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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–31]

Morris & Dickson Co., LLC; Decision and Order

On May 2, 2018, the Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause (OSC) and Immediate Suspension of Registration (ISO) to Morris & Dickson Co., LLC (Respondent), of Louisiana. Administrative Law Judge (ALJ) Exhibit (ALJX) 1, at 1. The OSC informed Respondent of the immediate suspension of its Certificates of Registration Nos. RM0314790 and RM0335732 (registrations)¹ and proposed their revocation pursuant to 21 U.S.C. 824(a)(4) and 823(b) because it alleged that Respondent's continued registrations were inconsistent with the public interest. *Id.*

Respondent requested a hearing before a DEA ALJ, which was conducted from May 13 to May 16, 2019. On August 29, 2019, the ALJ issued a Recommended Decision (RD), which was transmitted to the Agency along with the administrative record on November 26, 2019.² The Agency has incorporated portions of the ALJ's RD herein.

The Government presented a *prima facie* case. Respondent ultimately admitted to and accepted some responsibility for its failures in effectively applying its customer due

¹ Respondent sought and obtained a temporary restraining order against enforcement of the ISO. See ALJX 89, at 7. On May 18, 2018, the DEA Acting Administrator rescinded the ISO issued on May 2, 2018. Tr. 12; see *Stip.* 26.

² On October 8, 2019, Respondent filed Exceptions to the Recommended Decision (Resp Exceptions) and on November 7, 2019, the Government filed a response to Respondent's Exceptions. On January 5, 2022, Respondent filed a Motion to Reopen the Administrative Record. On January 14, 2022, the Government filed an opposition to this motion and on January 21, 2022, Respondent filed a Reply Memorandum in Support of its Motion to Reopen the Administrative Record. The Agency addresses the Exceptions throughout and the Motion to Reopen at the end of this Decision.

diligence in assessing orders of controlled substances, its failures to implement a suspicious order monitoring system “consistent with best practices for compliance,” and its failures to adequately resolve red flags on orders that it shipped. See *infra* section V. Respondent also admitted that its three suspicious order reports to DEA during the relevant time period were insufficient. *Id.* Nonetheless, Respondent presented testimony and evidence aimed at rebutting the Government's case with regard to the scope of its regulatory noncompliance during the relevant time period.

After thoroughly reviewing the entire record, the Agency finds substantial record evidence that Respondent's continued registration is inconsistent with the public interest in light of the long-term, egregious failures of Respondent in its responsibility as a distributor to maintain effective controls against diversion of controlled substances. Furthermore, the Agency finds that Respondent has failed to demonstrate that the Agency should continue to entrust it with its controlled substance registrations.

I. Summary of the Allegations

1. The OSC primarily alleged that Respondent failed to maintain effective controls against diversion when it failed to report to DEA thousands of unusually large orders for hydrocodone and oxycodone, which constituted potential suspicious orders, and when it shipped orders to customers without resolving red flags of diversion or reporting the orders to DEA in violation of 21 U.S.C. 823(b)(1) and (e)(1) as well as 21 CFR 1301.71(a) and 1301.74(b). OSC, at 2. Further, the OSC alleged that Respondent failed to adequately design and operate a system to alert Respondent to suspicious orders of controlled substances and failed to report the suspicious orders to DEA in violation of 21 CFR 1301.74(b). *Id.*

2. The allegations included that, from January 2014 until April 2018, Respondent shipped approximately 7,000 unusually large orders of oxycodone and almost 5,000 unusually large orders of hydrocodone. OSC, at 5; Govt Prehearing, at 8. During this time, Respondent filed a total of only three suspicious order reports with DEA.

3. Furthermore, the OSC alleged that, from approximately January 2014 to April 2018,³ Respondent failed to carry

³ The allegations for three of the exemplar pharmacies only spanned a subset of this timeframe: Wellness Pharmacy, January 2014–December 2017; Wilkinson Family Pharmacy, January 2014–April 2017; Hephzibah Pharmacy, April 2017–May 2017. Govt Prehearing, at 3.

out its due diligence and suspicious order monitoring policies and failed to conduct or failed to document the resolution of meaningful due diligence into orders placed by the following pharmacies: Wallace Drug Company, Inc.; Bordelon's Super-Save Pharmacy; Folsie Pharmacy; Pharmacy Specialties Group, Inc.; Dave's Pharmacy; the Wellness Pharmacy, Inc.; Wilkinson Family Pharmacy; and Hephzibah Pharmacy, L.L.C. (hereinafter, the exemplar pharmacies).

II. The Witnesses

A. The Government's Witnesses

The Government presented its case through the testimony of six witnesses and the introduction of 70 exhibits. The Government's first witness was the Acting Section Chief of the Pharmaceutical Investigation Section of the DEA (the Section Chief), who testified generally regarding the regulatory requirements for distributors. Tr. 47–87. The Government also presented testimony from two Diversion Investigators (DI 1 and DI 2) regarding the history of the investigation and the identification of Government exhibits.⁴ See RD, at 11–12 (citing Tr. 94–101; 144–177). Next, the Government presented testimony from the Chief of the Statistical Services Section of DEA, G.R., who was qualified without objection as an expert in “developing and implementing statistical models and methods of analyzing large and complex data sets.” RD, at 13 (citing Tr. 192). G.R. testified to the methodology he employed in analyzing the statistical data that was used by DEA in its determination that Respondent had failed to report suspicious orders.⁵ RD, at 12–15 (citing Tr. 187–245). The Government also presented testimony from the Group Supervisor of the New Orleans Field Division (the GS), who was accepted as an expert in “the identification of common red flags suggestive of an illicit pharmaceutical operation and as well [as] with respect to the requirements imposed on DEA registrants to identify and investigate

⁴ The Government presented testimony from a third Diversion Investigator (DI 3) to rebut the testimony of Respondent's witness, however, the Agency agrees with the RD that the testimony of DI 3 was not essential to the case and is therefore not including it herein. RD, at 20.

⁵ G.R. testified that he had corrected DEA's admitted error in the calculations in the OSC, which applied a Three Interquartile Range (IQR) to the median of the data set, or the 50th percentile, instead of the 75th percentile, and as a result, produced a larger group of outliers. Tr. 204, 208–09. G.R. further acknowledged that the error was identified by Respondent's expert. Tr. 218.

such red flags when they become aware of them.” RD, at 16 (citing Tr. 282).⁶

B. Respondent's Witnesses

Respondent presented its case through the testimony of three witnesses and the introduction of ten exhibits. Respondent's first witness was Kenneth A. Weinstein, Tr. 501–689, who was the Vice President of the consulting firm Analysis Group, Inc. (AGI), and was accepted without objection as an expert in statistical analysis related to controlled substance distribution and in pharmacy ordering and inventory management. RD, at 22 (citing Tr. 513–14; 520–21). Weinstein authenticated Respondent Exhibit (RX) 14, pages 15–19, and RX 28 and 29. Tr. 506, 562–68. Weinstein testified generally regarding the use of the Tukey analytical model in developing Suspicious Order Monitoring systems and testified specifically regarding what he found to be deficiencies in G.R.'s statistical analysis in this case. Weinstein also testified regarding AGI's compliance work for Respondent after DEA had issued the OSC.

Respondent's second witness was Scott Irelan, Tr. 693–840, who had worked for Respondent for 31 years before becoming the Director of Corporate Compliance and Security in May 2018 after the OSC was issued. Irelan testified regarding his current role at Respondent, the remedial measures that Respondent had put in place since the issuance of the OSC, Respondent's preexisting compliance measures during the relevant time period, and Respondent's acceptance of responsibility.

Respondent's final witness was Louis Milione,⁷ Tr. 841–1057, who was, at the time, the Senior Managing Director of Guidepost Solutions. Respondent hired Guidepost Solutions to enhance Respondent's compliance system. Tr. 878–79. Milione was previously the Assistant Administrator of the Diversion Control Division at DEA and was offered and accepted without objection as an expert “in diversion.” Tr. 851. He testified regarding his factual interactions with Respondent during his tenure at DEA⁸ and regarding the work

Guidepost performed for Respondent to improve its compliance with DEA requirements.⁹

III. Findings of Fact

The Parties agree to 47 stipulations (Stips.), which are accepted as facts in these proceedings. The Agency incorporates all of these into the record—the most relevant of which are summarized here. See RD, at 33–38. Between January 2014 and May 2018, Respondent submitted a total of three suspicious order reports to DEA. Stip. 7. In this same approximate timeframe, Respondent supplied controlled substances, including oxycodone and hydrocodone, to Wallace, Bordelon's, Folsie, Pharmacy Specialties, and Dave's pharmacies. Respondent also supplied Hephzibah with controlled substances, including oxycodone and hydrocodone, between April and May 2017, Wellness Pharmacy between January 2014 and December 2017, and Wilkinson¹⁰ between January and April 2017. See Stips. 11–20. The timeframe of the allegations in the OSC are hereinafter referred to as “the relevant timeframe.”

A. DEA's Investigation

In 2017, while investigating pharmacies in Louisiana selling high volumes of oxycodone and hydrocodone, the DEA New Orleans Division discovered that some of those pharmacies were supplied by Respondent. Tr. 92. During a subsequent audit, Respondent told DEA that it used Pro Compliance Reports and its employees to identify suspicious orders. Tr. 93.

occurred in August 2016 when Milione was in the role of Assistant Administrator of the Diversion Control Division at DEA. Tr. 856–861; RX 21; RX 11 (PowerPoint slide deck). Milione testified that, at that meeting, he believed that Paul Dickson, Sr., was committed to his regulatory obligations and sincere. Tr. 873. The powerpoint slides from that meeting, which Respondent submitted into evidence, generally support Respondent's statements regarding the workings of its previous SOM at a high level and its termination of customers pursuant to its due diligence efforts. RX 11; see *infra* n.61 regarding termination of Respondent's customers, and *infra* n.89 regarding evidence of the sincerity of Paul Dickson, Sr.

