taking all of his medication. Tr. 263. And if a pharmacy suspected that a patient was diverting his medication, the proper response is to notify the prescriber and document the discussion. *Id*. A uniform questionnaire does not absolve the Respondent of this responsibility. If the pharmacist believes that the patient is diverting controlled substances, it must cease dispensing controlled substances to that patient. Tr. 264.

Patient R.B. also disclosed on her questionnaire that she lived more than 100 miles from the Respondent. GX 44, p. 1. R.B.'s reason for filling prescriptions at the Respondent despite living more than 100 miles away was the Respondent's "cheaper" prices and because "they are good people." *Id*. These reasons fail to resolve the red flag raised by R.B. living more than 100 miles away from the

"lower lumbar starts hurting bad while I stand for long or lay/sit down too long." GX 18, p. 1. He stated that his injury occurred "from motorcycle accidents throughout the years." *Id*. Patient R.B. wrote that she was being treated "for my back and legs, I was in a bad car [accident]" in 2005. GX 44, p. 1. Judging from these two examples, it appears the Respondent did not require a significant level of detail provided in the questionnaires as Mr. Clement, Jr., made it seem. This is not the only inconsistency between Mr. Clement, Jr.'s, description of the Respondent's diligence in documentation and the actual records. I note that Mr. Clement, Jr., reported the Respondent sees only a few patients per day, allowing more individualized care and investigation into red flags. Tr. 508-509, 537-38, 540, 553. Heightened scrutiny by the Respondent, however, is not reflected within the pharmacy's records.

Respondent. Tr. 315. Dr. Sullivan provided the same opinion of R.B.'s certification that she was taking her medication and not diverting it, as he stated for A.G. *Id*.

While the evidence establishes that the Respondent failed to document resolution of red flags in the patients' profiles, the evidence does not reveal whether, consistent with Mr. Clement, Jr's., claim, the Respondent sometimes documented resolution on the relevant original hardcopy prescriptions. We do not know because the Government only introduced copies of twelve prescriptions.[40] These twelve prescriptions related to only two of the eleven patients. GX 18, pp. 6-9; GX 44, pp. 6-9. Although these twelve prescriptions do not contain any legible resolution of red flags, we do not know whether that is true of the remaining prescriptions filled for the eleven patients at issue, which were not introduced into evidence.[41]

Twelve Prescriptions Introduced into Evidence

With respect to the twelve prescriptions introduced into evidence, the Government sustained its burden to show that the prescriptions raised red flags and the Respondent failed to document any information pertaining to resolution of those red flags on the prescriptions or in the patients' profiles. The Government's

[40] The record actually contains thirteen prescriptions, however, I am not counting the prescription for folic acid, a non-controlled medication. GX 18, p. 6.

[41] I decline to draw an adverse inference against either party for failing to introduce the remaining prescriptions into evidence. Under the rule of adverse inference, "'when a party has relevant evidence within his control which he fails to produce, that failure gives rise to an inference that the evidence is unfavorable to him.'" *Callahan v. Schultz*, 783 F.2d 1543, 1545 (11th Cir. 1986) (quoting *Int'l Union (UAW) v. NLRB*, 459 F.2d 1329, 1336 (D.C. Cir. 1972)). An adverse inference could ordinarily be applied to the Government, because it has the prescriptions within its possession, those prescriptions are relevant to show whether red flags were resolved, and the Government failed to introduce them. *See* Tr. 43 (DI Albert testifying that he reviewed hardcopy prescriptions produced pursuant to a subpoena); Tr. 516 (Mr. Clement, Jr., testifying that the DEA seized most of the hardcopy prescriptions during its inspection); Tr. 520 (Respondent's counsel stating that the Government sent him copies of the prescriptions). I will decline, however, to apply such an inference against the Government because the Respondent also possessed the same prescriptions and, therefore, the same adverse inference could be drawn against it. *See* Tr. 520 (Respondent's counsel stating that copies of the hardcopy prescriptions were sent to his office). Because both parties had the same relevant evidence within its control and chose not to introduce it, an adverse inference against only one party is not warranted. *See United States v. Boston*, 194 Fed. App'x 890, 892 (11th Cir. 2006) (applying adverse inference rule in context of witness testimony, and explaining that adverse inference is inappropriate if the witness is equally available to both parties); *United States v. Nahoom*, 791 F.2d 841, 846 (11th Cir. 1986) (holding that an adverse inference is only acceptable where a witness "is peculiarly within the control of one party"). Although these cases dealt with witnesses, the same reasoning applies here. Both the Government and the Respondent, by the time of the hearing, had equal access to this same evidence; therefore, an adverse inference against either party is impermissible.

evidence shows that (1) the Respondent filled twelve controlled substance prescriptions for A.G. and R.B.; (2) those prescriptions raised red flags that the Respondent should have recognized; and (3) the Respondent failed to conclusively resolve the red flags by documenting resolution on the hardcopy prescriptions or in the patient profiles. *JM Pharm. Grp.*, 80 Fed. Reg. 28667, 28685 (2015) (quoting *Holiday CVS*, 77 Fed. Reg. 62316, 62341 (2012)).

The seven prescriptions for A.G. raised the red flags of cash payments, long distance, and highest strength. GX 18, pp. 6-9; *supra* pp. 71-73. The prescription filled on April 12, 2019, raised the additional red flag of being filled early. Tr. 257; ALJ Ex. 42, p. 12; GX 14.

The five prescriptions for R.B. raised the red flags of cash payments, long distance, and highest strength. GX 44, pp. 6-9; *supra* pp. 84-86. The prescription filled on January 22, 2019, raised the additional red flag of being dispensed after a lapse in opioid treatment. Tr. 312; ALJ Ex. 42, p. 42; GX 40. The prescription filled on February 18, 2019, raised the additional red flag of being dispensed early. *Id*.

With respect to both patients, neither the hardcopies of these prescriptions nor the corresponding patient profiles contain the information needed to adequately resolve the concern raised by the prescriptions. *Supra* pp. 71-73, 84-86. The red flags raised, combined with the absence of documentation on the prescriptions and patient profiles, demonstrates that the Respondent filled the subject prescriptions for A.G. and R.B. with the requisite degree of scienter. *JM Pharmacy Grp., Inc.*, 80 Fed. Reg. at 28669. Failing to document resolution of red flags demonstrates that the Respondent was "deliberately ignorant" of the prescriptions' apparent lack of medical legitimacy. *Trinity II*, 83 Fed. Reg. at 7329-30. Thus, the Government's evidence establishes that the Respondent violated its corresponding responsibility under 21 C.F.R. § 1306.04(a) with respect to A.G. and R.B.

The Remaining Prescriptions

With respect to the remaining prescriptions, the evidence does not reveal whether these prescriptions contain handwritten notes addressing the multiple red flags they raised because they were not introduced into evidence. Even if these prescriptions contained notes resolving the various red flags raised, the Respondent would still have violated Florida law by failing to properly document information needed to resolve the concern in the patient profiles. Fla. Admin. Code r. 64B16-27.800; *Trinity II*, 83 Fed. Reg. at 7330.

While violating Florida law in that respect would constitute negative experience under either Factor Two or Four, it would be insufficient to find that the Respondent violated its corresponding responsibility because it could have documented the resolution on the hardcopy prescriptions. To prove a violation of its corresponding responsibility, the Government would need to show that (1) the Respondent filled a controlled substance prescription; (2) the prescription raised a red flag that the Respondent recognized or should have recognized; and (3) the Respondent failed to conclusively resolve the red flag before filling the prescription. *JM Pharm. Grp.*, 80 Fed. Reg. at 28685 (2015) (quoting *Holiday CVS*, 77 Fed. Reg. 62316, 62341 (2012)). With respect to the prescriptions for which hardcopies have not been introduced, the Government's evidence establishes the first two criteria, but falls short with respect to the third because there is not enough evidence in the record to determine whether the Respondent failed to "conclusively" resolve red flags. There is not enough evidence because the record lacks copies of the prescriptions, which could contain documentation of red flag resolution.

Documenting resolution on the prescriptions would be the incorrect place under Florida law, but it would still show (if it happened) that the pharmacy fulfilled its corresponding responsibility under 21 C.F.R. § 1306.04(a), since the DEA does not require resolution to be in any specific place. Mr. Clement, Jr., testified that

sometimes the Respondent made notes on the hardcopy prescriptions instead of the patient profiles. Tr. 543, 550-51. He also testified that the Respondent documented "patient profile information" in a notebook kept at the pharmacy.[42] Tr. 555. Dr. Sullivan stated that he would expect a pharmacy to document red flag resolution "somewhere." Tr. 228. That "somewhere" could have been the original hardcopy prescriptions, the majority of which are not in evidence. In other words, without looking at all the prescriptions, I am unable to conclude that the Respondent failed to ensure the prescriptions were written for legitimate medical purposes and issued within the usual course of professional practice under its corresponding responsibility in 21 C.F.R. § 1306.04(a).

Violating Florida law by failing to document information relevant to resolving red flags in the patients' profiles, however, would be sufficient to show that the Respondent dispensed controlled substances outside the usual course of professional practice, in violation of 21 C.F.R. § 1306.06. I am able to make this finding because the usual course of professional practice is defined by the state. Florida law requires pharmacies to document information needed to resolve red flags in the patient profiles. Tr. 453, 455, 489; Fla. Admin. Code r. 64B16-27.800; *Trinity II*, 83 Fed.

