blamed others, and has no concrete remedial plan. Given these facts, the tribunal can only conclude that granting Respondent a COR would put the public at risk of Respondent's previous fraudulent behavior. Moreover, with respect to general deterrence, the Agency bears the responsibility to deter conduct similar to Respondent's past misconduct. *Ruben,* 78 FR at 38385. Granting a COR to an applicant who has neither unequivocally taken responsibility for his misconduct, nor demonstrated sufficient remedial measures to ensure such conduct will not happen again, would send a message to all that there will be few consequences to defrauding federal health care programs.

C. Egregiousness

Finally, this tribunal finds that Respondent's behavior was egregious. While Respondent did not divert controlled substances, defrauding federal health care programs is egregious. *See Stein,* 84 FR at 46973 (finding that the respondent's actions were egregious because he defrauded the government of taxes and misused his position of trust); *Ramirez-Gonzalez,* 58 FR at 52788 (''fraud perpetrated by the respondent casts doubt upon his integrity, and as such supports an action against his registration''); *Osafo,* 58 FR at 37509 (''Respondent's submission of fraudulent medical claims and subsequent convictions of larceny indicated that Respondent placed monetary gain above the welfare of his patients, and in so doing, endangered the public health and safety.''). Respondent engaged in a four-year conspiracy to defraud federal health care programs and the cost of that fraud, as reflected in the restitution amount imposed at his sentencing, was $5,991,417.13. Tr. 71–73; Gov. Ex. 5 at 2–5.

Moreover, the Agency ''relies heavily on a registrant's honesty and integrity 'to complete its mission of preventing diversion within such a large regulated population.' '' *Michael Jones, M.D.,* 86 FR 20728, 20731 (2021) (quoting *Stein,* 84 FR at 46974). ''Because DEA depends on the integrity of those it entrusts with controlled substance privileges, it takes a close look at a registrant's fraudulent activity.'' *Jones,* 86 FR at 20731 (citing *Ramirez-Gonzalez,* 58 FR at 52788). Even if the fraud does not involve controlled substances, ''fraudulent activity indicates that a registrant places monetary gain above the welfare of his patients, and in so doing, endangers the public health and safety.'' *Jones,* 86 FR at 20731–32 (internal quotations omitted); *see also Osafo,* 58 FR at 37509. Respondent's behavior demonstrates that he lacks integrity and cannot be trusted. In particular, his admission that he ''was not 100 percent truthful on [being a manager]'' when he pleaded guilty under oath (Tr. 100) is stark proof that the Agency cannot rely on Respondent's honesty as a registrant. His lack of remorse and acceptance of responsibility further shows that he does not recognize the seriousness of his actions, so he should not be entrusted with a COR.

Accordingly, it is herein respectfully recommended that Respondent's application for a DEA registration be *denied.*

Dated: October 12, 2021.

Teresa A. Wallbaum,

Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824 and 823(f), I hereby deny the pending application for a Certificate of Registration, Control Number W20055916C, submitted by Gilbert Y. Kim, D.D.S. as well as any other pending application of Gilbert Y. Kim, D.D.S. for additional registration in New York. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07717 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

George Pharmacy, Inc.; Decision and Order

On August 1, 2019, a former Acting Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to George Pharmacy, Inc. (hereinafter, Registrant) of Dayton Beach, Florida. Government's Request for Final Agency Action (hereinafter, RFAA) Exhibit 1 (OSC). The OSC informed Registrant of the immediate suspension of its DEA Certificate of Registration Number FG5612127 (hereinafter, registration or COR) and proposed its revocation, the denial of any pending applications for renewal or modification of such registration, and the denial of any pending applications for additional DEA registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because Registrant's ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4) and 823(f)).

The OSC notified Registrant of its right to request a hearing on the allegations or to submit a written statement while waiving its right to a hearing, the procedures for electing either option, and the consequence of failing to elect either option. *Id.* at 10–11 (citing 21 CFR 1301.43).

In response to the OSC, Registrant filed a timely request for an administrative hearing. RFAAX 3 (Request for Hearing). After both parties filed prehearing statements, and Registrant moved to continue the hearing, the Chief Administrative Law Judge (hereinafter, Chief ALJ), set a hearing date of December 17, 2019, in Arlington, Virginia. RFAAX 4. On December 12, 2019, Registrant filed a motion to terminate proceedings, stating that Registrant ''respectfully withdraws its prior request for hearing and desires that the administrative hearing presently scheduled be cancelled, and the proceedings terminated.'' RFAAX 5. On the same day, the Chief ALJ granted Registrant's motion and cancelled the hearing. RFAAX 6.

On March 12, 2020, the Government forwarded an RFAA, along with the evidentiary record for this matter, to my office. Having considered the record in its entirety, I find that the record establishes, by substantial evidence, that Registrant committed acts rendering its continued registration inconsistent with the public interest. I further find that Registrant's conduct was egregious, and that Registrant's failure to respond to the Government's allegations weighs strongly against continuation of its registration. Accordingly, I conclude that the appropriate sanction is the revocation of Registrant's DEA registration.

I. Findings of Fact

A. Registrant's DEA Registration

Registrant was registered with DEA as a retail pharmacy in Schedules II through V under DEA registration number FG5612127, at the registered address of 948 Orange Avenue, Dayton Beach, Florida 32114–0000. RFAAX 8 (DEA Certificate of Registration). According to Agency records, this registration expired on February 28, 2019. *Id.*[1]

[1] Although Registrant's COR has expired, the Agency has discretion to adjudicate this Order to Show Cause to finality. *See Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68479 (2019) (declining to dismiss an immediate suspension order as moot when the registrant allowed the subject registration to expire before final adjudication). As my predecessor identified in *Olsen,* ''[b]ecause nothing in the CSA

Continued

B. Government's Allegation That Registrant Dispensed Controlled Substances Unlawfully

In its RFAA, the Government alleged that Registrant violated federal and state law by ''fill[ing] prescriptions outside the usual course of professional practice and in violation of the minimum standard of care that governs the practice of pharmacy in the State of Florida.'' RFAAX 1, at 3. Specifically, the Government alleged that for a three-year period from December 12, 2016, to March 26, 2019, Registrant repeatedly filled controlled substance prescriptions for numerous patients without addressing or resolving red flags of drug abuse or diversion. *Id.*

To support this allegation, the Government submitted declarations of the DEA Diversion Investigator (hereinafter, DI) [2] and Group Supervisor (hereinafter, GS),[3] who were assigned to the investigation of Registrant, as well as a declaration of Dr. Thomas Hamilton, who was retained by the Government to opine on Registrant's dispensing patterns. *See* RFAAX 9 (Declaration of DI); RFAAX 10 (Declaration of GS); RFAAX 11 (Declaration of Dr. Thomas Hamilton). The Government also submitted copies of administrative subpoenas, prescription data, patient profiles, and google maps printouts showing the distances traveled by Registrant's customers. RFAAX 9, at App'x A–AY.