⁹The testimonies of Weinstein, Milione, and Irelan are afforded full credibility in this Decision on all points that are within their expertise and relevant to the final decision as further found herein. This Decision has found all major points of conflict between the Government's and Respondent's witnesses to be largely irrelevant to the Agency's adjudication of the allegations. The Agency analyzes the evidentiary weight of portions of the testimony of these witnesses in balance with other evidence on the record where relevant. It is noted that, although Irelan's testimony regarding acceptance of responsibility is analyzed in the Sanction Section *infra*, it is afforded full credibility.

¹⁰Wilkinson Family Pharmacy voluntarily surrendered its DEA Certificate of Registration for Cause. Stip. 20.

DEA served Respondent with three separate subpoenas and several requests for clarification between February 1, 2018, and April 2018.¹¹ RD, at 44–50. The subpoenas related to Respondent's identification of suspicious orders, due diligence, internal investigations, and internal policies and practices, and also identified specific pharmacies. Government Exhibits (GX) 7, 8, 10, 12, 15. Respondent responded via letters and produced some documentation. For example, GX 9 contains an undated letter from Jacob Dickson, stating that Respondent submitted only two suspicious order reports to DEA because it “utilizes a pro-active approach to avoid diversion of controlled drugs, including: screening new pharmacy customers; aggressively monitoring orders for controlled drugs; and eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments, fill prescriptions for the ‘Holy Trinity’ and/or other unacceptable practices.” GX 9, at 1; Tr. 319. The undated letter also states that “DEA and applicable regulations do not require that a wholesale distributor maintain records of each and every internal investigation conducted on *possible* suspicious orders.” GX 9, at 1–2 (emphasis in original); Tr. 319–20. The letter further explained that once Respondent has cleared a possible suspicious order, “no record is maintained.” GX 9, at 2. The undated letter explained that Respondent used a “four-fold approach to monitor all prescription drug orders and detect unusual ordering patterns, amounts, and cash payments to identify potentially suspicious orders.” GX 9, at 2; Tr. 321. The four-fold approach included: use of Pro Compliance Reports; preparing a Market Basket Report of each customer on a monthly basis; since April 2017, use of software that identifies orders that are more than 10 times the “average dosage units ordered on a given drug on a certain day with the last 90 days of ordering patterns of the same drug”; the experience of the employees who fill the orders for controlled substances; and the input of delivery drivers and salesmen. GX 9, at 3–4.

Government Exhibit 11 is Respondent's (signed by Paul Dickson) supplemental undated response to DEA following up on subpoenas issued to Respondent. Tr. 144–45, 324; GX 11, at 2. This response states that “[b]ecause formal records are not kept in the regular course of business on the

⁶The Agency adopts the ALJ's credibility findings regarding the Section Chief, the DIs, G.R., and the GS. RD, at 11–12, 15, 19.

⁷Milione is currently the Principal Deputy Administrator of DEA. Despite his return to the Agency, it is noted that Milione has not had any contacts with the Administrator nor anyone participating in the decisionmaking in this matter about and due to his prior involvement with this case.

⁸Respondent presented evidence, including testimony from Milione, about a meeting with Respondent at Respondent's invitation that

¹¹The Agency adopts the findings of fact in the RD related to these subpoenas and Respondent's response and summarizes herein. RD, at 44–50.

investigation of orders which do not result in the finding of a ‘suspicious order’ per 21 CFR 1301.74, the email communications produced herewith represent the most responsive records maintained.” GX 11, at 2; Tr. 324.

At the same time, Respondent produced an external hard drive containing documents in response to the February subpoenas. Tr. 146. Again, DEA emailed Respondent to ensure a complete response, which Respondent generally affirmed and also then provided a phone log¹² with the earliest entry dated January 5, 2016. GX 12–14. In response to the subpoena for policies and trainings, Respondent informed DEA that its training of employees on suspicious order monitoring “does not necessitate or result in the production of documents.” GX 16, at 1. Respondent’s reply included two policy and procedure documents, which Respondent described as containing “some limited direction as to suspicious order monitoring.” *Id.*; Tr. 174–76; GX 17, 18.

B. General Regulatory Obligations

21 CFR 1301.74(b) requires distributors to

. . . design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Id.

Respondent received a copy of a letter sent on September 27, 2006, by DEA to distributors of controlled substances. Tr. 62–63; GX 3, at 1. The letter emphasized that “[d]istributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned,

distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.” GX 3, at 1. The letter therefore, reminded distributors of their “responsibilities . . . in view of the prescription drug abuse problem our nation currently faces.” *Id.* Further, the letter reminded distributors of their duty under the regulation to “design and operate a system to disclose to the registrant suspicious orders of controlled substances,” and their duty to report suspicious orders to DEA upon discovering the suspicious order. *Id.* at 2. In addition, the letter reminded distributors of their duty to exercise due diligence to avoid filling suspicious orders. *Id.* Finally, the letter provided distributors with 14 examples derived from DEA investigations of a customer’s behavior that might be indicative of diversion. *Id.* at 3. The letter states that these examples are not all-inclusive and that “[d]istributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).” *Id.* DEA sent the same letter a second time on February 7, 2007. Tr. 64–65; GX 69.

Government Exhibit 4 is a December 20, 2007 letter that the DEA sent to every distributor of controlled substances. Tr. 63–64; GX 4, at 1. The stated purpose of this letter was to again remind distributors of the requirement to inform DEA of suspicious orders. GX 4, at 1. The letter reminded distributors that in addition to “maintain[ing] effective controls against diversion,” they are also required to “report suspicious orders of controlled substances.” *Id.* The letter reminded registrants that the regulation requires that these orders be reported “*when discovered* by the registrant.” *Id.* (emphasis in original). The letter also reminded distributors “that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels” in accordance with their requirements to maintain effective controls against diversion in 21 U.S.C. 823(e). *Id.* The letter also informed registrants that DEA interpreted the list of types of suspicious orders to be “disjunctive and [] not all inclusive.” 21 CFR 1301.74(b).

DEA maintains an Automation of Reports and Consolidated Orders System (ARCOS). Tr. 69–70. Distributors are required to report to ARCOS all shipments of controlled substances in schedules I and II and all narcotic controlled substances in schedule III. Stip. 9; Tr. 70. In April 2008, DEA met with Respondent’s President Paul Dickson, Sr., and discussed Respondent’s legal obligations and requirements as a distributor, including suspicious order requirements, the need to know its customers, and the need to conduct due diligence. Tr. 67–68. At the time, DEA reviewed its ARCOS data with Respondent to show customers who had anomalies and to demonstrate “things that [Respondent] should be looking at and questioning [its] customers [about].” Tr. 68–69. In 2013 and 2015, DEA conducted distributor conferences and Jacob Dickson, Respondent’s compliance officer,¹³ attended both conferences. Tr. 66–67. Both sides also presented evidence about a meeting with Jacob Dickson, Paul Dickson Sr., C.G. (a former compliance officer at Respondent) and officials from DEA, including Milione, in which Respondent presented its Suspicious Order Monitoring (SOM) system to DEA. See RX 11 (powerpoint); see *supra* n.8.

Respondent filed three suspicious order reports during the relevant time period. Stip. 7. The first, dated April 7, 2014, states that “[a]t this time, and pending further review by you or M&D, M&D has stopped selling schedule II through schedule V drugs to the captioned pharmacy.” GX 6, at 1. The next report is dated April 26, 2017, and states that the pharmacy in question “purchased a quantity of 60 cartons of prefilled 10 mg morphine sulphate syringes . . . This was a substantial increase over a total sales of one carton in the prior four months.” GX 6, at 35. The letter states that the order was investigated but does not discuss the resolution of this investigation, nor whether the order was filled. *Id.* The final report was filed on the same day, April 26, 2017, and gives no facts related to what order was deemed suspicious nor any information about an investigation or whether the order was shipped. GX 6, at 36.

Distributors are required to design and operate a suspicious order monitoring system that identifies suspicious orders. 21 CFR 1301.74(b). Suspicious orders include, but are not

¹² Regarding the exemplar pharmacies, the phone log contains two entries concerning the Pharmacy Specialties Group, with a DEA registration number ending in “589.” GX 14, at 4, 31; GX 23, at 1. Those entries are dated March 7, 2016, and December 13, 2017. GX 14, at 4, 31. There is one entry concerning Dave’s Pharmacy, with a DEA registration number ending in “386.” GX 14, at 23; GX 24, at 1. That entry is dated February 16, 2017. GX 14, at 23. There are three entries concerning Hephzibah Pharmacy, with a DEA registration number ending in “695.” GX 14, at 23, 26; GX 25, at 1. Those entries are dated March 17 and 21, 2017, and June 20, 2017. GX 14, at 23, 26. There are five entries concerning Wilkinson Family Pharmacy, with a DEA registration number ending in “198.” GX 14, at 24; GX 27, at 1. Those entries are dated April 19, 20, 21, and 24, 2017. GX 14, at 24. There are three entries concerning Wallace Drugs, with a DEA registration number ending in “363.” GX 14, at 31; GX 20, at 1. Those entries are all dated January 9, 2018. GX 14, at 31; RD, at n.12. See *supra* section III.D.

¹³ The GS testified that “one time [Jacob Dickson] was marked as president and then in the other time it was compliance officer.” Tr. 67. In a letter to DEA in response to subpoenas, Jacob Dickson’s title was listed as Vice President, SOM Manager. GX 9, at 4.

limited to, three stated criteria: orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.*

Additionally, a distributor's general duty to prevent diversion includes the duty to perform due diligence on its customers. *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36500 (2007); *see also Masters Pharmaceuticals, Inc.*, 80 FR 55418, 55476 (2015), *pet. for review denied, Masters Pharmaceuticals, Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The GS testified that if the required due diligence at the customer level identifies red flags indicative of diversion, Tr. 328, those red flags render an individual order suspicious and trigger the investigation or reporting requirement, even if the regulatory criteria in 21 CFR 1301.74(b) are not present, *e.g.*, the order size is not unusual. Tr. 477–478; *see also Masters Pharm., Inc.*, 80 FR at 55477 (stating that “an order is not only suspicious by virtue of its internal properties—*i.e.*, being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order]”).