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[42] If the Respondent maintained a notebook as part of its patient record system, then I would be unable to sustain the Government's dispensing allegations because the notebook could contain red flag resolution. I do not credit Mr. Clement, Jr.'s, testimony about the notebook because the Respondent never introduced the notebook to corroborate his claim. *See Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7322 n.42 (2018) (finding "more likely than not that [the respondent] did not produce any [documents] because they do not exist"); *Pharm. Doctors Enters. d/b/a Zion Clinic Pharm.*, 83 Fed. Reg. 10876, 10887 (2018) (finding pharmacist's testimony that she resolved various red flags merited no weight because she failed to produce documentary evidence to corroborate her claim). Registrants should not be empowered to deflect allegations of misconduct so easily by simply claiming they kept those records without producing them. There is nothing in the record establishing that the Government received the notebook which allegedly contains red flag resolution and then elected to proceed without introducing it into evidence. If that were the case, it would be much harder to rule in the Government's favor. The Government, however, requested any and all documentation pertaining to red flag resolution in two subpoenas, GX 67; GX 68; and during service of an AIW, and there is no indication that the Government obtained a notebook (or any other records containing red flag resolution) and then failed to introduce them. For these reasons, I cannot credit Mr. Clement, Jr.'s, testimony about a notebook that is not in evidence. The Government has produced patient profiles that lack red flag resolution. If the Respondent has something to show that it, in fact, resolved red flags, it should have introduced it at the hearing to rebut the Government's case. This reasoning does not apply to the hardcopy prescriptions, however, because we know the Government has those hardcopy prescriptions within its control. Tr. 43; *supra* note 41.

Reg. at 7330. And as already discussed, the patient profiles lack any information that would have enabled the Respondent to dispel the suspicion raised by numerous red flags.

While I cannot conclude that the Respondent violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), I find that the Government has presented a preponderance of the evidence to prove that the Respondent dispensed numerous controlled substance prescriptions that raised multiple red flags of drug abuse and/or diversion for at least eleven patients without documenting information relevant to red flag resolution in the patients' profiles, as required by Florida Administrative Code r. 64B16-27.800. Tr. 453, 455, 489. Failing to follow a critical requirement imposed by its state of registration that is intended to prevent the abuse and diversion of controlled substances constitutes negative experience in complying with applicable state law (Factor Four). 21 U.S.C. § 823(f)(4).[43]

I further find that failing to comply with Florida Administrative Code r. 64B16-27.800 constitutes conduct outside the usual course of professional practice in Florida, in violation of 21 C.F.R. § 1306.06. For these reasons, and all the reasons and analysis set forth in this section, the allegation that the Respondent violated Florida law by failing to document resolution of red flags in the patients' profiles, in violation of Florida Administrative Code r. 64B16-27.800 and 21 C.F.R. § 1306.06, is **SUSTAINED.** Furthermore, the allegation that the Respondent violated 21 C.F.R. §§ 1306.04(a) and 1306.06 is **SUSTAINED** with respect to the twelve prescriptions in evidence for patients A.G. and R.B.

[43] While the Respondent's failure to comply with Florida law by documenting information needed to resolve red flags in the patients' profiles could be weighed under Factors Two and Four, I will only consider that misconduct under Factor Four to avoid double-counting the same misconduct.

Analysis of Unlawful Manufacturing Allegation

Finally, the Government alleges that the Respondent engaged in "manufacturing" controlled substances, as that term is defined in the CSA, without a separate DEA registration authorizing the manufacture of controlled substances, in violation of 21 U.S.C. § 841(a)(1) and 21 C.F.R. § 1301.13(e). ALJ Ex. 1, ¶ 20-28. Specifically, the Government alleges that the Respondent compounded oxycodone and hydromorphone capsules in such large quantities that this activity constituted manufacturing rather than permissible compounding for individual patients. *Id*.

DEA regulations require registrants to obtain a separate registration for each regulated business activity in which they engage. 21 C.F.R. § 1301.13(e). Section 1301.13(e) provides ten separate business activities, to include manufacturing and dispensing.[44] *Id*. at (e)(1)(i), (iv). Each business activity is "deemed to be independent of each other." 21 U.S.C. § 1301.13(e). In other words, a registration for one activity does not authorize the registrant to engage in another activity. *Id*. To engage in both dispensing and manufacturing, a registrant would need to apply for and obtain separate registrations for each activity. No person or entity may engage in a regulated business activity "until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person [or entity]." 21 C.F.R. § 1301.13(a).

Requiring separate registrations for manufacturing and dispensing is more than mere formality. In fact, the CSA imposes stricter requirements on manufacturers than dispensers, not to mention a different standard for issuing a sanction. *Wedgewood Village Pharm.*, 71 Fed. Reg. 16593, 16594 (2006); *compare* 21 U.S.C. § 823(a) (setting forth six public interest factors for manufacturers of

[44] Although not relevant to this case, the other business activities include distributing, reverse distributing, research (Schedule I), research (Schedules II-V), narcotic treatment programs, importing, exporting, and chemical analysis. 21 U.S.C. § 1301.13(e)(1).

Schedule I and II controlled substances), *with* 21 U.S.C. § 823(f) (establishing five similar, yet different, public interest factors for practitioners, which includes pharmacies engaged in dispensing). Additionally, the CSA imposes higher standards for recordkeeping, reporting, and security on manufacturing than it does on dispensing. 71 Fed. Reg. at 16594. Manufacturers are also required to obtain a registration annually, whereas dispensers are only required to obtain a registration every three years. *Id*. (citing 21 U.S.C. § 822(a)(1)-(2)).

The Respondent is registered with the DEA as a "retail pharmacy." GX 1. Pursuant to this registration, the Respondent may dispense controlled substances in Schedules II-V. *Id*.; 21 C.F.R. § 1301.13(e)(1)(iv). The Respondent's registration as a retail pharmacy authorizing it to engage in the regulated activity of dispensing does not permit the Respondent to manufacture controlled substances; thus, any manufacturing it performed would be unlawful. To prevail on its claim that the Respondent manufactured controlled substances, the Government must show by a preponderance of the evidence that the Respondent engaged in an activity that met the CSA's definition of "manufacturing."

Although the CSA does not define what the term "to compound" means, it does define "manufacture." *Wedgewood Village Pharm. v. DEA*, 509 F.3d 541, 543 (D.C. Cir. 2007) (noting the CSA does not define "compounding"). "[T]he term 'manufacture' means the production, preparation, propagation, *compounding*, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container." 21 U.S.C. § 802(15) (emphasis added). Importantly, the CSA includes compounding in its definition of manufacturing. *Id*. Not all compounding, however, is considered to be manufacturing. The definition of manufacturing "does not

include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice." *Id*. Stated differently, compounding does not require a registration to manufacture so long as the compounding (1) conforms to State and local laws, and (2) is conducted "as an incident to [the] administration or dispensing" of the compounded drug.

The critical question here is whether the Respondent compounded controlled substances as an incident to dispensing them. If so, then its activity qualified for the exemption to manufacturing and the Respondent would be properly registered. If not, however, then its compounding activity would be considered manufacturing, for which it is not registered. In *Wedgewood*, the Agency framed this question as whether the pharmacy compounded "as an adjunct to dispensing controlled substances." 71 Fed. Reg. at 16594. If the pharmacy compounded "as an adjunct to dispensing controlled substances to specific patients," *Wedgewood* continued, then the pharmacy would be exempt from the definition of manufacturing. *Id*. The Agency concluded "that to be exempt from the definition of manufacturer under the CSA a DEA practitioner registrant must be engaged in compounding controlled substances on an individual patient basis. That is, a pharmacy must receive a prescription for a specific patient from a physician or other individual practitioner and must deliver or dispense that medication to the patient." *Id*. at 16595. A pharmacy may avoid the regulatory requirements associated with manufacturing, including the requirement to obtain a separate registration, so long as the pharmacy compounds "for a specific patient on a patient by patient basis." *Id*. at 16596.

In reaching this conclusion, the Agency turned to the traditional definition of compounding articulated by the Supreme Court in *Thompson v. Western States Medical Center*. 71 Fed. Reg. at 16595-96 (citing 535 U.S. 357 (2002)). In that

case, the Supreme Court defined compounding as "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication *tailored to the needs of an individual patient*. Compounding is typically used to prepare medications that are *not commercially available*, such as medication for a patient who is allergic to an ingredient in a mass-produced product." 535 U.S. 357, 361 (2002) (emphases added). The critical element of this definition, that compounding is done on a patient-by-patient basis after having received a prescription, is also found in the Fifth Circuit's view of compounding.[45] The Agency also found support for its conclusion in the legislative history of the Food, Drug, and Cosmetic Act (FDCA).

Like the CSA, the FDCA exempts compounding pharmacies from manufacturing requirements. 71 Fed. Reg. at 16595 (citing 21 U.S.C. § 353a). Around the time *Wedgewood* was decided in 2006, the Food and Drug Administration (FDA) had expressed concerns, however, that some pharmacies were circumventing manufacturing requirements by mass-producing drugs in a manner that appeared at first blush to be compounding, but was in fact manufacturing. *Id*.; *see also Wedgewood Village Pharm.*, 509 F.3d at 543 (noting the same concern). A House Conference Report concerning the Food and Drug Administration Modernization Act of 1997, the law which amended the FDCA at 21 U.S.C. § 353a to exempt compounding from certain requirements, states that "[i]t is the intent of the conferees to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so

[45] The Fifth Circuit defined compounding as "the process whereby a pharmacist combines ingredients pursuant to a physician's prescription to create a medication for an individual patient." *Prof. & Pat. For Customized Care v. Shalala*, 56 F.3d 592, 593 (5th Cir. 1995). This process, the Fifth Circuit added, is typically needed when a medication is not commercially available. *Id*. In another case, the Fifth Circuit stated that compounding is a process designed "to create a medication to meet the unique needs of an individual . . . patient." *Med. Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 387 (5th Cir. 2008). According to the American Pharmacists Association, as cited in *Mukasey*, pharmacists compound "patient-specific medication." *Id*.

as to prevent manufacturing under the guise of compounding." 71 Fed. Reg. at 16595 (quoting 1997 U.S.C.C.A.N. 2880).