1. The Investigation

DI's and GS's declarations summarize DEA's investigation, including DEA's onsite inspections, subpoena requests, and meetings with Registrant.

i. October 31, 2018 Onsite Inspection

On October 31, 2018, GS, DI, and two additional DIs performed an onsite inspection of Registrant. RFAAX 9, at 1–3; RFAAX 10, at 1–2.[4] They spoke to Vivian Khalil, Registrant's owner, and Maher Hanna, Registrant's pharmacist-in-charge. *Id.* According to GS and DI, DEA asked Mr. Hanna to explain how Registrant resolves red flags. *Id.* Mr. Hanna stated that before filling a prescription, someone will obtain a copy of the patient's identification, contact the doctor's office to verify the prescription, check the patient's information on Florida's Prescription Data Monitoring Program (E–FORSCE), and check that the prescribing doctor's license is valid on the Florida Department of Health (hereinafter, DOH) website. *Id.* He stated that someone would make notes on the back of the prescription (including indicating who verified the prescription) and attach a printed copy of the patient's E–FORSCE report to the prescription. *Id.* All of the due diligence that Registrant's pharmacists perform is noted on the back of the prescriptions. *Id.* As long as the physician's license is legitimate, Registrant would fill the prescription. *Id.* Mr. Hanna asked the DEA what other red flags would have to be addressed ''if the doctor is legitimate and the script is legitimate.'' *Id.* Mr. Hanna stated that checking E–FORSCE and DOH was enough due diligence. *Id.*

According to GS and DI, DEA warned Mr. Hanna that Registrant had been filling prescriptions for controlled substances in the face of obvious red flags of abuse and diversion. *Id.* DEA also questioned Mr. Hanna and Mrs. Khalil about the high cash payments made by Registrant's patients, as well as the long distances traveled by Registrant's customers to obtain and fill their prescriptions. *Id.* DEA also warned Mr. Hanna and Mrs. Khalil about the large quantities of hydromorphone prescriptions that Registrant purchased. *Id.* In response, Mr. Hanna and Mrs. Khalil asked for one more chance and the opportunity to take continuing education classes. *Id.*

ii. November 2018 Administrative Subpoena

On November 7, 2018, DEA served an administrative subpoena on Registrant for pharmacy records and patient profiles, including but not limited to due diligence documentation, prescriptions, electronic dispensing logs, and other files related to the dispensing of controlled substances for certain patients between November 1, 2015, and October 31, 2018. RFAAX 9, App'x B (November 2018 Administrative Subpoena). In approximately February 2019, DEA hired Dr. Thomas E. Hamilton as a pharmacy expert in this case. *Id.* at 3. DEA provided Dr. Hamilton with Registrant's dispensing log, prescriptions, patient profiles, and E–FORSCE reports for the patients listed in the November 7, 2018 subpoena. *Id.*

iii. March 12, 2019 Meeting With Registrant

On March 12, 2019, GS, DI, and another DI visited Registrant again and spoke with both Mrs. Khalil and Mr. Hanna. RFAAX 9, at 3–4; RFAAX 10, at 3. At this meeting, DI told Mrs. Khalil and Mr. Hanna that DEA had hired a Florida pharmacy expert to review prescriptions and patient profiles of some of Registrant's customers. *Id.* DI explained Dr. Hamilton's expert opinion about Registrant's dispensing behavior. *Id.* In particular, DI stated that Dr. Hamilton had identified numerous red flags with many of the prescriptions that Registrant had filled, and found no documentation supporting adequate resolution of these red flags. *Id.* In response, Mr. Hanna informed DI that Registrant had stopped filling prescriptions for those patients whose prescriptions were the subject of Dr. Hamilton's opinion (including Patients J.Y., J.S., C.A., L.K., A.O., M.S., M.J., A.M., K.S., and L.S.). *Id.*

DI told Mr. Hanna and Mrs. Khalil that DEA was pursuing administrative action for the revocation of Registrant's COR and asked them to surrender Registrant's COR. *Id.* Mr. Hanna and Mrs. Khalil refused to surrender. *Id.*

iv. Further Investigation in April and July 2019

Upon reviewing Registrant's E–FORSCE report, DEA identified several additional customers whose prescriptions presented red flags of abuse and diversion, such as large cash payments and long distances traveled. *See* RFAAX 9, at 4–5. DEA served additional administrative subpoenas and performed additional onsite inspections in order to obtain documents related to Registrant's dispensing to those additional patients. *Id.* at App'x C (April 22, 2019 Notice of Inspection Form); App'x D (July 15, 2019 Administrative Subpoena); App'x E (July 23, 2019 Notice of Inspection Form). DEA provided these additional materials to Dr. Hamilton. *Id.* at 5.

prohibits an individual or an entity from applying for a registration even when there is . . . a history of having a registration suspended or revoked[,]. . . . having a final, official record of allegations, evidence, and the Administrator's decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.'' *Id.* Here, absent a final adjudication, there would be no final record of the allegations and evidence from this matter. Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Registrant's owners, employees, or other persons who were associated with Registrant. Moreover, ''a final adjudication is a public record of the Agency's expectations for current and prospective members of that community,'' which ''helps current and prospective registrants comply with the CSA and avoid ISOs/OSCs.'' *Id.*

[2] DI has been a DI for approximately two years. RFAAX 10, at 1. She was originally assigned to the Orlando District Office, but is currently assigned to the Jacksonville District Office. *Id.*

[3] GS has worked for DEA for approximately 30 years and has been a GS for approximately two years. RFAAX 10, at 1. He is currently assigned to the Orlando District Office of the Miami Field Division. *Id.*

[4] DEA presented Registrant with a Notice of Inspection Form, which Registrant signed. RFAAX 9, App'x A.