The Agency's decision in *Masters* sets forth that a distributor must either investigate suspicious circumstances on an order and resolve all indicia of diversion or decline to fill the order and report it to DEA. *Masters Pharm., Inc.*, 80 FR at 55478.

C. Red Flags—Customer Due Diligence

The record evidence establishes that customer red flags indicative of potential diversion include a pharmacy customer that: dispenses a high volume of narcotics; dispenses the trinity drug cocktail;¹⁴ dispenses disproportionately more controlled substances than non-controlled substances;¹⁵ fills

¹⁴ The trinity drug cocktail consists of an opioid, such as hydrocodone, a benzodiazepine, such as alprazolam, and a muscle relaxer, such as Soma, and the combination of substances is still a red flag even if each element is prescribed by different prescribers. Tr. 55, 300, 344.

¹⁵ The record contains varying evidence as to the threshold percentage of a pharmacy customer's controlled substance fills relative to its non-controlled substance fills that would trigger a red flag for the distributor. *See* Tr. 351, 461 (The GS testifying that if the percentage of controlled substance prescriptions filled exceeds 15 percent of total prescriptions, it is a red flag); Tr. 1030 (Milione testifying that if a pharmacy is filling controlled substance prescriptions at a percentage exceeding the national average, then the distributor can resolve the red flag without reporting a suspicious order); Tr. 867 (Ireland testifying that the previous SOM system involved monitoring “for customers that were getting a little closer to 20 percent of that ratio”); RD, at n.5 (noting that the *Masters* decision found the threshold to be around 20 percent for controlled versus 80 to 90 percent for non-controlled, *Masters Pharm., Inc.*, 80 FR at

prescriptions for customers who live far away from the pharmacy; fills prescriptions for a high volume of patients who pay for prescriptions in cash;¹⁶ fills prescriptions for practitioners whose DEA registrations cannot be verified;¹⁷ fills a

55480, but finding that the GS presented the most credible evidence at 15 percent).

The Agency finds the exact percentage threshold to be largely irrelevant to determine in this case, because in every instance of the Government's allegations, this particular red flag was flagged by the Pro Compliance Reports that were created for Respondent. Furthermore, all of the pharmacy customers in the allegations were dispensing controlled substances at 20 percent or more of their total dispensing—with one customer at one point dispensing as high as 69 percent controlled substances, *see* GX 26, at 11 (Wellness). The only exception was Bordelon's dispensing at 17 percent controlled substances, but which Pro Compliance reported as being “slightly higher than national average.” GX 21, at 6. Furthermore, seven of the eight exemplar pharmacies demonstrated multiple red flags in addition to this one. It is indisputable that Respondent was aware of this red flag for each of these customers at a customer level due to the Pro Compliance Reports in its possession.

¹⁶ The record contains varying evidence as to the threshold percentage of cash payments for controlled substance prescription fills at a pharmacy customer that would trigger a red flag for the distributor. *See* Tr. 328 (The GS testifying that any pharmacy customer exceeding 9 percent cash payments from customers should raise red flags); *see also* 1036–37 (Milione testifying that a high percentage of cash in controlled versus non controlled prescriptions is a red flag, but can be resolved with due diligence, the records of which must be maintained); Tr. 681 (Weinstein testifying that if a pharmacy has “a substantially higher percentage of cash payments for controlled substances than it did for a non-controlled substances, that would be a [potential] red flag of diversion,” but that he does not have “a particular definition of substantial or significant,” because it was more of a “relative comparison”); *but see* Tr. 649 (Weinstein answered that it was “fair” to say that when a distributor becomes aware of factors, such as cash payments, “they're significant red flags of diversion.”).

Again, the Agency finds the exact percentage threshold for cash payments to be largely irrelevant to determine in this case, because in every instance of the Government's allegations, this particular red flag was flagged by the Pro Compliance Reports that were created for Respondent. As detailed herein, the percentages of cash paid by Respondent's customers at issue were also particularly high, *see, e.g.*, 41 percent, GX 22, at 12 (Folse). It is indisputable that Respondent was aware of this red flag for each of these customers at a customer-level based on the Pro Compliance Reports in its possession.

¹⁷ The Pro Compliance Reports additionally contain reports of prescribers whose DEA controlled substance registrations “could not be verified through DEA-Verify.com” and whose controlled substance prescriptions were filled by Respondent's customers. *See, e.g.*, GX 22, at 17; Tr. 336 (June 2017 Report showing that Folse filled controlled substances prescribed by 23 practitioners whose registrations could not be verified). Both Ireland and Milione testified that the portion of the Pro Compliance Reports concerning the verification of prescriber DEA numbers is unreliable. Tr. 765–66, 797, 901. Milione also testified that a distributor needs to hold and report a suspicious order if it is aware that a customer is filling prescriptions for a practitioner with no DEA registration. Tr. 1025. Although the Agency agrees with the RD, at n.14,

disproportionate volume of controlled substance prescriptions written by only a few prescribers; and/or orders excessive quantities of a limited variety of controlled substances. Tr. 297, 299–301, 335, 411, 427, 489–90, 648–49, 681, 1037; *see also* Pro Compliance Reports GX 20–56. Weinstein noted that red flags are visible in a pharmacy's dispensing data and not its ordering data.¹⁸ Tr. 679. Ireland admitted that, during the relevant time period, due diligence was not being applied at the ordering level.¹⁹ Tr. 722–23.

The GS testified that when Respondent received the Pro Compliance Reports in GX 20–56 that demonstrated red flags of diversion, it was obligated to resolve the red flags and document their resolution. Tr. 474–76. Based on the record testimony of the experts, and the *Masters* decision, the Agency finds that when a distributor is aware of red flags indicating diversion of controlled substances from a customer, at a minimum, it is obligated to investigate further and resolve the red flags, or, if it chooses not to investigate and resolve, it must report the order as suspicious to DEA and not ship the controlled substances. *See infra*, section IV.A.4.

that during the relevant timeframe, there is no evidence in the record that Respondent resolved the red flags presented by these reports demonstrating unverified registrations, even if they were unreliable, the Agency also finds that there is more than enough evidence on the record that Respondent did not resolve the other clearly established red flags of diversion and therefore finds it unnecessary to address these additional red flags in this Decision.

¹⁸ The fact that the red flags applied to the customer generally and not to each individual order, *see* ALJX 89, at 99, is irrelevant to this adjudication, because under the relevant legal requirements, Respondent cannot ignore red flags that demonstrate that its customers are potentially diverting controlled substances and continue to fill those individual orders without resolving each of those red flags. *See* Tr. 477–478. At a minimum, Respondent must either have stopped the shipments and reported orders to DEA or resolved and documented each of the red flags. *See Masters Pharm., Inc.*, 861 F.3d at 222–23.

¹⁹ It is noted that Respondent attempted to introduce and the ALJ rejected, Exhibit 32C, based on lack of identification. Tr. 447. Respondent's stated purpose was to impeach the Government's witness in demonstrating that Respondent's due diligence files did include photographs as described in its policy, Tr. 447, contrary to the GS's testimony that he did not “recall any” photographs, Tr. 322; RX 32C. The GS testified credibly that he did not recall seeing the file with the photograph “at all.” Tr. 447. The Agency has reviewed the document and notes that it did include a photograph; however, the Agency is not finding that Respondent's compliance with its policy on this issue is relevant to this decision and, therefore, the exhibit marked for identification as RX 32C plays no role in the adjudication of this matter. Further, if this exhibit had been included in the record, standing alone, it bodes poorly for Respondent concerning its failure to report suspicious orders for terminated customers. *See infra* n.61.

D. Pro Compliance and Market Basket Reports

In conducting customer due diligence, Respondent used, at least up to and including during the hearing, Pro Compliance Reports,²⁰ which provide analysis of a pharmacy's dispensing data to include key indicators of red flags of diversion, such as the percentage of a customer's business that represents controlled substance dispensing, the volume of cash payments, and the amount of trinity drug cocktails filled. Tr. 464–65, 716–17. In this case, the reports in Respondent's possession for the exemplar pharmacies demonstrated numerous red flags of diversion, and the Agency finds substantial record evidence that Respondent did not adequately document the resolution of those red flags or report the orders to DEA as suspicious.²¹ Additionally, the reports in evidence for the exemplar pharmacies appear to demonstrate violations of Respondent's purported policy of "eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments, prescribe the 'Holy Trinity' and/or other unacceptable practices." GX 9, at 1. According to Respondent, Market Basket Reports²² were prepared for each customer on a monthly basis as part of its due diligence. GX 9, at 3–4. The reports identified percentages of controlled substances in total dispensing. *Id.*; *see, e.g.*, GX 59. Respondent no longer uses Market Basket reports but continues to use Pro Compliance Reports. Tr. 716.

²⁰ Each Pro Compliance Report contains a statement regarding the Controlled Substances Act (CSA) requirement on manufacturers and distributors to design and operate a system that will disclose suspicious orders of controlled substances. *See, e.g.*, GX 23, at 11; Tr. 355.

²¹ Respondent argues that "the Government offered no evidence to demonstrate that Respondent failed to dispel suspicion." ALJX 89, at 100. The Agency finds this argument to be circular. Respondent did not maintain adequate documentation of its resolution of red flags or suspicious orders, so there is no evidence to demonstrate whether it did or did not conduct the due diligence necessary to resolve the red flags. *See infra* n.80. As described herein, the Agency requires documentation of Respondent's due diligence for many reasons.