By citing this portion of the FDCA's legislative history, the Agency made clear that it shares the FDA's concern about one of the challenges of regulating compounding and manufacturing; namely, that a pharmacy could compound on such a large scale that its operation would, in essence, be akin to that of a manufacturer. Based on this concern shared between two federal agencies charged with regulating pharmaceuticals, it is understandable why in *Wedgewood* the Agency chose to limit the manufacturing exemption to compounding conducted on an individual patient basis after the pharmacy receives a prescription. 71 Fed. Reg. at 16595-96.

The view that compounding is exempt from the definition of manufacturing only when it is conducted pursuant to a prescription for a particular patient is also consistent with the CSA's definition of "dispense" as well as the language "incident to" in the definition of "manufacture." Under the CSA, "dispense" means "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the *lawful order* of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or *compounding* necessary to prepare the substance for such delivery." 21 U.S.C. § 802(10) (emphases added). The fact that the definition of "dispense" includes "compounding necessary to prepare the substance" for delivery, and the fact that compounding "incident to" dispensing exempts a pharmacy's activity from the definition of "manufacture," shows that the CSA drafters contemplated compounding as "an incident to" dispensing when needed to prepare a substance for delivery to a patient pursuant to the patient's prescription. Compounding large quantities of a substance in anticipation of receiving prescriptions for that substance would not be "necessary to prepare the substance for" delivery pursuant to a patient's prescription.

Furthermore, the reference to compounding as "necessary" in the definition of "dispense," combined with the "incident to" clause in the manufacturing exemption, illustrates that the CSA drafters intended compounding to be dependent on dispensing, and for dispensing to be dependent on receipt of a valid prescription. In other words, the logical sequence of events is that (1) a pharmacy receives a prescription, (2) in some cases compounding will be "necessary" to prepare that prescription, and (3) because compounding is necessary to prepare the substance for dispensing, (4) it is viewed as incidental[46] to the act of dispensing, and (5) therefore, the necessary act of compounding to fill that prescription is exempt from the definition of manufacturing. 21 U.S.C. §§ 802(10), (15). But it would only be exempt to the extent that it was necessary to prepare a substance for delivery pursuant to a prescription. *Id*.

The thrust of the Respondent's argument is that because the CSA does not define compounding, the appropriate question is whether the Respondent complied with Florida law and other federal laws. Resp't PHB, at 37-38. The Respondent argues that it engaged in anticipatory compounding (i.e., compounding before receiving a prescription), which is permissible under Florida law and the FDCA. *Id*. at 37-41. Florida law provides that lawful compounding includes "[t]he preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns." Fla. Admin. Code r. 64B16-27.700(1)(a).

[46] As pointed out by the Government, the view that the phrase "incident to" implies that compounding is dependent on dispensing is also consistent with the Black's Law Dictionary definition of "incident to" as "dependent on, subordinate to, [or] arising out of." Gov't PHB, at 43. Perhaps this is the reason why the CSA drafters declined to define "compounding": because they viewed it only as an accessory to dispensing. In other words, they viewed compounding as a necessary, but limited, means to an end, to be performed only in relation to dispensing and dependent on dispensing. Under this approach, the CSA allows pharmacies to compound on an as-needed basis in order to engage in their primary activity of dispensing, but any compounding that is not done as a means of engaging in an activity that meets the definition of "dispense" would fall under the definition of "manufacture"; thus, triggering the requirement to be registered as a manufacturer and to meet stricter standards.

The Respondent also argues that it complied with the anticipatory compounding provision of the FDCA. Section 353a of Title 21, United States Code, governs pharmacy compounding under the auspices of the FDA. *Thompson*, 535 U.S. at 362; *Allergan USA v. Imprimis Pharm., Inc.*, No. 8:17-cv-01551-DOC-JDE, 2019 WL 4545960, at *5 (C.D. Cal. March 27, 2019). This section falls under the FDCA. *Allergan USA*, 2019 WL 4545960, at *5. This section of the FDCA, commonly referred to as Section 503A, exempts certain compounded drug products from the FDCA's "new drug" approval requirements. *United States v. Conigliaro*, 384 F. Supp. 3d 145, 160 (2019). This provision resolves issues arising from the question of whether a compounded medication qualifies as a "new drug" requiring FDA approval. *Mukasey*, 536 F.3d at 389. Section 503A also establishes "safety and quality standards" for compounding ingredients (21 U.S.C. §§ 353a(b)(1)(A)-(B)); prohibits pharmacists from producing "carbon copies of commercially available drug products" (21 U.S.C. § 353a(b)(1)(D)); and prohibits pharmacists from "soliciting customers," or advertising or promoting particular compounded drugs (21 U.S.C. § 353a(c)). *Conigliaro*, 384 F. Supp. 3d at 160.

In order to receive Section 503A's exemption from "new drug" approval requirements, the compounded drug product must meet certain criteria, the most relevant of which requires the compounding to be done "in response to a valid prescription" or that the compounding be limited to situations where a professional relationship already existed between the patient, pharmacist, and prescriber. *Conigliaro*, 384 F. Supp. 3d at 160 (citing 21 U.S.C. § 353a(a)). In essence, Section 503A allows compounding in only two scenarios: (1) after receiving a prescription, or (2) before receiving a prescription if the pharmacist has previously received valid prescriptions issued within the same established relationship between the pharmacist, patient, and prescriber. *Allergan USA*, 2019 WL 4545960, at *5. For ease of reference, the second scenario will be referred to as anticipatory

compounding.

The fact that the Respondent may have complied with the anticipatory compounding allowance under the FDCA, as the Respondent argues, does not mean that its conduct also complied with the CSA.[47] In fact, meeting the criteria for permissible compounding under the FDCA only means that the Respondent is

[47] I am not making any finding about whether the Respondent violated (or complied with) the FDCA. As the Government points out in its post-hearing brief, the FDA, the agency tasked with implementing the FDCA, is responsible for ensuring the safety and effectiveness of new drugs for their intended purposes. Gov't PHB, at 44 (citing *Am. Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824, 830 (D.D.C. 1974)). The DEA, in contrast, is the federal agency charged with enforcing the CSA and combatting the "unlawful diversion" of controlled substances. *Id*. (citing *id*.). By establishing the FDA and DEA, Congress manifested its intent to create two distinct institutions responsible for regulating drugs. *Weinberger*, 377 F. Supp. at 830. On the one hand, the FDA is responsible for "determining which new drugs should be permitted to enter the flow of commerce." *Id*. On the other hand, once a drug is approved to enter the marketplace, the DEA is responsible for ensuring that a particular class of drugs, controlled substances, is not diverted outside the lawful chain of distribution from manufacturer to patient. *Id*.; *see also Gonzales v. Raich*, 545 U.S. 1, 13 (2005) (stating that in enacting the CSA, Congress created "a closed regulatory system" to curb "the diversion of drugs from legitimate to illicit channels").

There is, undoubtedly, overlap between the scope of FDA's and DEA's authority. *Weinberger*, 377 F. Supp. at 831. In a broad sense, both agencies are responsible for protecting the public from unsafe or dangerous drugs. *Weinberger*, 377 F. Supp. at 831. These are similar regulatory missions. And yet, it is important to keep in mind, as the D.C. District Court explained in *Weinberger*, that the FDA ensures a drug is safe before entering the market, while the DEA protects the public from the diversion of controlled substances after entering the stream of commerce. 377 F. Supp. at 830-31.

Given this distinction, it is understandable why the Agency has stopped short when it comes to interpreting the FDCA or holding respondents accountable for violating the FDCA. For example, in *Wedgewood*, the Agency stressed that it did "not rely on FDA's position" when applying the CSA's "compounding" provisions, even though its interpretation happened to be consistent with FDA guidelines and statutes. 71 Fed. Reg. at 16596. In two other DEA cases, the Agency explicitly stated that it lacked the authority to interpret the FDCA or to declare violations of the FDCA. *Paul Weir Battershell, N.P.*, 76 Fed. Reg. 44359, 44368 n.27 (2011); *Tony T. Bui, M.D.*, 75 Fed. Reg. 49979, 49989 (2010). First in *Bui*, then reinforced in *Battershell*, the Agency emphasized that the "DEA is not charged with administering the [FDCA]"; therefore, any attempt to "definitively interpret" the FDCA would be outside the scope of its delegated authority. *Id*. Similarly, this lack of authority to interpret the FDCA "bars the Agency from deciding whether Respondent violated the statute." *Battershell*, 76 Fed. Reg. at 44368 n.27. Simply put, the issue of whether a registrant violated the FDCA is "outside of the Agency's authority to adjudicate." *Bui*, 75 Fed. Reg. at 49989.