2. Dr. Hamilton's Unrebutted Expert Opinion

Dr. Hamilton is a doctor of pharmacy with 19 years of experience as a pharmacist. RFAAX 11, at 2, App'x A. He received his Doctor of Pharmacy from Nova Southeastern University in May 1999 and was licensed by the Florida Board of Pharmacy in August 1999. *Id.* He is also a member of the Broward County Pharmacy Association. *Id.*

Dr. Hamilton currently works as a full-time pharmacy manager with Publix Supermarkets and has worked for Publix for most of his career. RFAAX 11, at 1. His responsibilities include ensuring that the pharmacy follows all federal, state, and local regulations; overseeing the ordering and quality of inventory; reviewing patient records; reviewing prescriptions to ensure accuracy and identify possible interactions; and dispensing prescribed medications for patient care. *Id.* He also provides information to pharmacy customers regarding drug interactions, side effects, and proper dosage, and monitors patient profiles. *Id.*

From February 2006 until April 2014, Dr. Hamilton was a pharmacy supervisor with Publix Supermarkets, where he was responsible for the operation of 40 pharmacies. *Id.* During this time, his responsibilities consisted of opening new stores and ensuring that staff was properly trained and operating within the rules and standards set forth by the Florida Board of Pharmacy. *Id.* He was also involved in the analysis, evaluation, and purchase of other retail pharmacies from Key West to West Palm Beach. *Id.* While evaluating pharmacies, he inspected several key areas including their inventory, invoices, sales, and purchasing habits. *Id.*

i. Corresponding Responsibility and Course of Professional Practice in Florida

Dr. Hamilton opined that pharmacists have a corresponding responsibility to ensure that a prescription for a controlled substance is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. *Id.* at 2 (referencing 21 CFR 1306.04 (2022). Dr. Hamilton also opined that Florida pharmacists must ''exercise[e] sound professional judgment'' and ''attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.'' *Id.* (referencing Fla. Admin. Code r. 64B16–27.831) (2022).[5] Additionally, Florida pharmacists must review every new and refill prescription to identify red flags of abuse and diversion, such as (a) Over-utilization or under-utilization; (b) Therapeutic duplication; (c) Drug-disease contraindications; (d) Drug-drug interactions; (e) Incorrect drug dosage or duration of drug treatment; (f) Drug-allergy interactions; (g) Clinical abuse/misuse. *Id.* (referencing Fla. Admin. Code r. 64B16–27.810 (2022)).[6]

Dr. Hamilton identified additional red flags that pharmacists must ''address or resolve'' prior to filling a prescription, including long distances traveled, cocktail medications, cash payments at inflated prices, inappropriate drug dosages and durations of treatment, and pattern prescribing. *Id.* at 3–5.

Long Distances Traveled

Dr. Hamilton opined that patients traveling extremely long distances to obtain or fill their controlled substances prescriptions is a well-known red flag of abuse or diversion that Florida pharmacists must ''address or resolve.'' *Id.* at 3.

Cocktail Medications

Dr. Hamilton opined that another common red flag of abuse that Florida pharmacists must ''address or resolve'' is when a physician prescribes ''cocktail medications.'' *Id.* He explained that cocktail medications are potent combinations of controlled substances that are widely known to be abused or diverted. *Id.* He further explained that one well-known cocktail medication is the ''Trinity'' cocktail, which is a combination of opioids (Schedule II controlled substances), benzodiazepines (Schedule IV controlled substances, such as alprazolam and clonazepam), and muscle relaxants (Schedule IV controlled substances, such as carisoprodol, or non-controlled drugs such as cyclobenzaprine). *Id.* Dr. Hamilton opined that these drugs are widely known to be abused, because when taken together, their pharmacological impact is similar to heroin. *Id.*

Cash Payments at Inflated Prices

Dr. Hamilton opined that another red flag of abuse or diversion that Florida pharmacists must ''address or resolve'' is when patients are willing to pay inflated prices for their prescriptions with cash. *Id.* He explained that when a patient is willing to pay for their prescriptions at prices that exceed what other pharmacies would charge, a Florida pharmacist must be concerned that it is dispensing controlled substances to someone who is abusing or diverting the drugs. *Id.* Dr. Hamilton opined that a reasonable Florida pharmacist must also be suspicious for the same reasons when patients are paying cash for a large quantity of controlled substances. *Id.* He explained that between 2017 and 2019, other pharmacies in Florida sold hydromorphone for approximately $1.60 per pill and oxycodone for approximately $1.40[7] per pill. *Id.* Therefore, he opined that patients willing to pay in cash well above those prices is a red flag of abuse or diversion that Florida pharmacists must address or resolve. *Id.* For example, as discussed in more detail below, Registrant's customers often paid more than five times the prices charged at other Florida pharmacies, which Dr. Hamilton determined to be a red flag. *See supra,* I.B.2.ii. Dr. Hamilton opined that customers taking prescriptions for legitimate medical needs would not pay such extreme prices for medication that could have been purchased elsewhere for a fraction of the amount. *Id.* at 3–4.

Inappropriate Drug Dosages and Durations of Treatment

Dr. Hamilton opined that Florida pharmacists must review patient records and prescriptions for inappropriate drug dosages and durations of treatment before dispensing controlled substances. *Id.* at 4 (referencing Fla. Admin. Code r. 64B16–27.810). He explained that this is based upon the pharmacist's obligation to promote the therapeutic appropriateness of prescribed medication. *Id.*

Dr. Hamilton opined that Patients receiving prescriptions for immediate-release opioids, such as hydromorphone and oxycodone, for several months at a time is a red flag of abuse or diversion.

[5] This rule was amended in 2018, during the timeframe that relevant misconduct in this case took place; however, there were no relevant, substantive modifications to this regulation in 2018.

[6] There were no substantive changes to the relevant portions of Fla. Admin. Code r. 64B16–27.810 (2022) during the time period of the allegations in this case.

[7] Dr. Hamilton's Declaration does not identify supporting sources for his findings as to the average prices of these controlled substances; however, Dr. Hamilton's opinions in this matter were based on his 19 years of training and experience as a Florida pharmacist. RFAAX 11, at 1. As a pharmacy supervisor with Publix Supermarkets for eight years, Dr. Hamilton operated 40 Publix pharmacies and opened new Publix pharmacies. *Id.* He was also involved in evaluating other Florida retail pharmacies for potential purchase, which included ''inspect[ing] key areas including their inventory, invoices, sales, and purchasing habits.'' *Id.* There is no evidence to rebut Dr. Hamilton's opinions regarding average prices. Additionally, as explained further below, the differences in the prices charged by Registrant are so vastly in excess of the average prices identified by Dr. Hamilton that I find that the evidence weighs in favor of a finding that Registrant was charging excessive prices.