²² Respondent points out that the GS's testimony regarding the Market Basket reports was possibly based on a misinterpretation of the numbers. ALJX 89, at 30 (citing Tr. 409, 423–425). In adjudicating the allegations, this Decision focuses on the Pro Compliance Reports in which there is more than enough information to support the Agency's finding that the alleged customers presented red flags of diversion, the resolution of which was not adequately documented, yet Respondent continued to ship. The Market Basket Reports are only considered to demonstrate that Respondent was conducting some due diligence.

The GS testified that he did not find evidence that Respondent ever rejected a controlled substance order from any of the exemplar pharmacies, nor did he find documentation that Respondent dispelled all of the red flags in these reports. Tr. 385–86, 316,²³ 413.

1. Folsie Pharmacy

The record evidence demonstrates that the Pro Compliance Initial Risk Evaluation Report provided to Respondent for Folsie Pharmacy designated the pharmacy as "high risk." GX 22, at 5; Tr. 328. Further, Pro Compliance Reports for Folsie Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Folsie Pharmacy's dispensing practices raised numerous red flags, including: high percentages²⁴ of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,²⁵ an increase²⁶ in the number of oxycodone dosage units dispensed, and dispensing of trinity cocktail prescriptions.²⁷ *See* RD, at 51–53. Furthermore, in June 2017, a Pro Compliance Report recommended that Respondent engage with Folsie's owner to "gain a better understanding of [its] dispensing practices" GX 22, at 17. The record does not include evidence of an investigation into or resolution of the red flags identified. Further, the record is clear that Respondent did not report any orders from this customer to DEA as suspicious and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 340; Stip. 13.

²³ Respondent points to Irelan's testimony to contest the notion that Respondent was not stopping shipments based on reports; however, the citations to his testimony support that Respondent was generally conducting some due diligence as it had described in its letters to DEA in response to the subpoena, not that the red flags at issue for the exemplar pharmacies were resolved. ALJX 89, at 16; *see also, e.g.*, RX 31.001 (notes on pharmacies other than exemplar).

²⁴ According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 30 to 36 percent of Folsie's total dispensing. GX 22, at 12–17.

²⁵ According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 18 to 41 percent. GX 22, at 12–14, 17.

²⁶ Between September 2013 and November 2014, the number of oxycodone dosage units dispensed increased from 40,812 to 52,571. GX 22, at 12; Tr. 330–31 (The GS describing this increase as "a very big red flag"); *see also* Tr. 471–74.

²⁷ In June 2017, Folsie dispensed nine trinity drug cocktails and in September 2016, Folsie dispensed twenty-two trinity drug cocktails. GX 22, at 17, 14; Tr. 300, 335–36.

2. Bordelon's

Pro Compliance Reports for Bordelon's Super Save Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Bordelon's dispensing practices raised numerous red flags, including: high percentages²⁸ of controlled substance prescriptions, higher than average oxycodone and hydrocodone units, and dispensing of trinity cocktail prescriptions.²⁹ *See* RD, at 53–54. In March 2017, a Pro Compliance Report recommended that Respondent engage with Bordelon's owner to "gain a better understanding of [its] dispensing practices" GX 21, at 6. The record is clear that Respondent did not report any orders from this customer to DEA as suspicious and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 347–48; Stip. 12.

3. Wallace Drug Company

Pro Compliance Reports for Wallace in Respondent's possession demonstrated that during the time period of the allegations, Wallace's dispensing practices raised numerous red flags, including, but not limited to: high percentages of controlled substance prescriptions paid for in cash,³⁰ higher than average dosages of oxycodone and hydrocodone, and dispensing of trinity cocktail prescriptions.³¹ *See* RD, at 54–55. In August 2017, a Pro Compliance Report recommended that Respondent engage with Wallace's owner to "gain a better understanding of [its] dispensing practices." GX 20, at 6. Respondent produced phone log entries on January 9, 2018, for Wallace. *See* GX 14, at 31 (note stating that the pharmacy salesman had been contacted and Respondent recommended that he return the order, noting "might need to check on this guy" and "looks like he is hitting this stuff hard!"). Another note on the same date states that the customer was contacted and the customer explained the large order. According to the note, Respondent's employee recommended the return of the hydrocodone and the customer returned it. This note did not occur

²⁸ In March 2017, the percentage of controlled substances dispensed represented 17 percent of Bordelon's total dispensing, which Pro Compliance reported to be "slightly higher than national averages." GX 21, at 5–6.

²⁹ In March 2017, Bordelon's dispensed four trinity drug cocktails. GX 20, at 5–6.

³⁰ In August 2017, 31 percent of controlled substance prescriptions filled by Wallace were paid for in cash. GX 20, at 5.

³¹ In August 2017, Wallace dispensed three trinity drug cocktails. GX 20, at 5–6; Tr. 349–50.

until five months after the Pro Compliance Report for Wallace, which demonstrated multiple additional red flags of diversion for which there is no documented resolution. Therefore, it is unclear whether the employee flagging this particular order knew that there might be further reason to suspect that this pharmacy was engaging in diversion in order to be able to adequately resolve the suspicious circumstances surrounding the order. Even if this note arguably provided a documented resolution of an unusually large order, the other red flags for this customer are unresolved and unaccounted for. There is also no record evidence that Respondent reported the unusually large order or any orders from this customer to DEA and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports or notes. Tr. 353; Stip. 11.

4. Pharmacy Specialties Group

Pro Compliance Reports for Pharmacy Specialties in Respondent's possession demonstrated that during the time period of the allegations, Pharmacy Specialties' dispensing practices raised numerous red flags, including: high percentages³² of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,³³ an increase³⁴ in the number of hydrocodone, oxycodone, and benzodiazepine dosage units dispensed, and dispensing of trinity cocktail prescriptions.³⁵ See RD, at 55–57. In February 2016, a Pro Compliance Report recommended that Respondent engage with Pharmacy Specialties' owner to "gain a better understanding of [its] dispensing practices." GX 23, at 6. Respondent's phone logs demonstrate that an employee raised a concern on March 7, 2016, regarding Pharmacy Specialties Group; however, there is no record documentation of how the concern was resolved and Respondent

³² According to the Pro Compliance Reports in evidence, the percentages of controlled substances ranged from approximately 24 to 30 percent of Pharmacy Specialties' total dispensing. GX 23, at 5, 18; Tr. 353–54.

³³ According to the Pro Compliance Reports in evidence, the percentages of controlled substances dispensing paid for in cash ranged from approximately 28 percent to 31 percent. GX 23, at 5–6, 16, 18, 18.

³⁴ From February 2016 to October 2016, the number of hydrocodone dosage units dispensed increased by 25 percent, while from October 2016 to September 2017, the number of dosage units of oxycodone, hydrocodone, and benzodiazepines dispensed increased by 148, 89, and 106 percent respectively. GX 23, at 16, 18; Tr. 358–59.

³⁵ In February 2016, October 2016, and September 2017, Pharmacy Specialties dispensed trinity drug cocktails. GX 23, at 6, 16; Tr. 355, 358–59.

continued to distribute. See GX 14, at 4 ("[C]heck out this guys usage for item [] compared to his overall warehouse purchasing, this seems quite elevated to me. . . .????"). This note identifies a suspicious order; however, according to the record evidence, Respondent did not report the order to DEA. Further, there is no documented investigation or resolution of the concern raised by the employee in the record. On December 13, 2017, another note reads, "Henry will give the customer a warning about his Oxy purchases. Too much cash, too much growth. Will re-run and if no improvement will either restrict or cut off completely." *Id.* at 31. Although this note seems to set forth a plan for compliance, it does not include any indication of an investigation into or resolution of the red flags identified. Further, the record evidence is clear that Respondent did not report this order or any orders from this customer to DEA and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 362; Stip. 14.

5. Dave's Pharmacy

Pro Compliance Reports for Dave's Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Dave's dispensing practices raised numerous red flags, including: high percentages³⁶ of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,³⁷ increases³⁸ in the number of oxycodone dosage units dispensed, and dispensing of trinity cocktail prescriptions.³⁹ See RD, at 57–59. In March 2014, a Pro Compliance Report recommended that Respondent engage with Dave's owner to "gain a better understanding of [its]

³⁶ According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 20 to 22 percent of Dave's total dispensing. GX 24, at 5, 18–21, 24, 30; Tr. 362–67.

³⁷ According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 17 to 35 percent. GX 24, at 18–21, 23, 24, 30; Tr. 364–67.

³⁸ For example, from March 2014 to January 2015, the number of oxycodone dosage units dispensed increased from 17,889 to 29,994, and from May 2014 compared to December 2015, the number of dosage units of oxycodone increased by 205 percent. GX 24, at 18, 19, 21; Tr. 364; *see also* RD, at 57–59.

³⁹ Between March 2014 and January 2015, Dave's dispensed 57 trinity drug cocktails. GX 24, at 18; Tr. 364. Between May 2014 and December 2015, Dave's dispensed 27 trinity drug cocktails, and between December 2015 and June 2016, Dave's dispensed 33 trinity drug cocktails. GX 24, at 19–20, Tr. 365–66. Further, between June and November 2016, Dave's dispensed 37 trinity drug cocktails and in June 2017, Dave's dispensed 14. GX 24, at 21, 24.

dispensing practices. . . ." ⁴⁰ GX 24, at 6. It also states that this pharmacy "represents a relatively *high risk* to [Respondent]." *Id.* (emphasis in original). A year later, on February 16, 2017, Respondent's phone logs contain the following note about Dave's: "Talked to [D.J.] about the issues at his store. He will let the doctors know that he will no longer be filling these scripts." GX 14, at 23. According to the record evidence, Respondent did not elicit or document an explanation for the red flags and the record is clear that Respondent never reported this order or any orders from this customer to DEA. Further, there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 384–85; Stip. 15.

6. Hephzibah Pharmacy

A Pro Compliance Report for Hephzibah Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Hephzibah's dispensing practices raised numerous red flags, including: high percentages⁴¹ of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,⁴² and dispensing of trinity cocktail prescriptions.⁴³ See RD, at 59–60. In February 2017, a Pro Compliance Report recommended that Respondent engage with Hephzibah's owner to "gain a better understanding of [its] dispensing practices. . . ." GX 25, at 6.