Although the Agency has stated that interpreting or declaring violations of the FDCA is outside its authority, the extent to which violating the FDCA may be considered under Factor Five is another matter. In *Battershell*, the Agency noted that respondent's plea agreement established that he violated the FDCA and that evidence of such violation could "be considered under factor five" for the "purpose of assessing the likelihood of Respondent's future compliance with the CSA." 76 Fed. Reg. at 44368 n.27 (citing *Wonderyears, Inc.*, 74 Fed. Reg. 457, 458 n.2 (2009) (stating unlawful conduct related to non-controlled drugs is relevant in determining whether respondent can be trusted to comply with the CSA)). Although a violation of the FDCA adjudicated in another forum could be analyzed under Factor Five to evaluate the Respondent's likelihood of following the CSA, the Government has not advanced any such theory in this case. In fact, the Government's only Factor Five allegation is that the Respondent's business consisted almost exclusively of dispensing controlled substances to patients presenting numerous red flags. Gov't PHB, at 39-40. Because the Government has not argued that the Respondent's compounding should be assessed under the FDCA in a Factor Five analysis, I will not consider whether the Respondent violated or complied with the FDCA under Factor Five. *David W. Bailey, M.D.*, 81 Fed. Reg. 6045, 6046 n.2 (2016) (stating no findings may be made under Factor Five unless the Government specifically advances a theory under that factor).

exempt from satisfying the FDA's "new drug" approval process. It does not mean that the Respondent is exempt from the CSA's definition of manufacturer.

The same is true with respect to Florida law. Although the Respondent's practice of anticipatory compounding may have been permissible under Florida law, that fact alone does not automatically render the practice in accord with the CSA's definitions. While I agree with the Respondent that part of the CSA's manufacturing exemption includes "conformity with applicable State or local law," the CSA also requires that compounding be done "as an incident to . . . dispensing" in order to be exempt from the definition of manufacturer. 21 U.S.C. § 802(15). And as already shown, anticipatory compounding is inconsistent with the phrase "as an incident to . . . dispensing." *Id*. It is also inconsistent with the Agency's view of permissible compounding articulated in *Wedgewood*. 71 Fed. Reg. at 16595.

The Respondent's post-hearing arguments address neither *Wedgewood* nor the "incident to" language in the CSA's definition of manufacture. The Respondent's primary argument is that both Florida law and the FDCA allow anticipatory compounding, and that "the evidence appears to suggest that the Respondent engaged in permissible anticipatory compounding in compliance with applicable federal and state law." Resp't PHB, at 41. I reject the Respondent's argument that it can seek refuge under Florida's anticipatory compounding allowance for three reasons. First, I recognize that consistent with *Gonzales v. Oregon*, the Agency typically looks to the standards of practice in the registrant's state of registration as the appropriate benchmark against which to evaluate the registrant's conduct. *See* 546 U.S. 243, 270 (2006) (noting the CSA "manifests no intent to regulate the practice of medicine generally" and that the CSA rests "upon a functioning medical profession regulated under the States' police powers"); *Joseph Gaudio, M.D.*, 74 Fed. Reg. 10083, 10090 (2009) (explaining the DEA looks to state standards to evaluate whether a bonafide doctor-patient relationship was formed).

Deference to state standards of medicine is based, in part, on the Supreme Court's finding that the CSA "conveys unwillingness to cede medical judgments to an executive official," such as the U.S. Attorney General, "who lacks medical expertise." *Oregon*, 546 U.S. at 266. Deciding to limit compounding to an activity dependent on dispensing, as the CSA does, is not, however, a medical judgment that requires medical expertise, in the same way that determining proper medical treatment is a medical judgment requiring medical expertise. Defining what is and is not manufacturing is wholly different than interfering with a state's police power to regulate the practice of medicine.

Second, while compounding is generally a matter left to state regulators, drug manufacturing remains subject to federal authority. *Prof. & Pat. For Customized Care*, 56 F.3d at 593. Accordingly, the CSA views anticipatory compounding as a form of manufacturing. And while registrants are obligated to follow state law, they are also obligated to follow the CSA, which includes its registration requirements. Nothing in the Florida law cited by the Respondent exempts the Respondent from the CSA's requirement to obtain appropriate DEA registration before engaging in certain regulated activities as the CSA defines them. And as already discussed, the CSA considers compounding (even if conducted in compliance with state law) to be manufacturing unless it is an incident to dispensing.

Third, federal law typically trumps state law. "The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail." *Gonzalez v. Raich*, 545 U.S. 1, 29 (2005). I view the conflict here as analogous to the conflict between state and federal regulation of marijuana. While many states have relaxed their restrictions around the cultivation, use, and sale of marijuana, that drug remains a schedule I controlled substance under the CSA. While Florida law may permit anticipatory compounding, that conduct meets the definition of manufacturing under the CSA, and therefore, triggers federal

obligations on top of state obligations, such as obtaining the proper federal registration.

The Respondent also argues that the evidence fails to show that the Respondent sold any of the drugs it compounded to a distributor or reseller, "as would be expected in the case of a traditional drug manufacturer." *Id*. The CSA's definition of manufacture, however, does not depend on to whom the drugs are sold after being created. 21 U.S.C. § 802(15). The CSA's definition of manufacture focuses on how the drug is created, not the manufacturer's business model for selling it. *Id*. Consequently, the Respondent can still be held accountable for manufacturing controlled substances without the proper registration regardless of the fact that it sold its compounded drugs directly to patients rather than to distributors or wholesalers.

This brings us to the evidence of record. The clearest evidence that the Respondent manufactured, rather than compounded for individual patients, comes from the closing inventory conducted by DI Albert and Mr. Clement, Sr., in September 2018. Tr. 52, 54, 56, 165-66; GX 7. The closing inventory documented the number of controlled substances the Respondent had on hand at the time. *Id*. DI Albert observed Mr. Clement, Sr., conduct the inventory and Mr. Clement, Sr., signed off on it. Tr. 56, 166.

The closing inventory shows that on September 10, 2018, the Respondent had 3,546 compounded capsules of hydromorphone 8 mg on hand and 574 compounded capsules of oxycodone 30 mg on hand. GX 7, p. 1. These capsules were sitting in a safe when they were counted. Tr. 56. Several thousand capsules sitting in a safe is not consistent with compounding for an individual patient's therapeutic needs as an incident to dispensing. It is consistent with manufacturing capsules in bulk and storing them until a prescription is presented.

The Respondent argues that no evidence of record proves that it "produced significantly large quantities of any drug." Resp't PHB, at 41. Whether the 4,120

capsules stored in the Respondent's safe on September 10, 2018, constitutes a "significantly large" quantity is beside the point. Whether the Respondent produced a large or small amount of compounded capsules, however, is relative, and my finding on this allegation has nothing to do with the amount of capsules produced. In fact, the Agency has instructed that "volume alone does not show that [a registrant's] activity is manufacturing rather than compounding." *Wedgewood*, 71 Fed. Reg. at 16597. While volume can be one relevant factor to consider,[48] the distinguishing factor is whether the pharmacy compounded "on an individual patient basis" as an adjunct to dispensing. *Id*. at 16594-95, 16597. And as already noted, storing over four thousand compounded capsules in a safe is not consistent with compounding "on an individual patient basis" as an adjunct to dispensing. *Id*. It is, in effect, manufacturing.

This is especially true when the Respondent typically filled only two to four prescriptions per day. Tr. 508. The rough math shows that four thousand compounded capsules could be enough for two weeks of dispensing. Considering that a month's supply of oxycodone would be roughly 112 tablets (GX 18, p. 6) and a month's supply of hydromorphone would be roughly 120 tablets (GX 44, p. 6), the Respondent had enough oxycodone capsules on hand to fill approximately 5 prescriptions and enough hydromorphone capsules on hand to fill about 29 prescriptions. Together, this would approximate the number of prescriptions the Respondent typically saw over the course of two weeks. This lends further support to my conclusion that the amount of compounded capsules the Respondent had on

[48] Based on Dr. Sullivan's testimony, the Government argued that "the extreme volume of Respondent's compounding indicated that it was not being done in response to the individualized patient needs." Gov't PHB, at 47. Compounding only 30 capsules would still be manufacturing if not done for an individual patient. Four thousand capsules, however, raises far more suspicions than 30 would. Thus, I have considered the amount of compounded capsules, and I find that it further supports my conclusion that the Respondent was manufacturing rather than compounding on a patient-by-patient basis. Per *Wedgewood*, however, the volume of compounding alone is not outcome determinative. 71 Fed. Reg. at 16597.

hand on September 10, 2018, is not consistent with compounding for individual patients as an incident to dispensing. Rather, it is consistent with manufacturing.

In addition to the closing inventory, the Government also points to statements made by Mr. Clement, Sr., in 2012. Gov't PHB, at 46. In May 2012, during execution of an administrative inspection warrant (AIW) at the Respondent pharmacy, TFO Shearer interviewed Mr. Clement, Sr., the Respondent's owner. Tr. 183. Mr. Clement, Sr., was not in custody at the time and was free to leave. *Id*. In the interview, Mr. Clement, Sr., told TFO Shearer about his process for manufacturing oxycodone and hydromorphone in capsules. Tr. 183-84. Mr. Clement, Sr., told TFO Shearer that he could buy a 100 gram bottle of oxycodone powder for $1,100, enough to manufacture about 6,000 dosage units. Tr. 185. Tablets of oxycodone purchased from commercial distributors cost roughly $2-$10 per pill. *Id*. In other words, $1,100 worth of powder could produce at least $12,000 worth of dosage units. Mr. Clement, Sr., told TFO Shearer that he manufactured thousands of capsules per batch because it was cost effective. Tr. 184-85. The batch records that TFO Shearer reviewed in 2012 documented that Mr. Clement, Sr., produced thousands of pills in each batch. *Id*. Mr. Clement, Sr., also told TFO Shearer that he persuaded patients to take capsules even if they did not want them because capsules have the same effect as tablets.[49] Tr. 185-86.