Id. He explained that this is because immediate-release medication should only be used to treat short-term, acute pain, and patients with legitimate chronic pain would eventually be switched to safer, long-term pain medication. *Id.* Moreover, Dr. Hamilton opined that Florida pharmacists should also address and resolve the red flag of patients receiving large quantities of opioids at their highest available strengths. *Id.* He explained that the Centers for Disease Control and Prevention (CDC) recommends avoiding or carefully adjusting Morphine Milligram Equivalent (MME) dosages prescribed beyond 90 mg a day. *Id.*

Dr. Hamilton opined that opiate-naive patients receiving more than 24 mg per day of hydromorphone (96 MME) or more than 80 mg per day of oxycodone (120 MME) is a red flag of abuse or diversion. *Id.* He explained that starting dosages this high are potentially lethal for opiate-naive patients. *Id.*

Pattern Prescribing

Dr. Hamilton opined that another common red flag of abuse or diversion that Florida pharmacists must address before filling is ''pattern prescribing,'' which refers to a physician who regularly prescribes common drugs of abuse or diversion in the same dosages and quantities to many patients sharing the same surnames and/or addresses, and uses the same diagnosis codes to justify these prescriptions. *Id.* at 5. He explained that ''pattern prescribing'' is a red flag of abuse or diversion because it indicates that the physician is focused on distributing drugs with high street value rather than on examining his patients and developing individualized treatment plans. *Id.*

Dr. Hamilton opined that the manner in which a Florida pharmacist addresses and resolves red flags of abuse or diversion must be documented on the prescription and/or in the patient's profile. *Id.* He explained that Florida pharmacists must maintain a patient record system, or patient profile, that documents how the pharmacists resolved the red flags of abuse or diversion. *Id.* (referencing Fla. Admin. Code r. 64B16–27.800 (2022)).[8]

ii. Dr. Hamilton's Opinion That Registrant Repeatedly Dispensed Controlled Substances Outside the Usual Course of Professional Practice

Dr. Hamilton reviewed prescriptions, patient profiles, and E–FORSCE reports for Registrant's customers J.Y., J.S., C.A., L.K., A.O., M.S., B.B., E.R., S.R., M.J., C.K., K.L., A.M., K.S., and L.S. *Id.* (referencing RFAAX 9, at App'x F–AX). Dr. Hamilton opined that each prescription that he reviewed presented red flags of abuse and diversion, and that Registrant failed to address these red flags on the customers' prescriptions or in their patient profiles. *Id.* Dr. Hamilton concluded that Registrant failed to follow the minimum requirements for Florida pharmacists, and therefore acted outside the usual course of professional practice in filling each prescription. *Id.*

J.Y.

Registrant filled the following three prescriptions for J.Y. on six separate occasions from January 13, 2017, to June 30, 2017: (1) 112 tablets of hydromorphone 8 mg, (2) 28 tablets of morphine sulfate extended release (ER) 30 mg, and (3) 28 tablets of clonazepam 2 mg. RFAAX 9, at App'x H (Prescriptions for J.Y.); *see also id.* at App'x G (J.Y.'s E–FORSCE report), App'x F (J.Y.'s Patient Profile).[9] On each occasion, Registrant also dispensed cyclobenzaprine, which is a non-controlled muscle relaxant. *Id.* at App'x H. Dr. Hamilton opined that J.Y.'s prescriptions presented the red flags of cocktail medications and long distances traveled. RFAAX 11, at 6–7.

Dr. Hamilton opined that it was a red flag that Registrant dispensed the widely-abused ''Trinity'' cocktail on each occasion specified above. *Id.* at 6. In this case, the ''Trinity'' cocktail consisted of two opioids (hydromorphone and morphine sulfate ER), a benzodiazepine (clonazepam), and a muscle relaxant (cyclobenzaprine),[10] all of which were prescribed by the same prescriber. *Id.* Additionally, Dr. Hamilton opined that it was a red flag that J.Y. traveled at least 106 miles roundtrip to obtain and fill her prescriptions. *Id.* J.Y.'s residence was at least 53 miles from her doctor's office and 37 miles from Registrant, and her doctor's office was approximately 16 miles from Registrant. RFAAX 9, at 11, App'x AY; *see also* RFAAX 11, at 6.

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on J.Y.'s prescriptions or patient profile. RFAAX 11, at 7. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

J.S.

On 12 separate occasions between February 23, 2017, and June 1, 2018, Registrant filled prescriptions for J.S. for 90 tablets of oxycodone 30 mg. RFAAX 9, at App'x K (Prescriptions for J.S.); *see also id.* at App'x I (J.S.'s patient profile), App'x J (J.S.'s E–FORSCE report).[11] Additionally, on at least nine occasions between November 30, 2017, and August 30, 2018, Registrant filled prescriptions for J.S. for 150 tablets of oxycodone-acetaminophen 10/325 mg and a range of 30 to 60 tablets of carisoprodol 350 mg within the same month. *Id.*[12] On at least six of these occasions, Registrant dispensed both of the prescriptions within two or fewer days of each other. *Id.*

Dr. Hamilton opined that J.S.'s prescriptions presented the red flags of cocktail medications and cash payments at inflated prices. RFAAX 11, at 7–8. Dr. Hamilton opined that it was a red flag that Registrant repeatedly filled prescriptions for J.S. for oxycodone-acetaminophen (an opioid) and carisoprodol (a muscle relaxant), even though J.S. was filling prescriptions for benzodiazepines at another pharmacy during the same timeframe. *Id.* at 7. Thus, J.S. was receiving the ''Trinity'' cocktail, and on several occasions, all three prescriptions were written by the same prescriber. *Id.* Additionally, Dr. Hamilton opined that it was also a red flag that J.S. paid approximately $903 in cash for 90 tablets of oxycodone 30 mg on at least 12 occasions, which amounted to approximately $10.03 per tablet. *Id.* Dr. Hamilton opined that

[8] There were no substantive changes to the relevant portions of Fla. Admin. Code r. 64B16–27.800 (2022) during the time period of the allegations in this case.

[9] These prescriptions were filled on January 13, February 10, March 10, April 7, May 5, and June 30, 2017. *Id.*

[10] Cyclobenzaprine is not a controlled substance. Therefore, it is only relevant to my Decision to the extent that Dr. Hamilton opined that is potentially dangerous to prescribe cyclobenzaprine concurrently with opioids and benzodiazepines, and that Registrant should have addressed and resolved this red flag before filling the controlled substance prescriptions.