Jacob Dickson sent an email to a DI stating that Respondent had ceased business with Hephzibah because Respondent did not support the customers who "wished to change their business model;" however, Respondent "did not find these accounts to exhibit suspicious activity or excessive orders." GX 72, at 1. Respondent's phone logs state on March 17, 2017, that "they must work on clearing up issues that Pro Compliance found, high cash, trinity & high quantities on Hydrocodone and Oxycodone. Will re-run in 90 days." GX 14, at 23. On March 21, 2017, there is a follow up entry that states, "After a couple of months, they decided they would rather change wholesalers than cooperate with our compliance program." *Id.* at 26. Although the notes demonstrate that Respondent was

⁴⁰ This Pro Compliance Report identifies Dave's second highest prescriber as having eighty-five incidents of prescribing trinity drug cocktails.

⁴¹ In February 2017, controlled substance prescriptions constituted 27 percent of Hephzibah's total dispensing. GX 25, at 6; Tr. 370–71.

⁴² In February 2017, the percentage of controlled substance dispensing paid for in cash was 36 percent. GX 25, at 6, 12; Tr. 371.

⁴³ In February 2017, Hephzibah dispensed nine trinity drug cocktails. GX 25, at 5–6; Tr. 371.

conducting some due diligence, this statement contradicts Jacob Dickson's email asserting that Respondent terminated the business relationship and also that Respondent did not find the accounts to exhibit suspicious activity when it clearly had identified red flags through Pro Compliance Reports. See GX 72, at 1 (listing Hephzibah Pharmacy as an account that Respondent "chose to close").⁴⁴

7. The Wellness Pharmacy

Pro Compliance Reports for the Wellness Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Wellness's dispensing practices raised red flags of very high percentages of controlled substance prescriptions and high numbers of dosage units of hydrocodone and oxycodone. See RD, at 60–61. Although Pro Compliance's initial risk assessment evaluated Wellness as "low risk," it also revealed that between April and June 2013, 67 percent of all prescriptions dispensed by Wellness were for controlled substances. Further Pro Compliance Reports during the relevant time period demonstrated that Wellness's percentage of controlled substance prescriptions continued to range from approximately 64 to 69 percent. GX 26, at 10–12, 14, 21; Tr. 374. There is no record evidence that Respondent reported these orders to DEA or any orders from this pharmacy, documented the resolution of the red flags, or stopped shipping to this customer as a result of the red flags that these reports identified. Tr. 384–85; Stip. 17.

8. Wilkinson Family Pharmacy

Pro Compliance Reports for Wilkinson Family Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Wilkinson's dispensing practices raised numerous red flags, including: high percentages⁴⁵ of controlled substance prescriptions, increases in oxycodone, high percentages of controlled substance prescriptions paid for in cash,⁴⁶ higher

than average dosages of oxycodone and hydrocodone, and dispensing of trinity cocktail prescriptions.⁴⁷ See RD, at 61–63. In January 2017, a Pro Compliance Report recommended that Respondent engage with Wilkinson's owner to "gain a better understanding of [its] dispensing practices." GX 27, at 26.⁴⁸ There is no record evidence that Respondent reported these orders or any orders from this customer to DEA, or stopped shipping to this customer as a result of these reports. Tr. 384–85; Stip. 19.

The Government has presented substantial record evidence that Respondent distributed controlled substances to the exemplar pharmacies during the relevant time period in the face of red flags of diversion, including high percentages of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash, dispensing of trinity cocktail prescriptions, and increases and higher than average dosages of particular schedule II controlled substances. All of these red flags were specifically identified by Pro Compliance Reports in Respondent's possession. Although some of the notations provided by Respondent demonstrated that employees had suspicions about certain orders and had made some contacts,

⁴⁷ Between March 2014 and January 2015, Wilkinson dispensed twenty-six trinity drug cocktails. GX 27, at 21; Tr. 378. Between January 2015 and January 2016, Wilkinson dispensed twenty-one trinity drug cocktails, and between December January 2016, and August 2016, Wilkinson dispensed twenty trinity drug cocktails. GX 27, at 22–23. Tr. 379. Further, in January 2017, Wilkinson dispensed fourteen trinity drug cocktails, and in June 2017, Wilkinson dispensed 14. GX 27, at 26, 32.

⁴⁸ Respondent produced an email from March 4, 2014, from Wilkinson, which appeared to be in response to a Pro Compliance Report that Respondent had sent to Wilkinson. Wilkinson's explanation primarily focuses on cash payments. RX 05.001. The GS testified that this showed "some" due diligence. Tr. 452. There was extensive dispute about the introduction of this exhibit during the hearing. Tr. 453–458. It appeared that Respondent did try to offer the exhibit into evidence, Tr. 453, and then offered it subject to connection. Tr. 455. The ALJ ultimately determined to send it to the Agency as part of the administrative record. RD, at 104 n.41. The Agency has considered this exhibit because the contested nature of the hearing at this point has made it difficult to determine whether this exhibit was offered. The exhibit demonstrates that Respondent conducted "some" due diligence on Wilkinson. However, it is noted that the document does not demonstrate the resolution of each of the red flags of diversion, nor does it reflect any independent analysis of Respondent's statements regarding the cash red flag. Ultimately, the Agency accepts that Respondent conducted "some" due diligence for Wilkinson. Further, even if Respondent had adequately resolved the red flags for this pharmacy, there is more than enough evidence of Respondent's failures to conduct due diligence to support the Agency's finding that Respondent's registrations are inconsistent with the public interest.

none of the notations adequately resolved the red flags and none of the orders were reported to DEA as suspicious. In the documents Respondent produced to DEA, the GS did not find any indication that the Compliance officer stopped shipment of any order of controlled substances identified as suspicious. Tr. 315–16, 385. It is noted that most of these customers displayed not just one red flag, but multiple red flags of diversion—most of them well over any arguable threshold that would require investigation, see *supra* notes 15–16—and there is insufficient record evidence that Respondent conducted or documented due diligence to resolve these numerous red flags of diversion presented by its customers.

E. Suspicious Orders Under 21 CFR 1301.74(b)

The Government alleged that Respondent failed to design and operate an effective system to disclose to Respondent suspicious orders and to report those orders to DEA. OSC, at 8. DEA used statistical analysis of orders placed by Respondent's customers for oxycodone and hydrocodone to "identify extremely large individual pharmacy transactions and extremely large monthly volume totals," in order to demonstrate the failures of Respondent's SOM system and reporting. *Id.* The GS explained that the reporting of suspicious orders is particularly important for DEA to be able to "conduct an investigation" and identify potential diversion. Tr. 284–86.

G.R. testified regarding the statistical analysis that he performed for the investigation, including his use of a statistical methodology called the Tukey method to identify outlier transactions that represented possible suspicious orders. Tr. 225; 236–37. G.R. testified that Tukey uses an interquartile range, which is the difference between the first and third quartiles, and then is multiplied by a factor of one-and-a-half to six (IQR multiplier). Tr. 202. Although there is no single multiplier to use, Tr. 523, the higher the IQR multiplier, the fewer outliers will be identified. Tr. 523–24. G.R. used an IQR multiplier of 3 to calculate a smaller group of outliers to identify "what are called far out or extreme outliers." Tr. 203, 233, 242. G.R. testified that the transactions that he identified using three IQR above the 75th percentile represented unusually large transactions, which would normally occur less than one percent of the time. Tr. 238–39.

G.R. testified that he analyzed Respondent's sales of oxycodone and

⁴⁴ The Agency agrees with the ALJ's finding that the phone log note deserves more weight as to what occurred with this pharmacy than Jacob Dickson's email. RD, at 136 n.60.

⁴⁵ According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 9 to 42 percent of Wilkinson's total dispensing. GX 27, at 20–23. 25–26; Tr. 367, 378–380.

⁴⁶ According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 17 to 38 percent and cash paid for non-controlled substance prescriptions was significantly lower. GX 27, at 20–23; Tr. 378–380.

hydrocodone from January 1, 2014, to April 30, 2018, and compared every transaction the pharmacy made from January 1, 2014, to April 30, 2018, against every other transaction made during the same time period to the same pharmacy, which he called a “fixed-frame analysis.” Tr. 197–98; 226–27. He credibly testified that he used the fixed-

frame analysis because he was looking for “a ballpark estimate of scale, size of outlier population,” as opposed to the exact number of outliers. Tr. 227, 234.

Government Exhibits 65 and 66 contain all of the transactions concerning oxycodone shipments that Respondent reported to DEA between January 1, 2014, and April 30, 2018, as

well as the results of G.R.’s corrected analysis using the above-described methodology. Tr. 71–72. GX 65, 66; Tr. 71–72, 211–12. G.R.’s corrected analysis identified the following amounts of Respondent’s oxycodone and hydrocodone sales as outliers, *i.e.*, unusually large, from January 1, 2014, to April 30, 2018.

| Substance | 2014 | 2015 | 2016 | 2017 | ⁴⁹ 2018 | Total |
|-------------------|-------|-------|-------|-------|--------------------|-------|
| Oxycodone | 2,097 | 1,857 | 1,546 | 1,361 | 391 | 7,252 |
| Hydrocodone | 1,919 | 1,314 | 1,006 | 536 | 173 | 4,948 |

Tr. 212–13; GX 65–66, at Summary tab; Government Demonstrative Exhibit (GDX), at 10.