Although these statements were made in 2012, they demonstrate that the Respondent had a system in place to compound thousands of capsules at a time. Tr. 184-85. These statements also demonstrate that the Respondent's motive for mass-compounding thousands of capsules per batch was cost effectiveness, rather than patients' unique therapeutic needs. Tr. 184-86. These statements provide

[49] While reliable hearsay statements may be admissible in these administrative proceedings, Mr. Clement, Sr.'s, statements to TFO Shearer in 2012 are not hearsay. They enjoy enhanced credibility as they would qualify as statements by a party opponent and would, therefore, be excluded from the definition of hearsay. Fed. R. Evid. 801(d)(2).

additional support to the conclusion that the Respondent's compounding was cost-driven rather than patient-driven, and that the Respondent was, therefore, manufacturing and not compounding as the CSA understands those terms.

The Government also points to the batch records obtained pursuant to the 2017 subpoena. Gov't PHB, at 46; Tr. 27. A batch record documents the production of a controlled substance and lists the ingredients in the controlled substance. Tr. 33. The batch record is created by the person who makes the substance. *Id*. The batch records indicate how many capsules were used in the production of each batch. Tr. 38, 40-41. The batch records in Government Exhibit 5 document the production of hydromorphone 8 mg. The batch records in Government Exhibit 6 document the production of oxycodone 30 mg. The hydromorphone batch records show that the Respondent "compounded" from 600 to 2,400 capsules per batch, with 1,200 capsules being the most frequently occurring quantity. *See generally* GX 5. The oxycodone batch records show that the Respondent "compounded" from 600 to 1,800 capsules per batch, with 1,200 capsules being the most frequently occurring quantity. *See generally* GX 6. These numbers are consistent with the number of compounded capsules found during the 2018 closing inventory and with Mr. Clement, Sr.'s, statements to TFO Shearer in 2012. These numbers are also consistent with manufacturing rather than compounding on an individualized patient basis.

Furthermore, the Respondent's dispensing records also demonstrate that the patients for whom the Respondent compounded oxycodone and hydromorphone did not have valid therapeutic needs for compounded medication. Dr. Sullivan explained that compounding is only done when necessary "to meet the individual, unique therapeutic needs of a patient." Tr. 231. Compounding would be necessary, he continued, if the patient had an allergy to the commercially available version or if the patient needed a unique dose or strength that was not available in the mass-

produced product. Tr. 230-31. Dr. Sullivan's testimony on this topic is consistent with case law. As already noted, the Fifth Circuit described compounding as a process designed "to create a medication to meet the unique needs of an individual . . . patient." *Mukasey*, 536 F.3d at 387. The Fifth Circuit further noted that compounding is necessary to create "patient-specific medication." *Id*. The Supreme Court has observed that one reason why a pharmacist would need to compound patient-specific medication is if the patient is allergic to an ingredient in the commercially manufactured drug. *Thompson*, 535 U.S. at 361. Other reasons, the Fifth Circuit has also recognized, include "diluted doses for children and altered forms of medications for easier consumption." *Prof. & Pat. For Customized Care*, 56 F.3d at 593.

Dispensing records, however, show that the Respondent dispensed both commercially manufactured tablets and compounded capsules to the same patient. The fact that the Respondent dispensed both commercially available tablets and compounded capsules of the same controlled substances to the same patients indicates that the patients lacked "unique therapeutic needs" for the compounded version. Tr. 231, 256. For example, the Respondent dispensed seven prescriptions of oxycodone 30 mg tablets to patient A.G. from June 2017 to August 2018. ALJ Ex. 42, p. 11. During that same time period, the Respondent also dispensed to A.G. three prescriptions of oxycodone 30 mg compounded capsules. *Id*. A note dated March 13, 2017, in A.G.'s profile states that a doctor approved dispensing medication to A.G. in compounded capsules. GX 15, p. 1; ALJ Ex. 42, p. 13. After March 2017, however, the Respondent continued dispensing both tablets and compounded capsules to A.G. ALJ Ex. 42, p. 11. Thus, even if a doctor approved of A.G. taking compounded capsules, it was not for a therapeutic or medical reason since he continued to alternate between capsules and tablets.

In another example, the Respondent dispensed both tablets and compounded capsules to patient R.G. to fill the same oxycodone prescription. GX 49; Tr. 325-26. Dr. Sullivan opined that R.G. clearly had no valid therapeutic need for compounded capsules since he also took the tablet form of the same drug. Tr. 326. Patient R.G. also received oxycodone in capsules on 15 occasions from June 2017 to September 2018, and in tablets on 2 occasions during the same time period. ALJ Ex. 42, p. 45. As Dr. Sullivan observed, the fact that the Respondent dispensed oxycodone to R.G. in both capsule and tablet forms, and dispensed capsules and tablets together on one occasion, demonstrates that the Respondent was not compounding for R.G. in response to a unique therapeutic need for compounded capsules. Tr. 325-26. Furthermore, no profile for any of the patients documents an allergy that would have necessitated compounded capsules. Tr. 339; GX 15, 20, 23, 26, 29, 32, 35, 38, 41, 47, 51.

Dr. Sullivan pointed out numerous other instances where the Respondent's dispensing history demonstrated that patients lacked legitimate therapeutic justification for compounded capsules. From January 2018 to December 2018, the Respondent dispensed compounded capsules of hydromorphone 8 mg to A.H. on eight occasions: January 4; February 15; March 5; April 3; May 2; August 16; September 11; and December 5. ALJ Ex. 42, pp. 15-16; GX 19; GX 21. The Respondent then dispensed tablets of hydromorphone 8 mg to A.H. on the following five occasions in 2019: January 22; February 15; February 27; March 14; and April 18. *Id*. The fact that the Respondent dispensed capsules of hydromorphone to A.H. on eight occasions in 2018 and then tablets of hydromorphone on five occasions in 2019 demonstrates that A.H. had no unique therapeutic justification that required the Respondent to compound hydromorphone capsules for him. Tr. 255-56, 258-59, 269.

Dr. Sullivan noted a lack of therapeutic justification to compound hydromorphone for B.S. since he received hydromorphone in both tablets and capsules. Tr. 274. From August 2017 to August 2018, the Respondent filled 12 hydromorphone prescriptions with compounded capsules for B.S.: August 22, 2017; September 27, 2017; October 18, 2017; November 15, 2017; December 12, 2017; January 4, 2018; January 29, 2018; February 28, 2018; March 26, 2018; April 23, 2018; May 22, 2018; and August 24, 2018. ALJ Ex. 42, p. 19; GX 24. On February 5, 2019, the Respondent filled a hydromorphone prescription for B.S. with tablets. ALJ Ex. 42, p. 20; GX 22. The fact that the Respondent dispensed hydromorphone tablets to B.S. in 2019 shows that B.S. had no unique therapeutic justification that required the Respondent to compound hydromorphone capsules for him on 12 occasions in 2017 and 2018. Tr. 255-56, 258-59, 269, 274.

The Respondent dispensed oxycodone capsules and tablets to C.R., indicating that there was no valid therapeutic reason for the Respondent to compound oxycodone capsules for her. Tr. 255-56, 258-59, 269, 274, 279-80. On July 19, 2017, and October 26, 2017, the Respondent filled oxycodone prescriptions for C.R. with compounded capsules. ALJ Ex. 42, p. 23; GX 27. The Respondent then filled four oxycodone prescriptions for C.R. with tablets: March 6, 2018; April 19, 2018; July 12, 2018; and August 28, 2018. *Id*.

Dr. Sullivan observed that J.M. alternated between tablets and capsules of oxycodone, demonstrating that there was no valid therapeutic need for the Respondent to compound oxycodone capsules for her. Tr. 290. First, the Respondent dispensed oxycodone tablets to J.M. on January 25, 2018, and then filled J.M.'s next oxycodone prescription with compounded capsules on March 1, 2018. ALJ Ex. 42, p. 30; GX 33; Tr. 290. The next month the Respondent switched back to oxycodone tablets on April 4, 2018, followed by oxycodone capsules on April 19, 2018, and then switched back again to tablets on May 16, 2018. *Id*. The fact that

the Respondent alternated between dispensing oxycodone tablets and capsules to J.M. demonstrates that there was no valid therapeutic reason for the Respondent to compound oxycodone capsules for her. Tr. 255-56, 258-59, 269, 274, 279-80, 290.

Dr. Sullivan observed that the Respondent dispensed oxycodone tablets and compounded capsules to M.M. Tr. 295, 297. From June 2017 to August 2018, the Respondent filled 14 oxycodone prescriptions for M.M. with compounded capsules. Tr. 295, 297; ALJ Ex. 42, pp. 33-34; GX 34; GX 36. From January 2019 to April 2019, the Respondent filled five oxycodone prescriptions for M.M. with tablets. *Id*. The fact that the Respondent dispensed compounded oxycodone capsules to M.M. for over a year and then switched to dispensing oxycodone tablets to her for several months demonstrates that there was no valid medical reason for the Respondent to have compounded oxycodone for her. Tr. 255-56, 258-59, 269, 274, 279-80, 290, 295, 297.

Dr. Sullivan observed that the Respondent compounded hydromorphone capsules for N.B. without any apparent therapeutic justification. Tr. 302. From June 2017 to August 2018, the Respondent filled twelve hydromorphone prescriptions for N.B. with compounded capsules. ALJ Ex. 42, p. 37; GX 39.