[11] These prescriptions were filled on February 23, March 27, April 26, May 23, June 20, July 18, August 15, September 7, October 6, and November 2, 2017; and February 23, and June 1, 2018. *Id.*

[12] These prescriptions were filled on November 30, 2017 (150 tablets of oxycodone-acetaminophen 10-325 mg and 30 tablets of carisoprodol 350 mg); December 22, 2017 (150 tablets of oxycodone-acetaminophen 10-325 mg and 60 tablets of carisoprodol 350 mg); January 12, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); January 19, 2018 (60 tablets of carisoprodol 350 mg); February 2, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); February 16, 2018 (60 tablets of carisoprodol 350 mg); March 22, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg and 60 tablets of carisoprodol 350 mg); May 8, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); May 10, 2018 (60 tablets of carisoprodol 350 mg); June 27, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg and 60 tablets of carisoprodol 350 mg); July 23, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); July 24, 2018 (30 tablets of carisoprodol 350 mg); August 17, 2018 (150 tablets of oxycodone-acetaminophen 10-325 mg); and August 30, 2018 (60 tablets of carisoprodol 350 mg). *Id.*

other pharmacies charge approximately $1.40 per tablet, which is approximately seven times less than what J.S. paid. *Id.* at 8.

Finally, on at least 11 occasions between November 30, 2017, and October 1, 2018, Registrant filled a range of 120 to 150 tablets of oxycodone-acetaminophen 10–325 mg for two patients with the same address and same surname, J.S. and L.S., within 14 days of each other. RFAAX 9, at App'x I, J, K, AV, AW, AX.[13] On at least seven occasions, the prescriptions were issued on the same day. *Id.*[14] Dr. Hamilton opined that these prescriptions were indicative of pattern prescribing. RFAAX 11, at 8.

Dr. Hamilton did not find any evidence that Registrant addressed the red flags of abuse or diversion on J.S.'s prescriptions or patient profile. *Id.* Dr. Hamilton also opined that there was no justification for Registrant to have repeatedly filled prescriptions written by a pattern-prescribing physician. *Id.* Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

C.A.

Between April 3, 2017, and February 26, 2018, Registrant filled 11 prescriptions for C.A. for a range of 84 to 112 tablets of hydromorphone 8 mg. RFAAX 9, at App'x N (C.A.'s Prescriptions); *see also id.* at App'x M (C.A.'s E–FORSCE report), App'x L (C.A.'s patient profile).[15] Dr. Hamilton opined that C.A.'s prescriptions presented the red flags of long distances traveled and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 9.

Dr. Hamilton opined that it was a red flag that C.A. traveled at least 107 miles roundtrip to obtain and fill her prescriptions. *Id.* C.A.'s residence was at least 37 miles from her doctor's office and 20 miles from Registrant, and her doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 11–12, App'x AY; *see also* RFAAX 11, at 9. Dr. Hamilton also opined that it was a red flag that C.A. received a large quantity of an immediate-release opioid at the highest available strength for nearly 11 months, in a dosage that amounted to approximately 96 to 158.12 MME per day. RFAAX 11, at 9. Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on C.A.'s prescriptions or patient profile. *Id.* at 9–10. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

L.K.

Registrant filled 18 prescriptions for L.K. for a range of 112 to 126 tablets of hydromorphone 8 mg from January 9, 2017, to May 2, 2018. RFAAX 9, at App'x Q (L.K.'s Prescriptions); *see also id.* at App'x P (L.K.'s E–FORSCE Report), App'x O (L.K.'s Patient Profile).[16] Dr. Hamilton opined that L.K.'s prescriptions presented the red flags of long distances traveled, cash payments at inflated prices, and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 10–11.

Dr. Hamilton opined that it was a red flag that L.K. traveled at least 120 miles roundtrip to obtain and fill his prescriptions. *Id.* L.K.'s residence was at least 27 miles from his doctor's office and 57 miles from Registrant, and his doctor's office was approximately 36 miles from Registrant. RFAAX 9, at 12, App'x AY; *see also* RFAAX 11, at 10. Dr. Hamilton also opined that it was a red flag that L.K. received the highest available strength of hydromorphone for approximately 16 months, which amounted to approximately 128 to 161.28 MME per day. RFAAX 11, at 11. Finally, Dr. Hamilton opined that it was a red flag that J.S. paid between $1,150 and $1,294 in cash for each prescription, or $10.27 per tablet. *Id.* at 10. Dr. Hamilton opined that other pharmacies charge approximately $1.60 per tablet for hydromorphone, which is approximately six times less than what L.K. paid. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on L.K.'s prescriptions or patients profile. *Id.* at 11. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

A.O.

On November 13, 2017, Registrant filled a prescription for A.O. for 112 tablets of oxycodone 30 mg. RFAAX 9, at App'x T (A.O.'s Prescriptions); *see also id.* at App'x S (A.O.'s E–FORSCE Report), App'x R (A.O.'s Patient Profile). On December 18, 2017, Registrant filled a prescription for A.O. for 140 tablets of oxycodone 30 mg. *Id.* Dr. Hamilton opined that it was a red flag that A.O. traveled at least 380 miles roundtrip to obtain and fill her prescriptions. *Id.* A.O.'s residence was at least 67 miles from her doctor's office and 194 miles from Registrant, and her doctor's office was approximately 128 miles from Registrant. RFAAX 9, at 12, App'x AY; *see also* RFAAX 11, at 11–12. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on A.O.'s prescriptions or patient profile. RFAAX 11, at 12. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

M.S.

Between April 7, 2017, and December 15, 2017, Registrant filled 11 prescriptions for M.S. for a range of 60 to 112 tablets of hydromorphone 8 mg. RFAAX 9, at App'x W (M.S.'s Prescriptions); *see also id.* at App'x V (M.S.'s E–FORSCE Report), App'x U (M.S.'s Patient Profile).[17] Dr. Hamilton opined that M.S.'s prescriptions presented the red flags of long distances traveled and cash payments at inflated prices. RFAAX 11, at 12–13.