G.R.’s corrected analysis also identified approximately 450 potential outliers for Respondent’s oxycodone and hydrocodone sales for seven ⁵⁰ of the exemplar pharmacies from January 1, 2014, to April 30, 2018. Tr. 213–14, 216–17, 243; GDX, at 11.⁵¹ See RD, at 68 for table. The Agency is considering the review of the exemplar pharmacies’ unusually large orders for oxycodone and hydrocodone only to further demonstrate the general failure of Respondent to identify, investigate and report suspicious orders.⁵²

In response to criticism from Respondent’s expert, G.R. also conducted a “look-back analysis,” which, according to G.R., produced results “consistent with what [he] found using the”⁵³ fixed-frame analysis

method. Tr. 228, 235. In his look-back analysis, G.R. looked at “the entire population” and not only the seven exemplar pharmacies in the OSC showing unusually large transactions. Tr. 230. G.R. testified that statistical analysis is “one piece of the analysis that is necessary to comply with DEA’s regulations governing distributors.” Tr. 223–24, 1084–90. See GX 73 and 74 (analysis using the look-back methodology that Weinstein recommended). The look-back analysis for oxycodone transactions revealed 6,816 outlier transactions, a 6 percent reduction when compared to the fixed-frame analysis of 7,252 that the Government previously found. Tr. 1091; GX 73, at Summary tab. The look-back analysis for hydrocodone transactions revealed 5,222 outlier transactions, a 5.5 percent increase when compared to the fixed-frame analysis of 4,948 that the Government previously found. Tr. 1092; GX 74, at Summary tab.⁵⁴

Respondent presented the testimony of its own expert, Weinstein, who opined that G.R.’s analysis failed to reliably identify unusually large or suspicious orders. Tr. 558. Weinstein based his criticism of G.R.’s analysis on four factors: (1) the use of a four-year fixed-frame as opposed to the look-back method; (2) the failure to consider the schedule change of hydrocodone in late 2014 from schedule III to schedule II; (3) the failure to consider package size and formulation; and (4) the use of the line item approach as opposed to a

cumulative approach. RD, at 70; Tr. 525–28, 541–46, 558.

Weinstein credibly explained his criticisms of G.R.’s analysis in detail, opining that the factors he identified both over-estimated, *see, e.g.*, Tr. 552, and under-estimated, *see, e.g.*, Tr. 552–53, the number of outliers that could have potentially constituted suspicious orders.

Weinstein notably “did not conduct an original analysis to determine, retrospectively, which of Respondent’s orders from 2014 through 2018 should have been identified as suspicious.” Resp Exceptions, at 40; *see also* RD, at 25, 75. Respondent argues that it is not Respondent’s burden to do so. Resp Exceptions, at 40 (citing *Steadman v. Securities and Exchange Comm’n*, 450 U.S. 91, 100–03 (1981); *Masters Pharm., Inc.*, 80 FR at 55473; 21 CFR 130.44(e)).

Even if the Agency fully credits Weinstein’s criticism of G.R.’s analysis, the Government has clearly demonstrated its *prima facie* case that Respondent failed to design and operate a system to identify suspicious orders and report them to DEA and Respondent admits as much. *See, e.g.*, Tr. 666 (Weinstein testifying that the numbers run in early 2018 would have identified suspicious orders in similar quantities to what Respondent is currently reporting); Tr. 813 (Irelan testifying that he accepts responsibility for the Government’s allegations in the OSC, paragraph 10, regarding the failure to design and operate an adequate SOM system). The G.R. analysis, according to G.R.’s credible testimony, offered a ballpark estimate of the scale of suspicious orders that Respondent neglected to identify and report to DEA. RD, at 12, and 136; *accord* Tr. 404 (The GS testifying that he asked G.R. to conduct an analysis “to get a sense of just mathematically quantifying how many suspicious orders could theoretically have been missed by

⁴⁹ January 1, 2018, to April 30, 2018. Tr. 212, 226.

⁵⁰ G.R.’s corrected analysis did not identify any unusually large transactions of oxycodone or hydrocodone that Respondent shipped to Hephzibah Pharmacy. ALJX 14, at 4; Tr. 230. However, the Pro Compliance Report for Hephzibah Pharmacy demonstrated multiple red flags of diversion. *Supra* section III.D.6.

⁵¹ The tables reflect transaction size, not frequency. Tr. 244.

⁵² It is noted that Weinstein conducted a “look-back” analysis of G.R.’s data; Tr. 537–38, 550–51, 693, RDX–4; *see also* RD, at 73 (table analyzing these amounts). The Agency acknowledges that Respondent demonstrated Weinstein’s analysis produced significantly lower results; “nearly half of the outlier transactions he identified in 2017 and 2018 would not have been identified as outliers.” ALJX 89, at 38 (citing Tr. 529–30, 568; RX 28 and 29)).

⁵³ Respondent argued in its Exceptions that G.R.’s look-back analysis could not be characterized as “substantially similar” to the fixed-frame analysis because although the numerical size of outliers was similar, each analysis found substantially different outliers. Resp Exceptions, at 41–42. Respondent’s point is noted; however, both analyses identified numerous outliers and, ultimately, the number of outliers that could have represented suspicious orders under both analyses far exceeded the three that Respondent reported to DEA during the relevant timeframe. Further, Respondent did not demonstrate adequate documentation of its resolution of suspicious orders nor is there

information on the record that Respondent stopped shipping.

⁵⁴ Respondent contests the Government’s introduction of this rebuttal evidence in its Exceptions. Resp Exceptions, at 40–41. As further explained herein, the Agency credits Weinstein’s criticism of G.R.’s analysis. The exact number of unreported suspicious orders is unnecessary for the Government to prove or the Agency to conclude in finding a violation because Respondent was responsible for creating and maintaining an adequate SOM system and identifying and reporting suspicious orders. Here, it is clear from the evidence that Respondent’s SOM system during the relevant timeframe was inadequate.

Morris & Dickson”⁵⁵). Respondent argued that the Government’s case was founded⁵⁶ on establishing specific outliers that Respondent failed report to DEA as suspicious orders. Resp Exceptions, at 43 (citing *e.g.*, OSC, at 37, 46, 54, 65, 74, 84, 93); *see also* ALJX 52, at 20. However, the Agency does not find it necessary to count and identify the exact number of specific outliers, and the reason why is simple. Respondent is charged with violating a non-prescriptive regulation, which clearly places the burden on the distributor to design and operate a system to disclose to the distributor suspicious orders of controlled substances under Agency guidelines.⁵⁷ The DEA regulations notably do not prescribe *exactly* what SOM system to use or what constitutes a suspicious order—what constitutes an order of unusual size, an order deviating substantially from a normal pattern, etc. Respondent, in its defense, did not attempt to demonstrate that the system that it had in place during the relevant time period adequately identified suspicious orders—in fact, Ireland took responsibility for Respondent’s SOM system failures and failure to adequately report suspicious orders to DEA. Tr. 731, 733. Based on the evidence in the record and Respondent’s admitted failures, the Agency finds that Respondent clearly violated 21 CFR

⁵⁵ It is noted that Respondent uses a different quote from the GS that stated that the intent of the analysis was “to quantify, you know, just how many orders are we talking about that fell outside of just a normal pattern or set amount” and that “the analysis showed that there were roughly, 14,000 orders that should have been reported as suspicious based on the quantity that was ordered.” Respondent’s Exceptions, at 45 (quoting Tr. 293). Given the several contextual parameters that the GS used in these statements, like “just a normal pattern or set amount” and “based on the quantity that was ordered,” the Agency does not find this statement to be inconsistent with the GS’s statement at Tr. 404, regarding the purpose of G.R.’s analysis.

⁵⁶ The Government’s Prehearing Statement states that G.R. “will testify that a standard statistical outlier analysis is a reasonable method to identify unusual transactions in the context of pharmaceutical distribution.” ALJX 7, at 6. The description of G.R.’s testimony in both the Government’s Prehearing Statement and Third Supplemental Prehearing Statement discusses the manner in which G.R. arrived at his calculations and established reasonable thresholds. *Id.* at 6–8; ALJX 52, at 20 (“G.R. will testify that his analysis identified the following unusually large transactions for the exemplar pharmacies.”). The Agency additionally agrees with the rationale of the ALJ that G.R.’s testimony regarding the intent of his statistical analysis did not give rise to a new allegation. *See* RD, at 96 n.33.

⁵⁷ The December 20, 2007 letter that DEA sent to manufacturers and distributors stated that “[t]he regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.” GX 4, at 1.

1301.74(b) in failing to design and operate its system and in failing to investigate or report suspicious orders to DEA. Respondent’s attempts to distract the Agency from the notion that it did not adequately meet the regulatory obligation by picking apart DEA’s ballpark estimate demonstrating the potential magnitude of Respondent’s violations are unavailing. The Agency notes that Respondent contests the quantity of suspicious orders that G.R. identified as unreported to DEA; but G.R.’s analysis, which he notably calibrated to only identify extreme outliers, Tr. 203, shows that the number of unreported suspicious orders for these two controlled substances during the relevant timeframe could have potentially been in the thousands.⁵⁸

F. Respondent’s Policies and Procedures During the Relevant Timeframe

Respondent produced a Policies and Procedure Manual and a Standard Operating Procedures (SOP) Manual in response to DEA’s investigation. GX 17 and 18. The Policies and Procedure Manual states, “Where a Compliance Officer sees a ratio of controlled drugs ordered out of the normal range, or the overall quantity is too high compared with the volume of the account, the Compliance Officer has a duty to investigate by calling the account. The Compliance Officer may stop shipment on any order if he or she finds the order to be unusually suspicious.” GX 17, at 12. The Policies and Procedures Manual notably does not indicate an obligation to report suspicious orders to DEA. The GS testified that in his review of Respondent’s records, he did not see documentation of stopped suspicious orders. Tr. 315–16. The SOP Manual⁵⁹ states that Respondent “keeps a system in operation which is designed to discover those purchasing patterns of controlled substances which exceed the norm and could possibly be related to diversion activities.” GX 18, at 19. The GS testified that this statement does not adequately reflect the obligations in 21 CFR 1301.74(b). Tr. 307. Further, although the SOP Manual describes various analytical reports regarding drug sales and drug volumes, the GS testified that he did not see any references to these reports in Respondent’s relevant

⁵⁸ Respondent further made arguments related to what it determined as inconsistent analysis in the RD related to G.R.’s outlier numbers. Resp Exceptions, at 44–46. The Agency finds that G.R.’s analysis provides a ballpark of the egregiousness of Respondent’s failures to design and operate the required system. *See* Tr. 227, 224.