Dr. Sullivan pointed out that the Respondent compounded hydromorphone capsules for R.B. without any apparent medical justification. Tr. 311, 319-20. From June 2017 to January 2019, the Respondent filled 14 hydromorphone prescriptions for R.B. with compounded capsules. GX 40; GX 43; ALJ Ex. 42, pp. 41-42. At least three of those prescriptions were originally written for tablets and were substituted for capsules by the Respondent. Tr. 319-20; GX 44, pp. 6-7. The Respondent then dispensed hydromorphone tablets to R.B. on three occasions from February to April 2019. ALJ Ex. 42, p. 42; GX 40. The fact that the Respondent dispensed tablets and capsules of hydromorphone to R.B., switching prescribed

tablets to capsules, demonstrates that there was no valid therapeutic reason for the Respondent to compound hydromorphone for R.B. Tr. 311, 319-21.

Lastly, Dr. Sullivan noted that the Respondent compounded capsules of hydromorphone for R.L. without any apparent medical justification. Tr. 331; ALJ Ex. 42, p. 49; GX 52. From June 2017 to September 2018, the Respondent filled 14 hydromorphone prescriptions for R.L. with compounded capsules. *Id*.

In sum, the evidence paints a picture of a pharmacy mass-compounding bulk quantities of oxycodone and hydromorphone in thousands of capsules per batch. The evidence further reveals the Respondent's motive for doing so: profit rather than patient need. The evidence shows that the Respondent's "compounding" was not incidental to the act of dispensing. Because the Respondent's "compounding" was not conducted "on an individual patient basis" after having received a prescription, it is not exempt from the CSA's definition of "manufacture." *Wedgewood*, 71 Fed. Reg. at 16595. This is true regardless of whether the Respondent complied with Florida law and the FDCA, since it must also comply with the CSA's registration requirements. Thus, the Respondent engaged in manufacturing thousands of controlled substance dosages over a period of several years without the proper registration. For these reasons, the Government's allegation that the Respondent illegally manufactured controlled substances is **SUSTAINED.** ALJ Ex. 1, pp. 8-10, ¶ 20-28.

Government's Burden of Proof and Establishment of a *Prima Facie* Case

Based upon my review of each of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. § 824(a). At the outset, I find that the Government has demonstrated and met its burden of proof in support of revocation through its case that the Respondent has failed to resolve red flags of

diversion and to document the resolution of red flags of diversion in accordance with Florida law and the usual course of professional practice in Florida. Furthermore, the Government has additionally demonstrated that the Respondent unlawfully manufactured controlled substances without the proper registration. Inasmuch as the Government has established by a preponderance of the evidence that the Respondent violated state and federal laws relating to controlled substances on numerous occasions and committed such other conduct which may threaten the public health and safety, it has met its *prima facie* burden of proving that the requirements for a sanction pursuant to 21 U.S.C. § 824(a) are satisfied.

PUBLIC INTEREST DETERMINATION: THE STANDARD

Pursuant to 21 U.S.C. § 823(f) (2006 & Supp. III 2010), the Acting Administrator[50] may revoke a DEA Certificate of Registration if persuaded that maintaining such registration would be inconsistent with the public interest. Evaluation of the following factors have been mandated by Congress in determining whether maintaining such registration would be inconsistent with "the public interest":

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

21 U.S.C. § 823(f).

"These factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*,

[50] This authority has been delegated pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2008).

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

Factors Two and Four: Experience in Dispensing, and Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government seeks the revocation of the Respondent's COR based primarily on conduct most appropriately considered under Public Interest Factors Two and Four.[51] The Government has also raised one allegation under Factor Five.

[51] 21 U.S.C. § 823(f)(2), (4). There is nothing in the record to suggest that a state licensing board made any recommendation regarding the disposition of the Respondent's DEA COR (Factor One). Likewise, the record contains no evidence that the Respondent has been convicted of (or charged with) a crime related to controlled substances (Factor Three).

Factor Two: Experience in Dispensing Controlled Substances

Factor Two requires consideration of the Respondent's experience in dispensing controlled substances. The plain language of Factor Two dictates that a registrant's prior experience in the regulated activity must be considered. The Agency has acknowledged that even a considerable level of benign or even commendable experience could be easily outweighed by evidence demonstrating that continued registration was inconsistent with the public interest.[52]

The Respondent did not offer specific direct evidence, either documentary or testimonial, relating to experience in dispensing. Although the Government has proved misconduct which could be considered under Factor Two and Factor Four, I will only weigh that misconduct under Factor Four to avoid double-counting the same violations under multiple factors.

Factor Four: Compliance with Applicable Federal, State, or Local Laws Relating to Controlled Substances

Evidence is considered under Factor Four when it reflects a respondent's compliance (or non-compliance) with laws related to controlled substances. Established violations of the CSA, DEA regulations, or other laws regulating controlled substances at the state or local level are cognizable under Factor Four. As DEA has held in the past, a registrant's "ignorance of the law is no excuse" for actions that are inconsistent with responsibilities attendant upon a registration. *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74800, 74809 (2015) (quoting *Sigrid Sanchez, M.D.*, 78 Fed. Reg. 39331, 39336 (2013) (citing *Patrick W. Stodola*, 74 Fed. Reg. 20727, 20735 (2009) and *Hageseth v. Superior Ct.*, 59 Cal. Rptr. 3d 385, 403 (Ct.

[52] *See, e.g.*, *Paul J. Caragine, Jr.*, 63 Fed. Reg. 51592, 51560 (1998) ("[E]ven though the patients at issue are only a small portion of Respondent Pharmacy's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future."); *Med. Shoppe-Jonesborough*, 73 Fed. Reg. at 386 (finding that the misconduct outweighed the fact that only a relatively small portion of the respondent's patient population was involved).

App. 2007) (a "licensed health care provider cannot 'reasonably claim ignorance' of state provisions regulating medical practice"))). Under Agency precedent, "[a]ll registrants are charged with knowledge of the CSA, its implementing regulations, as well as applicable state laws and rules." *Id*. at 74809 (internal citations omitted).

Standard of Care as to Charged Violations

Prescriptions for controlled substances may only be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id*. This "prohibits[s] a pharmacist from filling a prescription for a controlled substance when she either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharm.*, 78 Fed. Reg. 69441, 69445 (2013) (internal quotations, alterations omitted). This "standard of care refers to that generally recognized and accepted in the medical community rather than a standard unique to the practitioner." *Rene Casanova, M.D.*, 77 Fed. Reg. 58150, 58161 (2012) (citing *Robert L. Dougherty, M.D.*, 76 Fed. Reg. 16823, 16832 n.11 (2011) (internal citations omitted)). While "state law is a relevant factor in determining whether a practitioner is acting in the 'usual course of professional practice,' it is appropriate in the context of an inquiry under federal law to also consider 'generally recognized and accepted medical practices' in the United States." *Id*. (citing *Bienvenido Tan, M.D.*, 76 Fed. Reg. 17673, 17681 (2011)).

A pharmacy's standard of care for dispensing controlled substances is governed by federal and state law, as well as standards of practice accepted within the state. "A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. Under Florida law, a pharmacy is required to conduct a prospective drug

use review before filling or refilling any prescription for controlled substances. Fla. Admin. Code r. 64B16-27.810. Florida law also requires pharmacies to question suspicious prescriptions and to only fill a prescription if the pharmacy can validate the prescription's medical legitimacy. Fla. Admin. Code r. 64B16-27.831. Florida law also requires pharmacies to maintain a patient record system. Fla. Admin. Code r. 64B16-27.800. Dr. Sullivan explained that under Florida law, pharmacies must document information relevant to resolving red flags in the patient record system. Tr. 209, 453-55, 489. He further noted that a patient record system is synonymous with a patient profile. Tr. 209. The Agency has previously interpreted Florida law as requiring pharmacies to document information in the patient profile that they would need to resolve red flags. *Trinity II*, 83 Fed. Reg. at 7330. Failure to document information pertinent to red flag resolution in the patient profile would violate Florida law and, therefore, be outside the usual course of professional practice in Florida.

While violations of state law are cognizable under Factor Four, Agency precedent provides that "the mere fact that a violation of a state rule occurs in the context of the dispensing of controlled substances does not necessarily mean that the violation has a sufficient nexus to the CSA's core purpose of preventing the diversion and abuse of controlled substances." *Fred Samimi, M.D.*, 79 Fed. Reg. 18698, 18710 (2014). There must be a nexus between the state law that has been violated and the CSA's purpose of preventing drug abuse and diversion. *Id*. Therefore, the inquiry is twofold: it must be determined whether the Respondent's conduct violated the particular state law alleged and whether that state law has a nexus with the CSA's purpose of preventing drug abuse and diversion. *See Judulang v. Holder*, 565 U.S. 42 (2011) (actions of a regulatory agency must bear a rational relationship to the purposes of the statute it is charged with enforcing); *Tony T. Bui, M.D.*, 75 Fed. Reg. 49979, 49989 (2010) (holding that in order for a registrant's

"conduct to be actionable, there must be a substantial relationship between the conduct and the CSA's purposes of preventing drug abuse and diversion, and that the conduct may constitute a threat to public health and safety"); *see also Paul Weir Battershell, N.P.*, 76 Fed. Reg. 44359 n.27 (2011) (to same effect).

This condition is met here. The Florida laws that the Respondent violated share the CSA's purpose of combatting the diversion of controlled substances. Similar to DEA regulations, Florida law defines a valid prescription as one "based on a practitioner-patient relationship" and "issued for a legitimate medical purpose." *Compare* Fla. Admin. Code r. 64B16-27.831(1)(a), *with* 21 C.F.R. § 1306.04(a). Furthermore, Florida law places a priority on the medical legitimacy of controlled substance prescriptions. Florida pharmacies are required to confirm the medical legitimacy of a controlled substance prescription before filling it. Fla. Admin. Code r. 64B16-27.831(2)-(3). Florida law even provides steps the pharmacy should take in its process to validate the prescription. *Id*. If a pharmacy is unable to resolve the concerns raised by a controlled substance prescription, the pharmacy should refuse to fill it. *Id*. at 64B16-27.831(2)(c). The same regulation also requires Florida pharmacies to report prescribers suspected of diversion to the Florida Department of Health. *Id*. at 64B16-27.831(4).