Dr. Hamilton opined that it was a red flag that M.S. traveled at least 548 miles roundtrip to obtain and fill his prescriptions. *Id.* M.S.'s residence was at least 242 miles from his doctor's office and 258 miles from Registrant, and his doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 12, App'x AY; *see also* RFAAX 11, at 12. Additionally, Dr. Hamilton opined that it was a red flag that M.S. paid between $509 and $969 in cash for each prescription, or between $8.48 and $8.68 per tablet. RFAAX 11, at 12–13. Dr. Hamilton opined that other pharmacies charge approximately $1.60 per pill tablet for hydromorphone, which is approximately five times less than what M.S. paid. *Id.*

[13] These prescriptions were filled on November 30, 2017 (J.S. and L.S.); December 22, 2017 (J.S. and L.S.); January 12, 2018 (J.S.), and January 19, 2018 (L.S.); February 16, 2018 (L.S.), February 23, 2018 (J.S.); March 15, 2018 (L.S.), and March 22, 2018 (J.S.); April 13, 2018 (L.S.), and April 14, 2018 (J.S.); May 8, 2018 (J.S.), May 10, 2018 (L.S.); June 27, 2018 (J.S.), and July 6 (L.S.); July 23, 2018 (J.S.), and August 2, 2018 (L.S.); August 17, 2018 (J.S.), and August 30, 2018 (L.S.); September 21, 2018 (J.S.), and October 1, 2018 (L.S.). *Id.*

[14] The prescriptions were issued on the same day on November 30, 2017; December 22, 2017; February 2, 2018; February 22, 2018; April 16, 2018; June 26, 2018; and August 16, 2018. *Id.*

[15] These prescriptions were filled on April 3, May 4, June 2, June 30, July 28, August 25, September 22, October 19, November 15, 2017; and January 29 and February 26, 2018. *Id.*

[16] These prescriptions were filled on January 9, February 6, March 6, April 3, May 1, May 30, June 27, July 25, August 22, September 19, October 17, November 14, and December 12, 2017; and January 9, February 6, March 6, April 3, and May 2, 2018. *Id.*

[17] These prescriptions were filled on April 7, May 5, June 2, July 7, August 1, August 25, September 26, October 23, November 20, and December 15, 2017. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on M.S.'s prescriptions or patient profile. *Id.* at 12. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

B.B.

Between November 7, 2018, and March 26, 2019, Registrant filled six prescriptions for B.B. for a range of 84 to 100 tablets of oxycodone 30 mg. RFAAX 9, at App'x Z (B.B.'s Prescriptions); *see also id.* at App'x Y (B.B.'s E–FORSCE Report), App'x X (B.B.'s Patient Profile).[18] Dr. Hamilton opined that B.B.'s prescriptions presented the red flags of long distances traveled, cash payments at inflated prices, and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 13–14.

Dr. Hamilton opined that it was a red flag that B.B. traveled at least 101 miles roundtrip to obtain and fill his prescriptions. *Id.* B.B.'s residence was at least 34 miles from his doctor's office and 23 miles from Registrant, and his doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 12, App'x AY; RFAAX 11, at 13. Dr. Hamilton also opined that it was a red flag that B.B. received the highest available strength of oxycodone for nearly five months, which amounted to approximately 135 to 184.09 MME per day. RFAAX 11, at 13. Finally, Dr. Hamilton opined that it was a red flag that B.B. paid between $637 and $726 in cash for each prescription, or between $7.26 and $7.59 per tablet. *Id.* at 13–14. Dr. Hamilton opined that other pharmacies charge approximately $1.40 per tablet for oxycodone, which is approximately five times less than what B.B. paid. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on B.B.'s prescriptions or patient's profile. *Id.* at 14. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

E.R.

Between November 20, 2018, and March 18, 2019, Registrant filled five prescriptions for E.R. for 70 tablets of oxycodone 30 mg. RFAAX 9, at App'x AC (E.R.'s Prescriptions); *see also id.* at App'x AB (E.R.'s E–FORSCE Report), App'x AA (E.R.'s Patient Profile).[19] Dr. Hamilton opined that it was a red flag that M.S. traveled at least 158 miles roundtrip to obtain and fill his prescriptions. RFAAX 11, at 14–15. E.R.'s residence was at least 51 miles from her doctor's office and 24 miles from Registrant, and her doctor's office was approximately 73 miles from Registrant. RFAAX 9, at 13, App'x AY; *see also* RFAAX 11, at 14–15. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on E.R's prescriptions or in E.R.'s patient's profile. RFAAX 11, at 15. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

S.R.

Between November 2, 2018 and March 20, 2019, Registrant filled six prescriptions for S.R. for 100 tablets of hydromorphone 8 mg. RFAAX 9, at App'x AF (S.R.'s Prescriptions); *see also id.* at App'x AE (S.R.'s E–FORSCE Report), App'x AD (S.R.'s Patient Profile).[20] Dr. Hamilton opined that it was a red flag that S.R. traveled at least 108 miles roundtrip to obtain and fill her prescriptions. RFAAX 11, at 15–16. S.R.'s residence was at least 35 miles from her doctor's office and 23 miles from Registrant, and her doctor's office was approximately 50 miles from Registrant. RFAAX 9, at 13, App'x AY; RFAAX 11, at 15. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on S.R.'s prescriptions or patient profile. RFAAX 11, at 16. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

M.J.

Between January 31, 2017, and December 6, 2017, Registrant filled 12 prescriptions for M.J. for 112 tablets of hydromorphone 8 mg. RFAAX 9, at App'x AI (M.J.'s Prescriptions); *see also id.* at App'x AH (M.J.'s E–FORSCE Report), App'x AG (M.J.'s Patient Profile).[21] Dr. Hamilton opined that M.J.'s prescriptions presented the red flags of cash payments at inflated prices and long duration of treatment with high-dose, immediate-release opioids. RFAAX 11, at 16–17.

Dr. Hamilton opined that it was a red flag that M.J. received a large quantity of the highest available strength of hydromorphone for at least ten months, which amounted to approximately 128 MME per day. *Id.* at 16. Additionally, Dr. Hamilton opined that it was a red flag that M.J. paid between $919 and $967 in cash for each prescription, or between $8.20 and $8.63 per tablet. *Id.* Dr. Hamilton opined that other pharmacies charge approximately $1.60 per tablet for hydromorphone, which is approximately five times less than what M.J. paid. *Id.*

Dr. Hamilton did not see any evidence that Registrant addressed these red flags of abuse or diversion on M.J.'s prescriptions or patient's profile. *Id.* at 17. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

C.K.