⁵⁹ The SOP Manual states that the details of Respondent’s suspicious order monitoring program “are confidential and therefore are not made a part of this manual.” Tr. 306; GX 18, at 17.

records. Tr. 308–09, 491. The SOP Manual does clearly state that “[w]hen a suspicious pattern or purchase is identified by any of the above methods the customer is contacted in some but not all cases and asked for a written explanation for the unusual order. In all cases,⁶⁰ a letter is sent to the DEA indicating a possible suspicious order.” GX 18, at 20.

G. Respondent’s Former SOM System

Ireland testified that Respondent’s SOM system during the time period comprising the allegations (former SOM System) was “not as robust as what we have today.” Tr. 738–40 (citing *e.g.*, GX 19, at 3); *see also* RX 31.001 and 31.002 (notes that were part of Respondent’s former SOM System). The former SOM system included: know your customer efforts; an electronic customer profile (ECP); a market basket system; reports from Pro Compliance; direct contact with and soliciting of information from customers; and reliance on Respondent’s sales force and those who actually filled orders for controlled substances. Tr. 866–70; GX 9, at 2–3; GX 17, at 12; GX 18, at 19–20.

Ireland testified that Respondent’s former SOM system would send an email or text message to the compliance officer, C.G., when an order was flagged as suspicious and the order would ship if C.G. did not take action to stop it. Tr. 728, 778.

Ireland testified that Respondent’s former SOM system was “not consistent with best practices . . . because it didn’t hold the order. It didn’t give an opportunity to resolve red flags before shipping.” Tr. 729. Additionally, Ireland testified that “the calculation that the system was using [to identify potentially suspicious orders] was only using ten times a 90-day average,” which made it “inadequate.” Tr. 729; *see also* Tr. 321–22 (The GS testimony that 8 times the average could still be a suspicious order); Tr. 652 (Weinstein testifying that this calculation was not sufficient based on DEA guidance). Regarding the former SOM system, Milione testified that his “understanding is they accepted that there were things wrong with it, that the

⁶⁰ The GS testified that customers should be contacted in all cases. Tr. 484. *Masters* may provide some room for nuance if Respondent stops shipment of the orders and reports to DEA; however, none of this nuance is represented in the SOP Manual. Additionally, the policy states that “in all cases,” DEA is required to be notified, when in fact, DEA was only notified three times during the relevant time period and the record evidence established that Respondent neither reported to DEA nor adequately documented the resolution of red flags for the exemplar pharmacies or generally for suspicious orders during the relevant time period. *See supra* III.D.

reporting to DEA was insufficient.” Tr. 989. Further, he stated, “it was clear that there was an issue” and that after reviewing the system, his company told Respondent that “there are certain things that should be enhanced knowing what DEA expected.” Tr. 990–91. For example, “one of the big things was a way to flag orders [in] real time and in an appropriate way with some kind of an algorithm and then report those flagged orders to DEA.” Tr. 991.

Respondent also argues that as a result of its former SOM system, it had ceased supplying controlled substances to 42 pharmacies from 2014 to 2016. RX 11, at 14 (powerpoint slide); Tr. 871. Respondent’s expert acknowledged that if those customers had been terminated based on Respondent’s SOM program, it should have filed suspicious order reports with DEA. Tr. 1015–16; *see also Masters Pharm., Inc.*, 80 FR at 55477 (holding that a distributor discovering a suspicious order must either stop shipping and report to DEA or investigate and resolve the red flags). If Respondent stopped shipping and terminated a customer as a result of discovering a suspicious order, that order should have been reported to DEA. There is no evidence that the 42 customers from 2014 to 2016 were reported to DEA—in fact, the evidence establishes that there was only one suspicious order report filed during this timeframe on April 7, 2014. *See* GX 6, at 1.⁶¹

⁶¹ It is also noted that Jacob Dickson’s letter stated that Respondent had ceased supplying 142 retail pharmacies “due to questions and concerns that the pharmacies were overdispensing controlled substances. After ceasing doing business with these ‘bad accounts’ [Respondent] has seen very few examples which would justify the reporting of a suspicious order.” GX 9, at 5. Milione testified that Mr. Dickson “specifically took pride in being able to say, look, this—every year there has been this—this many customers that they focused on and identified. And I think—I don’t know the exact math. It was 125, 135 customers from 2008 to 2016 that were terminated or suspended . . . based upon their compliance suspicious order monitoring program.” Tr. 870–71. Respondent provided transcribed testimony from Mr. Dickson in a separate hearing stating that Respondent eliminated 142 customers “because in some form or fashion they might have been suspicious and diverting.” RX 1, at 61. It is unclear how many of these customers were terminated during the relevant timeframe—other than the 42 customers that were terminated during 2014 to 2016. Without the benefit of evidence or testimony regarding the circumstances of the terminations during the relevant timeframe, it is difficult for the Agency to determine what weight to give these terminations, *see* RD, at n.32; however, the language on the record describing these orders as “suspicious and diverting” or “overdispensing” or “bad accounts” certainly brings into question whether they could constitute additional violations of the suspicious order reporting requirement. *See also* RD, at 136. In sum, without further evidence explaining the circumstances of the terminations or the reasons why they were unreported to DEA, the Agency

H. Respondent’s New SOM System

Respondent requested confidentiality related to its current SOM system and policies; therefore, this Decision incorporates by reference the findings of the RD related to Respondent’s system and summarizes herein at as high a level as possible while appropriately adjudicating the facts.⁶² *See* RD, at 75–82. Guidepost⁶³ undertook seven corrective measures on Respondent’s behalf. Tr. 882. Those measures included: (1) establishing an anti-diversion compliance regulatory affairs team; (2) enhancing Respondent’s SOM system; (3) redeveloping Respondent’s ECP; (4) enhancing Respondent’s “know your customer protocols”; (5) enhancing Respondent’s due diligence investigative protocols; (6) conducting employee training; and (7) documenting everything and reporting to DEA. Tr. 882–900. The Analysis Group, Inc., (AGI) was also brought in to develop a live real-time order monitoring system that would identify suspicious orders. Tr. 885. Between May 14, 2018, and July 29, 2018, Respondent submitted 58 suspicious order reports to the DEA. RX 20. In those 58 reports, Respondent informed the DEA of approximately 3,915 suspicious orders. *Id.* Applying Respondent’s new SOM program to its orders from early 2018, Weinstein identified a similar number of suspicious orders.⁶⁴ Tr. 666, 676, 682–

cannot give Respondent’s terminations during the relevant timeframe the weight that Respondent requests to demonstrate its compliance. These terminations are not being considered as further violations of DEA regulations, but they are also not given weight for Respondent in the public interest inquiry. Finally, the Agency notes that whether Respondent’s SOM System was adequate prior to the relevant timeframe is not a matter currently before the Agency.

⁶² *See, e.g.*, Tr. 15 (Respondent requesting confidentiality based on “proprietary trade secrets of the Analysis Group regarding the customized suspicious order monitoring system that they have developed for the Respondent, as well as all of the different functionality of the Respondent’s suspicious order monitoring system.”); ALJX 82. The Agency has provided a high-level summary of these improvements to demonstrate consideration of the scope of Respondent’s remedial measures. The numbers of suspicious orders have been included because the Agency finds this information to be relevant to the adjudication of this matter.

⁶³ Respondent paid Guidepost a large sum of money between the time the OSC/ISO was issued and May 2019 to be brought into compliance with DEA regulations. Tr. 973–74, 992 (*see* RD, at 76 for further details). Milione testified that Respondent has “spared no expense” in becoming compliant with DEA regulations. Tr. 992.

⁶⁴ Although Respondent did not run its new system on the old data during the time period covered by the OSC, Tr. 682, 686, Weinstein did testify that Respondent applied its current SOM system to the orders Respondent received in early 2018 (covering some of the allegations in the OSC) and Weinstein testified that using the current SOM system “[c]ertainly there were some that would

83. Respondent’s current SOM system holds customer’s orders as “potentially suspicious” and prevents the orders from being shipped until the Compliance team has reviewed. Tr. 668–69, 672; 582. Furthermore, Respondent currently documents its due diligence regarding suspicious orders in the Enhanced Customer Profiles in a readily-retrievable format. Tr. 737, 716; RD, at 79.

IV. Analysis

A distributor’s registration may be suspended or revoked upon a finding that the distributor “has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section” 21 U.S.C. 824(a)(4). With regard to distributors of schedule II controlled substances, Congress has set forth five factors to consider when determining whether the distributor’s registration would be in the public interest. The factors to be considered are:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(b).⁶⁵

have been identified in those months. And in a similar number to what’s being identified currently.” Tr. 666; *see also* Tr. 676 (data from April 2018 (in the relevant timeframe) produced a roughly similar volume of flagged orders, which “tends to be in the hundreds each month that are identified by the thresholds”). It is noted that these numbers reflect the quantity of orders that would have been flagged for suspicion and does not “take into account any due diligence” etc. Tr. 677. This testimony is not included in this Decision to prove the number of suspicious orders that DEA should have received in early 2018, but, instead, is included to further support the Agency’s finding that Respondent’s suspicious order monitoring and reporting during the relevant timeframe was insufficient to meet the regulatory requirements.