Florida law also specifies that before dispensing medication, pharmacies should be on the lookout for signs of clinical abuse or misuse of prescriptions drugs. Fla. Admin. Code r. 64B16-27.810(1)(g). In addition to looking out for signs of abuse, Florida pharmacies are also required to maintain a patient record system for the purpose of documenting information relevant to resolving red flags of diversion or abuse. *Id*. at 64B16-27.800; Tr. 209, 453-55, 489.

The objectives of these Florida laws are to ensure prescriptions for controlled substances are issued for legitimate medical purposes; to impose on pharmacies a process to confirm the medical legitimacy of controlled substances before dispensing

them; to be on guard for evidence that drugs are being abused or misused; and to memorialize findings relevant to red flag investigation in the patient's records. These objectives demonstrate the same fundamental purpose of the CSA to ensure controlled substances remain within legitimate channels.

The Government has also raised allegations involving a pharmacy's corresponding responsibility under 21 C.F.R. § 1306.04(a). The DEA has consistently interpreted a pharmacist's corresponding responsibility "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'" *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 381 (2008) (quoting *Medic-Aid Pharmacy*, 55 Fed. Reg. 30043, 30044 (1990)). In short, a pharmacist has a "corresponding responsibility under Federal law" to dispense only lawful prescriptions. *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48887, 48895 (2011) (citation omitted). The regulation does not require the pharmacist to practice medicine, but instead, imposes a responsibility upon the pharmacist "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 [or has reason to know] that the issuing practitioner issued it outside the scope of medical practice." *E. Main St. Pharmacy*, 75 Fed. Reg. 66149, 66157 (2010) (quoting *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979)).

Providing further guidance concerning a pharmacist's corresponding responsibility the DEA has held:

> [W]hen the circumstances surrounding the presentation of a prescription would give rise to suspicion in a "reasonable professional," there is a duty to "question the prescription[]." *Ralph J. Bertolino, d/b/a/Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 4730 (1990). Though initially framed as a "reasonable professional" standard, the Agency has considered the duty to discharge the corresponding responsibility by evaluating the circumstances in light of what would

> be considered suspicious by a "reasonable pharmacist." *East Main Street Pharmacy*, 75 Fed. Reg. 66149, 66165; *see also Winn's Pharmacy*, 56 Fed. Reg. 52559, 52561 (1991). Accordingly, a pharmacist or pharmacy may not dispense a prescription in the face of a red flag (i.e., a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he or it takes steps to resolve the red flag and ensure that the prescription is valid. *Id.* Because Agency precedent limits the corresponding responsibility to circumstances which are known or should have been known, *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. 24523, 24530 (2011), it follows that, to show a violation of a corresponding responsibility, the Government must establish that: (1) the Respondent dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance. *See Sun & Lake Pharmacy*, 76 Fed. Reg. at 24532 (Finding that pharmacy violated corresponding responsibility where it took no steps to resolve red flags prior to dispensing controlled substances.). The steps necessary to resolve the red flag conclusively will perforce be influenced by the nature of the circumstances giving rise to the red flag.

Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195, 77 Fed. Reg. 62316, 62341 (2012).

Further, to establish a violation of a pharmacist's corresponding responsibility, the Government must establish the requisite degree of scienter. *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. 49816, 49835 (2016) (citing *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.*, 80 Fed. Reg. 28667, 28669 (2015)). To establish scienter, the Government can show that a pharmacist violated his or her "corresponding responsibility" by filling a prescription while knowing that it lacked a legitimate medical purpose. *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. at 49835. In the case before me, however, the Government presented no evidence that one of the Respondent's pharmacists filled a prescription with actual knowledge that the prescription was not legitimate. Absent actual knowledge, the Government can

establish scienter by showing that a pharmacist was "willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose." *Id.* To establish willful blindness, it is necessary to show that a pharmacist subjectively believed that there was a high probability that the prescription lacked a legitimate medical purpose and that the pharmacist deliberately avoided learning the truth. *Id.* Here, the Government argues that the Respondent's failure to document the resolution of numerous red flags when it filled many prescriptions establishes that the Respondent was willfully blind as to the medical legitimacy of those prescriptions. Gov't PHB, pp. 34-35.

The Government has introduced a preponderance of evidence to prove that the Respondent dispensed numerous controlled substance prescriptions for at least eleven patients. Those prescriptions raised classic red flags of drug abuse and/or diversion, to include early fills, travelling long distances, paying in cash, dangerous drug cocktails, and highest strength of the medication, among others. The Government also introduced the patient profiles for each of these eleven patients, as well as twelve hardcopy prescriptions for two of the patients. The profiles contain insufficient information, and in some cases no information, that would have enabled the Respondent to sufficiently resolve the suspicion raised by the prescriptions.

The evidence reveals a concerning pattern of a pharmacy that repeatedly ignored its state-mandated obligation to document information needed to resolve red flags in a patient record system. This concerning pattern demonstrates that regardless of the obvious signs of drug abuse and diversion that are well-known to the pharmacy community, and firmly-established in DEA precedent, the Respondent repeatedly dispensed controlled substances and rarely, if ever, documented any information in response to those red flags in the patient record. And when the Respondent documented information, it was always insufficient to resolve all the concerns raised by the prescription.

With respect to the twelve prescriptions in evidence, the Government has further demonstrated a violation of the Respondent's corresponding responsibility under 21 C.F.R. § 1306.04(a). While I declined to sustain the Government's allegation that the Respondent violated its corresponding responsibility with respect to prescriptions not in evidence, the other sustained violations are more than enough for the Government to establish its *prima facie* burden justifying sanction. The Government has proven this violation through documentary evidence and testimony from its expert witness.

Furthermore, the Respondent failed to rebut or discredit the Government's case. The Respondent did not introduce any documentary evidence and it only offered the testimony of a single witness, who failed to convincingly rebut the Government's evidence. In light of the record as to this factor, I find that the Government has overwhelmingly proven that the Respondent failed to comply with federal and state law with respect to resolving and documenting resolution of red flags of drug abuse and/or diversion, and with respect to its corresponding responsibility for the prescriptions in evidence.

Furthermore, I find that the Government has sponsored a preponderance of evidence to show that the Respondent engaged in unlawful manufacturing of controlled substances without the proper DEA registration, in violation of 21 U.S.C. § 841(a)(1) and 21 C.F.R. § 1301.13(e). Thus, the Government has introduced evidence against the Respondent with respect to two aspects of the controlled drug supply chain, dispensing and manufacturing. The totality of this evidence demonstrates a concerning lack of compliance with applicable federal and state law that poses a significant risk of diversion and threatens public health and safety. This evidence further demonstrates a lack of commitment on the Respondent's part with respect to its federal and state controlled substance obligations. Therefore, I find that this factor significantly favors revoking the Respondent's registration.

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

The Government argues that in addition to weighing the misconduct committed on a patient-by-patient basis, the Tribunal should also consider that the "Respondent's business consisted ***almost entirely*** of dispensing controlled substances to customers who exhibited one or more significant red flags." Gov't PHB, p. 39 (emphasis in original). To support this allegation, the Government contends that nearly all of the Respondent's customers paid cash and nearly all of them lived over 100 miles from the pharmacy. *Id*., pp. 39-40. The Government adds that controlled substances, specifically schedule II narcotics, constituted a grossly disproportionate percentage of the Respondent's overall dispensing. *Id*., p. 40. Thus, the Government urges that in addition to the "specific violations relating to specific patients" under Factors Two and Four, it is appropriate to "consider the pervasiveness of Respondent's misconduct" under Factor Five. *Id*., p. 39. This is the only misconduct the Government has alleged under Factor Five.

As I announced at the hearing, however, I will not sustain any allegations based solely on statistical grounds.[53] Tr. 18, 218. Although Dr. Sullivan suggested that the high number of patients provided compounded medication alone was proof positive that the subject compounding could not have been legitimate, Tr. 336-37, I don't accept that the law of averages alone may sustain the Government's burden of proving Respondent's subject alleged failures. Even if the Respondent's business consisted entirely of dispensing controlled substances to cash-paying patients who

[53] Due Process notice concerns may be implicated in allegations of "guilt" by statistical analysis. The essential requirements of due process "are notice and an opportunity to respond" before a person is deprived of a protectable property interest. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542, 546 (1985). Where a single misfeasance can justify sanction, does the allegation on the basis of a statistical overview provide the respondent with sufficient notice of charges in which to defend? *See Pope v. U.S. Postal Service*, 114 F.3d 1144, 1148-49 (1997) (concluding an employee's due process right to notice was not violated where, among other things, "the administrative judge required the Postal Service to break down the charges into multiple specifications, each directed to a specific act of misconduct, which helped alleviate due process notice concerns").

lived over 100 miles from the pharmacy, that fact alone would only be grounds for sanction if the Government proved Respondent violated its corresponding responsibility or dispensed controlled substances outside the usual course of professional practice by failing to resolve and document red flags. This Tribunal believes these evaluations must necessarily be individualized to specific prescriptions. Statistical analysis may be an important tool in focusing attention on particular practitioners warranting further investigation, and it may be evidence in support of an ultimate conclusion that an individual prescription was improperly compounded or dispensed, but it does not, in itself, constitute proof positive of any violations.[54] Accordingly, this Tribunal is not convinced that evidence of statistical probability constitutes proof positive of actionable misconduct, even under the catch-all provision of Factor Five.