Between November 6, 2018, and March 1, 2019, Registrant filled five prescriptions for C.K. for 84 tablets of oxycodone 30 mg. RFAAX 9, at App'x AL (C.K.'s Prescriptions); *see also id.* at App'x AK (C.K.'s E–FORSCE Report), App'x AJ (C.K.'s Patient Profile).[22] Dr. Hamilton opined that it was a red flag that C.K. paid $684 in cash for each prescription, or $8.14 per tablet. RFAAX 11, at 17. Dr. Hamilton opined that other pharmacies charge approximately $1.40 per tablet for oxycodone, which is approximately five times less than what C.K. paid. *Id.* Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on C.K.'s prescriptions or patient profile. *Id.* Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

K.L.

Between November 5, 2018, and March 25, 2019, Registrant filled six prescriptions for K.L. for 112 tablets of oxycodone 30 mg. RFAAX 9, at App'x AO (K.L.'s Prescriptions); *see also id.* at App'x AN (K.L.'s E–FORSCE Report), App'x AM (K.L.'s Patient Profile).[23] Dr. Hamilton opined that it was a red flag that K.L. received a large quantity of the highest available strength of oxycodone for nearly five months, which amounted to approximately 180 MME per day.

[18] These prescriptions were filled on November 7, December 4, 2018, January 4, January 29, February 26, and March 26, 2019. *Id.*

[19] These prescriptions were filled on November 20 and December 19, 2018, and January 16, February 19, and March 18, 2019. *Id.*

[20] These prescriptions were filled on November 2, November 29, and December 26, 2018; and January 24, February 20, and March 20, 2019.

[21] These prescriptions were filled on January 31, February 27, March 24, April 21, May 22, June 16, July 14, August 11, September 8, October 5, November 6, and December 6, 2017. *Id.*

[22] These prescriptions were filled on November 6 and December 4, 2018, and January 2, January 30, and March 1, 2019. *Id.*

[23] These prescriptions were filled on November 5, December 3, and December 31, 2018; and January 28, February 25, and March 25, 2019. *Id.*

RFAAX 11, at 18. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on K.L.'s prescriptions or patient profile. *Id.* Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

A.M.

On November 1, 2017, Registrant filled a prescription for A.M. for 112 tablets of hydromorphone 8 mg, at a starting dosage of 32 mg of hydromorphone per day (128 MME). RFAAX 11, at 18; RFAAX 9, at App'x AR (A.M.'s Prescriptions); *see also id.* at App'x AQ (A.M.'s E–FORSCE Report), App'x AP (A.M.'s Patient Profile). In the two years prior to filling this prescription, A.M. had not filled any opioid prescriptions in Florida. *See* RFAAX 9, at App'x AQ. Dr. Hamilton opined that this meant that A.M. was opiate naïve. RFAAX 11, at 18. Dr. Hamilton opined that it is a red flag for an opiate-naïve patient to receive more than 24 mg per day of hydromorphone (96 MME), because these doses could be potentially lethal. RFAAX 11, at 4. A.M.'s starting dose of 128 MME was well above 96 MME. RFAAX 11, at 18–19.

Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on A.M.'s prescriptions or in A.M's patient's profile. *Id.* at 19. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

K.S.

On September 21, 2017, Registrant filled a prescription for K.S. for 84 tablets of hydromorphone 8 mg, at a starting dosage of 32 mg of hydromorphone per day (128 MME). RFAAX 11, at 19; RFAAX 9, at App'x AU (K.S.'s Prescriptions); *see also id.* at App'x AT (K.S.'s E–FORSCE Report), App'x AS (K.S.'s Patient Profile). In the two years prior to filling this prescription, K.S. had only filled one opioid prescription in Florida, approximately six months before the September 21 prescription. *See* RFAAX 9, at App'x AT. Dr. Hamilton opined that this meant that K.S. was opiate naïve. RFAAX 11, at 19. Dr. Hamilton opined that it is a red flag for an opiate-naïve patient to receive more than 24 mg per day of hydromorphone (96 MME), because these doses could be potentially lethal. RFAAX 11, at 4. K.S.'s starting dose of 128 MME was well above 96 MME. *Id.* at 19. Dr. Hamilton did not see any evidence that Registrant addressed this red flag of abuse or diversion on K.S.'s prescriptions or patient profile. *Id.* at 19–20. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.*

L.S.

As discussed in more detail above, on at least 11 occasions between November 30, 2017, and October 1, 2018, Registrant filled a range of 120 to 150 tablets of oxycodone-acetaminophen 10–325 mg for two patients with the same address and same last name, J.S. and L.S., within 14 days of each other. RFAAX 9, at App'x AX (L.S.'s Prescriptions), App'x AW (L.S.'s E–FORSCE Report), App'x AV (L.S.'s Patient Profile). On at least seven occasions, the prescriptions were issued on the same day. *Id.* Dr. Hamilton opined that these prescriptions were written by a pattern-prescribing physician. RFAAX 11, at 8, 20.

Dr. Hamilton did not find any evidence that Registrant addressed this red flag on L.S.'s prescriptions or patient profile. *Id.* at 20. Dr. Hamilton also opined that there was no justification for Registrant to have repeatedly dispensed these prescriptions written by a pattern-prescribing physician. *Id.* at 8. Therefore, Dr. Hamilton opined that these prescriptions were filled outside the usual course of professional practice. *Id.* at 20.

II. Discussion

A. Registrant's Registration Is Inconsistent With the Public Interest

The Government alleged that Registrant's DEA registration should be revoked because Registrant committed acts that would render its registration inconsistent with the public interest as provided in 21 U.S.C. 823(f). The Government's case centers on Registrant's unlawful dispensing of controlled substances to 15 customers.

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

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant]'s experience in dispensing . . . controlled substances.

(3) The [registrant]'s conviction record under Federal or State laws relating to the . . . 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.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharm., LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). Accordingly, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

The Government has the burden of proving that the requirements for revocation of a DEA registration in 21 U.S.C. 824(a) are satisfied. 21 CFR 1301.44(e). When the Government has met its *prima facie* case, the burden then shifts to the registrant to show that revoking its registration would not be appropriate, given the totality of the facts and circumstances on the record. *Med. Shoppe-Jonesborough,* 73 FR 364, 387 (2008).

In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is most appropriately considered under Factors Two and

Four.[24] I find that the Government has satisfied its *prima facie* burden of showing that Registrant's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

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

In determining the public interest under Factors Two and Four, I consider evidence of Registrant's compliance (or non-compliance) with laws related to controlled substances and Registrant's experience dispensing controlled substances. The Government's case relies primarily on the actions of Registrant's dispensing pharmacists. Furthermore, the Agency ''has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee.'' *Perry Cty. Food & Drug,* 80 FR 70084, 70109 (2015) (citing *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Plaza Pharmacy,* 53 FR 36910, 36911 (1988)).

The Government alleged that Registrant violated federal and state laws related to controlled substances by repeatedly dispensing controlled substances to 15 customers without addressing or resolving red flags of drug abuse and diversion. OSC, at 2–3 (citing violations of 21 CFR 1306.06 and 1306.04(a); and Fla. Admin. Code. r. 64B16–27.800, 64B16–27.810, and 64B16–27.831).

i. Violations of Federal Law

According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). While the ''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.* The regulations establish the parameters of the pharmacy's corresponding responsibility:

> An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. ''The language in 21 CFR [§] 1306.04 and relevant caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990) (citing *United States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), cert. denied, 444 U.S. 866 (1979); *United States* v. *Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

To prove that a pharmacist violated his corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28667, 28670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR at 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Med. Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

In this case, I find that the Government has proven through Dr. Hamilton's unrebutted expert opinion that Registrant repeatedly filled prescriptions for controlled substances that presented obvious red flags of abuse or diversion, in violation of its corresponding responsibility under 21 CFR 1306.04(a), and outside the usual course of the professional practice of pharmacy in Florida, in violation of 21 CFR 1306.06. Registrant's customers traveled round-trip distances of up to 580 miles, paid enormous cash sums of up to $1,294, and presented prescriptions for high dosages and dangerous combinations of controlled substances, such as the ''Trinity'' cocktail, whose pharmacological effect is similar to heroin. *See supra* B.2.ii. Additionally, several of Registrant's customers presented prescriptions written by physicians who were pattern prescribing. *Id.* As discussed above, there is no evidence that Registrant made any attempt to address or resolve these red flags. *Id.* Agency decisions have consistently found based on credible expert testimony that prescriptions with similar red flags were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy.[25]

[24] In this case, I find that Factors One and Three weigh neither for nor against revocation. The record does not contain a ''recommendation of the appropriate State licensing board or professional disciplinary authority.'' 21 § U.S.C. 823(f)(1) Prior Agency decisions have found that where the record contains no evidence of a recommendation by a state licensing board, that absence does not weigh for or against revocation. *See, e.g., Ajay S. Ahuja, M.D.,* 84 FR 5479, 5490 (2019) (finding that ''where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation.''); *Holiday CVS LLC dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62316, 62340 (2012); *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011). Additionally, there is no evidence related to any convictions ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 § U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[25] *See, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10876, 10898, *pet. for*

Registrant's flagrant violations of federal law weigh strongly against a finding that Registrant's continued registration is consistent with the public interest.

ii. Violations of State Law

In addition to alleging that Registrant violated 21 CFR 1306.04(a) and 1306.06, the Government alleges that Registrant violated Florida State law by: (1) Failing to ''exercis[e] sound professional judgment'' and ''work with the patient and the prescriber to assist in determining the validity of the prescription''; [26] and by (2) failing to review each prescription for potential problems, such as ''[o]ver utilization or under-utilization'' and ''[c]linical abuse/misuse,'' and failing to ''take appropriate steps to avoid or resolve the potential problems.'' [27]

I find that the Government has provided substantial evidence that Registrant violated these state laws by dispensing controlled substances to the 15 customers outlined above without documenting any attempt to address or resolve the numerous red flags with these prescriptions. The records clearly do not support a finding that Registrant ''exercise[d] sound professional judgment'' or ''work[ed] with the patient and the prescriber to assist in determining the validity of the prescription,'' as required by Fla. Admin. Code. r. 64B16–27.831. Instead, Registrant repeatedly dispensed controlled substances to 15 customers without documenting any attempt to address or resolve the blatant red flags with these prescriptions, such as patients traveling extreme distances and paying enormous cash sums. *See supra* B.2.ii. Additionally, Registrant failed to identify and respond to factors that indicated a lack of ''therapeutic appropriateness'' of the drugs dispensed, as outlined in Fla. Admin. Code. r. 64B16–27.810. For example, on numerous occasions, Registrant dispensed dangerous and potentially-lethal combinations and dosages of controlled substances without documenting any attempt to address or resolve the red flags with these prescriptions. *See, e.g., supra* B.2.ii (J.Y., J.S., A.M., K.S.).

In light of Registrant's repeated failure to address or resolve blatant red flags of abuse or diversion, I conclude that Factors Two and Four overwhelmingly demonstrate that Registrant ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further conclude that Registrant has not rebutted the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Registrant's continued registration is inconsistent with the public interest, the burden shifts to the Registrant to show why it can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales,* 546 U.S. at 259. ''Because 'past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR at 463 (quoting *Med. Shoppe,* 73 FR at 387 (2008)); *see also Samuel S. Jackson,* 72 FR 23848, 23853 (2007); *John H. Kennnedy, M.D.,* 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual registrant; therefore, the Agency looks at factors, such as the acceptance of responsibility, and the credibility of that acceptance as it relates to the probability of repeat violations or behavior, and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Here the Registrant did not avail itself of the opportunity to refute the Government's case. In light of Registrant's egregious violations, which go to the heart of the CSA's purpose of ''prevent[ing] addiction and recreational abuse'' of controlled substances,[28] Registrant's silence weighs against the Registrant's continued registration. *Zvi H. Perper, M.D.,* 77 FR at 64142 (citing *Med. Shoppe,* 73 FR at 387); *see also Jackson,* 72 FR at 23853.

Accordingly, I find that the factors weigh in favor of revocation, and I shall order the sanctions that the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I hereby revoke DEA Certificate of Registration No. FG5612127 issued to George Pharmacy, Inc. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), I further hereby deny any pending applications for renewal or modification of this registration, as well as any other pending application of George Pharmacy for additional registration in Florida. Pursuant to the authority vested in me by 21 U.S.C. 824(f), as well as 28 CFR 0.100(b), I further order that any controlled substances seized pursuant to the Order of Immediate Suspension of Registration are forfeited to the United States. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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rev. denied, 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy,* 81 FR 49816, 49836–39 (2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59504, 59507, 59512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62316, 62317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66149, 66163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions).

[26] *See* Fla. Admin. Code. r. 64B16–27.831 (2022).

[27] *See* Fla. Admin. Code. r. 64B16–27.810 (2022). I am not including a finding based on Fla. Admin. Code. r. 64B16–27.800 because there is more than enough evidence on the record to revoke Registrant's registration based on consideration of the other found violations under Factors Two and Four.

[28] *Gonzales* v. *Oregon,* 546 U.S. at 274.