In the alternative, the Government has introduced evidence pertaining to eleven patients, sustaining its burden with respect to those patients by focusing on each dispensing event individually. That evidence has been evaluated under Factor Four. For these reasons, I decline to consider any conduct under Factor Five.

Acceptance of Responsibility

With the Government's *prima facie* burden having been met as to violations of the corresponding responsibility under 21 C.F.R. § 1306.04(a) with respect to twelve prescriptions; dispensing controlled substances outside the usual course of professional practice in violation of 21 C.F.R. § 1306.06 for failing to document red flag resolution in compliance with state law; and unlawfully manufacturing controlled substances without the proper DEA registration in violation of 21 U.S.C. § 841(a)(1) and 21 C.F.R. § 1301.13(e), an unequivocal acceptance of responsibility

[54] What would such a finding look like, "on average, the evidence proves that the Respondent must have prescribed at least a single compounded medication improperly"?

stands as a condition precedent for the Respondent to prevail. *George Mathew, M.D.*, 75 Fed. Reg. 66138, 66148 (2010).

This feature of the Agency's interpretation of its discretionary authority under the CSA has been sustained on review. *MacKay v. DEA*, 664 F.3d 808, 822 (10th Cir. 2011). Accordingly, the Respondent must present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008); *Samuel S. Jackson*, 72 Fed. Reg. 23848, 23853 (2007). As past performance is the best predictor of future performance, 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. *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995); *Medicine Shoppe*, 73 Fed. Reg. at 387; *see also Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005) (reasoning that "admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination). Likewise, in making the public interest determination, "this Agency places great weight on a registrant's candor, both during an investigation and in [a] subsequent proceeding." *Robert F. Hunt*, 75 Fed. Reg. 49995, 50004 (2010); *Hoxie*, 419 F.3d at 483.

Although correcting improper behavior and practices is very important to establish acceptance of responsibility, conceding wrongdoing is critical to reestablishing trust with the Agency. *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316, 62346 (2012); *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74800, 74801 (2015).

The Respondent has not unequivocally accepted responsibility for the proven violations. In fact, the Respondent has not tendered any acceptance of responsibility at all, whether equivocal or unequivocal. The Respondent's owner and pharmacist-in-charge never testified at the hearing in order to accept responsibility. Instead, the Respondent's sole witness, a pharmacy tech, never admitted that the Respondent

committed any wrongdoing. The Respondent's post-hearing brief is silent on this issue. Resp't PHB, p. 29, ¶ (i); p. 32, ¶ (ii); p. 36, ¶ (iii).

The Respondent took the similar approach in its opening statement, arguing that the Government has failed to satisfy its burden; accusing the DEA of never intending to clearly or objectively evaluate the evidence; attacking the credentials of the Government's expert; claiming that the Respondent exercised appropriate judgment when dispensing the relevant controlled substance prescriptions in compliance with Florida law; and complaining about the so-called "ivory tower aspirational" standard the DEA is imposing on its conduct. Tr. 503-05. In other words, the message from the Respondent's post-hearing brief and its opening statement is that it has done nothing wrong. These sentiments are inconsistent with a registrant that is remorseful for misconduct and determined to regain the Agency's trust. By failing to accept responsibility, the Respondent has failed to overcome the Government's *prima facie* case. In addition to failing to accept responsibility, the Respondent has also failed to offer any evidence of remediation.

Egregiousness and Deterrence

While a registrant must accept responsibility and demonstrate that it will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g.*, *Joseph Gaudio*, 74 Fed. Reg. 10083, 10094 (2009); *Southwood Pharm., Inc.*, 72 Fed. Reg. 36487, 36504 (2007). The egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer*, 76 Fed. Reg. 19386, 19387-88 (2011) (explaining that a respondent can "argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation"); *Paul H. Volkman*, 73 Fed. Reg. 30630,

30644 (2008); *see also Gregory D. Owens*, 74 Fed. Reg. 36751, 36757 n.22 (2009).

I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation. The proven misconduct involves repeated instances of dispensing high-strength schedule II controlled substances despite the presence of well-known signs of drug abuse and diversion. The proven misconduct also involves repeat instances of failing to follow state law and state standards of practice with respect to documenting red flag resolution in the patient profile. Continuously dispensing high-strength schedule II opioids, sometimes dangerously combined with high-strength benzodiazepines, to patients who raised multiple red flags of diversion, and failing to document any investigation into those red flags in the patient profiles, constitutes egregious misconduct because it allowed for the potential of unchecked diversion of controlled substances into illegitimate channels.

Finding that the Respondent's proven misconduct is egregious is warranted despite the fact that I only weighed the Government's evidence under Factor Four. The public interest factors are considered separately and any one or combination of factors may be considered when weighing the evidence. *Robert A. Leslie, M.D.*, 68 Fed. Reg. at 15230 (citation omitted). It is not necessary that a sanction be supported by findings under each factor. *Hoxie v. DEA*, 419 F.3d at 482; *Morall*, 412 F.3d at 173. It is also not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick v. DEA*, 861 F.2d at 76. The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest." *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. at 462. Thus, I find that sanction is justified and that the Respondent's conduct was egregious even though the evidence was only weighed under a single

factor.

In addition to the severity of the Respondent's dispensing misconduct, the Respondent also unlawfully manufactured thousands of capsules of schedule II controlled substances without being registered with the DEA as a manufacturer. As noted earlier, registered manufacturers of controlled substances are held to higher standards than practitioners with respect to recordkeeping, reporting, security, and frequency of renewing registration. Thus, manufacturing controlled substances without the DEA's blessing enabled the Respondent to produce thousands of dosage units of controlled substances over several years in the absence of regulatory monitoring. As with unlawful dispensing, unlawful manufacturing is an egregious violation and warrants the revocation of registration.

I further find that deterrence considerations weigh in favor of revocation. Allowing the Respondent to retain its COR despite the proven misconduct would send the wrong message to the regulated community. Imposing a sanction less than revocation would create the impression that registrants can maintain DEA registration despite repeatedly failing to resolve and document the resolution of red flags in accordance with state law, and despite engaging in a regulated activity without obtaining approval from the DEA to engage in that activity. Revoking the Respondent's COR communicates to registrants that the DEA takes all failings under the CSA seriously and that severe violations will result in severe sanctions.

Advice of Counsel

When the DEA executed an AIW at the Respondent in September 2018, the Respondent's owner and pharmacist-in-charge, Mr. Clement, Sr., refused to speak to DI Albert upon advice of counsel to not answer any questions. Tr. 168, 173, 177. The Respondent has an absolute right to seek advice of counsel, and no adverse inference from obtaining advice of counsel may be drawn. It does not provide,

however, any defense to actions taken, including failing to eventually respond to DEA inquiries following consultation with counsel, or lack of cooperation with the DEA's investigation.

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Acting Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008).

There is no evidence that suggests the Respondent has learned any lessons from its misconduct. As just discussed, the Respondent does not appear to believe it has done anything wrong. And the Government's evidence proves violations that occurred within the past few years, allowing a significant lapse of time for the Respondent to reform its ways.

These actions do not engender trust. The Respondent's failure to accept responsibility and present remediation evidence has convinced this Tribunal that the DEA cannot trust Respondent with the obligations of a DEA registration. Furthermore, on two occasions the Respondent exhibited a lack of trustworthiness. First, in May 2017, the Respondent's owner directed his wife to ask a DEA Diversion Investigator to leave the pharmacy during an inspection. Tr. 27. Secondly, during execution of an AIW in September 2018, the Respondent's owner refused to answer the same Diversion Investigator's questions upon advice of counsel. Tr. 168, 173, 177. As just noted, the Respondent is entitled to rely upon the advice of counsel; however, relying on advice of counsel cannot serve as a defense to actions taken, such as refusing to cooperate with the DEA's investigation. Both of these instances demonstrate a concerning reluctance on the Respondent's

part to work with the DEA in correcting its transgressions. If the DEA cannot trust the Respondent to cooperate with its investigators, it is hard to trust that it will take its duties under the CSA seriously. *See Satinder Dang, M.D.*, 76 Fed. Reg. 51424, 51425 (2011) (noting the ALJ determined a respondent's lack of cooperation with DEA investigators weighed against the respondent); *Kimberly Maloney, N.P.*, 76 Fed. Reg. 60922, 60929 n.25 (2011) (noting respondent's cooperation with investigators weighed in her favor). Thus, I find that the Respondent has lost a significant amount of trust and has failed to overcome that loss of trust by demonstrating to the Agency that it can be relied upon to lawfully discharge it's COR obligations.

RECOMMENDATION

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. Furthermore, I find that the Respondent has not accepted responsibility, or presented sufficient evidence demonstrating that the Agency can entrust it with a COR.

Therefore, I recommend that the Respondent's DEA COR No. FP2302076 should be **REVOKED**, and that any pending applications for modification or renewal of the existing registration, and any applications for additional registrations, be **DENIED.**

Signed: May 5, 2020

Mark M. Dowd
MARK M. DOWD
U.S. Administrative Law Judge

Certificate of Service

This is to certify that the undersigned, on May 5, 2020, caused a copy of the foregoing to be delivered to the following recipients: (1) John Beerbower, Esq., Counsel for the Government, via email to the DEA Government Mailbox at dea.registration.litigation@usdoj.gov; and (2) Dale R. Sisco, Esq., Sisco-Law, Counsel for the Respondent, via email at dsisco@sisco-law.com.

Bella A. Mapeso
Bella Mapeso, Secretary
Office of Administrative Law Judges