⁶⁵ 21 U.S.C. 823(e) also applies to distributors of controlled substances. The section sets forth the identical factors to be considered regarding a registration to distribute controlled substances in schedules III, IV, and V, as are contained in 21 U.S.C. 823(b) concerning schedules I and II. The Government’s allegations are focused primarily on Respondent’s distribution of schedule II controlled substances, but in 2014, during the time period of the allegations, hydrocodone was changed from a schedule III to a schedule II controlled substance. Tr. 539. Additionally, Respondent is a registered distributor of controlled substances in schedules II–

The Agency considers these public interest factors in the disjunctive and may rely on any one or a combination of factors and give each factor the weight the Agency deems appropriate in determining whether to revoke a registration or to deny a pending application for renewal of a registration. *Masters Pharm., Inc.*, 80 FR at 55472 (applying DEA decisions on the public interest factors in 21 U.S.C. 823(f) to the public interest factors for distributors in 21 U.S.C. 823(b) and (e)); *see also Southwood Pharm., Inc.*, 72 FR at 36497–98. Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993). There is no need to enter findings on each of the factors.⁶⁶ *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005); *Masters Pharm., Inc.*, 80 FR at 55473.

The Government bears the initial burden of proof and must justify revocation by a preponderance of the evidence. *Steadman*, 450 U.S. at 100–03; *Masters Pharm., Inc.*, 80 FR at 55473; 21 CFR 1301.44(e). If the Government makes a *prima facie* case for revocation, then the burden of proof shifts to the registrant to show why its continued registration would not be inconsistent with the public interest. *Masters Pharm., Inc.*, 80 FR at 55473; *see also Med. Shoppe—Jonesborough*, 73 FR 364, 387 (2008).

In this case, the Government contends that Respondent's continued registrations are inconsistent with the public interest based on Factors One and Four. ALJ–90, at 27–29.

*A. Respondent's Failure To Maintain Effective Controls Against Diversion and its Experience With Controlled Substances (Factors One and Four)*⁶⁷

With respect to Factor One, concerning the maintenance of effective

controls against diversion, DEA has promulgated regulations to guide the regulated community. Specifically,

All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in [21 CFR] 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR 1301.71(a).

DEA's security regulations further provide that:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 CFR 1301.74(b).

The OSC alleges that Respondent failed to maintain “effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels,” in violation of 21 U.S.C. 823(b)(1) and 21 CFR 1301.71(a). ALJX 1, at 3, paras. 7, 10. Second, the OSC alleges that Respondent failed to adequately “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and report them to DEA, in violation of 21 CFR 1301.74(b). ALJX 1, at 3, paras. 8, 10.

Factor Four involves a registrant's past experience in the distribution of controlled substances, which the Government has argued is appropriately considered along with its maintenance of effective controls against diversion. *See, e.g., Masters Pharm., Inc.*, 80 FR at 55473. In this case, Respondent argues that its experience in the distribution of controlled substances “is extensive,” as it was “founded in 1841 and distributes more than 33,000 products,” and that its history of compliance weighs against a finding that Respondent's registration is inconsistent with the public interest. ALJX 89, at 115–116 (citing RX 1, at 13:16, 15:10). Although Respondent's arguments have been considered, Respondent's misconduct as described further herein precludes a finding that Respondent's experience establishes a

“history of compliance.” *See Novelty Distributors, Inc.*, 73 FR 52689, 52702 (2008) (analyzing the identical factor for distributors under 21 U.S.C. 823(h)).

1. A Suspicious Order

To begin, the regulations require distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” 21 CFR 1301.74(b). The regulations provide that, at minimum, a suspicious order includes “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.*; *see* section IV.A.3. These three criteria are non-exclusive and registrants may encounter other considerations beyond those spelled out in the regulation that could qualify an order as suspicious. *Masters Pharm., Inc.*, 80 FR at 55473–74; *Masters Pharm., Inc.*, 861 F.3d at 221 (noting the regulatory criteria for suspicion are “exemplary rather than exhaustive”). For example, a distributor might find a pharmacy's orders for controlled substances to be suspicious not only based on their exhibiting the characteristics set forth in the regulation, but also based upon the “pharmacy's business model, dispensing patterns, or other characteristics.” *Masters Pharm., Inc.*, 80 FR at 55473–74; *see also id.* at 55477 (stating that “an order is not only suspicious by virtue of its internal properties—*i.e.*, being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order]”). The identification of a suspicious order that is based on the nature of the pharmacy's business takes place at the customer-level. *See infra* section IV.A.4.

In order to conclude that an order for controlled substances is suspicious, a “distributor is not required to establish, to a statistical certainty, that a pharmacy was likely diverting controlled substances.” *Masters Pharm., Inc.*, 80 FR at 55480. In fact, suspicion is a low standard, defined as merely one's “‘apprehension or imagination of the existence of something wrong based only on inconclusive or slight evidence, or possibly no evidence.’” *Masters Pharm., Inc.*, 80 FR at 55478 (quoting Black's Law Dictionary 1585 (9th ed. 2009)). Thus, if a distributor is aware of any indication of “the existence of something wrong” concerning the size, frequency, or pattern of an order, then the distributor is obligated to report it to the DEA. *Masters Pharm., Inc.*, 80 FR at 55478. Because suspicion is a low standard, a distributor's obligation to report suspicious orders is triggered long before the distributor would have

V; therefore, the Agency, even when referring only to (b), considers the identical public interest factors under both sections 823(b) and (e) in this section.

⁶⁶ Respondent argues that “an independent consideration of each of these [five] factors [at 21 U.S.C. 823(b)(1–5)] weigh[s] against a finding that Respondent's continued registration is inconsistent with the public interest.” ALJX 89, para. 291. In other words, although the Government only submitted evidence relevant to Factor One and Factor Four, Respondent urges the Agency to find evidence relevant to all five Factors. The Agency declines to adjudicate, at Respondent's request, arguments that the Government did not make, yet notes that if it were to do as Respondent requests, the ensuing analysis of all five Factors would continue to point to the revocation of Respondent's registration.

⁶⁷ While listing the five public interest factors of 21 U.S.C. 823(b), the Government specifically notes that it does not rely on Factors Three or Five and makes no argument concerning Factor Two. ALJ–90, at 27–29 & n.12. Further, the Government combines its analysis of Factors One and Four. *Id.*

at 28–44. The Government notes that where it has not made allegations with respect to Factors Three and Five, the factors do not weigh for or against revocation. *See* ALJX 90, at n.12. As such, although the Agency has considered all five factors, its analysis focuses on Factors One and Four.

probable cause to believe that a customer is engaged in diversion. *Id.* As *Masters* explains, suspicion is not contingent on evidence that the order will be diverted or that the customer is engaged in diversion. *Id.* With regard to the reporting requirement, the Agency's emphasis is on *suspicion* and not conclusive proof of diversion. *Id.* at 55420 (explaining that tying suspicion to evidence of diversion "imposes a higher standard than that of the plain language of the regulation, which requires only that the order be suspicious").

2. Respondent's Failure To Adequately Design and Operate a Suspicious Order Monitoring System

When a distributor's suspicious order monitoring (SOM) system places a hold on a customer's order for controlled substances because the order is of unusual size, pattern, or frequency, the order meets the specific criteria of being suspicious. *Masters Pharm., Inc.*, 80 FR at 55479; *Masters Pharm., Inc.*, 861 F.3d at 216–17 (affirming the Acting Administrator's ruling that "orders held by the [distributor's SOM systems] met the regulatory definition of 'suspicious orders'"). DEA has made clear that it does not endorse any particular system for identifying suspicious orders. GX 4, at 1; Tr. 59–60, 76, 210, 497, 646.

In this case, Respondent's SOM system during the relevant time period did not have the capability to hold an order that was flagged as "potentially suspicious." Tr. 728, 778. Therefore, the system could not comply with the DEA legal requirements. Tr. 729 (Irelan testifying that the SOM system was "not consistent with best practices" because "[i]t didn't give an opportunity to resolve red flags before shipping.")

Additionally, the witnesses were in agreement that Respondent's SOM system during the relevant time period was inadequate to identify orders of unusual size in that it only flagged orders that were "ten times a 90-day average," Tr. 729–30, 321, 652.⁶⁸

Further, while Respondent had written policies and procedures, those policies and procedures only identified three suspicious orders over a period of four years and four months that were reported to the DEA. Respondent admits that its previous policies were inadequate. Tr. 720–21. Respondent had a policy of producing monthly and daily reports, yet none is apparent in the Administrative Record, and although

Respondent maintained a proprietary database, RX 11, at 5, there is no record evidence from this database.

Finally, although Respondent argues that the record supports that it was conducting due diligence into its customers, Respondent admits that it did not adequately document that due diligence, nor did it apply that due diligence at an order level. *See infra* section IV.A.4. Respondent's policy of not documenting its due diligence, GX 9, was also inconsistent with the *Masters* decision. *See id.*

In sum, the Agency finds substantial record evidence that Respondent failed to design and operate an adequate SOM system in violation of 21 CFR 1301.74(b).

3. Respondent's Failure To Report Suspicious Orders Under the Listed Criteria in 21 CFR 1301.74(b)

As explained above, DEA regulations obligate distributors of controlled substances to not only design and operate a system to identify suspicious orders, but to also report all suspicious orders to DEA. 21 CFR 1301.74(b). In other words, DEA regulations require distributors like Respondent "to alert DEA when their retail-pharmacy customers *attempt* to obtain unusual amounts of a controlled substance, because such attempts are powerful evidence that the pharmacies are operating illegally." *Masters Pharm., Inc.*, 861 F.3d at 217–18 (emphasis in original).⁶⁹ Moreover, the Agency has previously held that filing ARCOS reports does not satisfy a distributor's obligation to notify DEA of suspicious orders, *Southwood Pharm., Inc.*, 72 FR at 36501, nor does filing reports on a routine or periodic schedule. *Masters Pharm., Inc.*, 80 FR at 55478.

The purpose of the DEA's reporting requirement is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." *Masters Pharm., Inc.*, 80 FR at 55483 n.169 (quoting *Southwood Pharm., Inc.*, 72 FR at 36501). As such, when a distributor obtains "information that an order is suspicious but then chooses to ignore that information and fails to report the order," the distributor violates its regulatory obligation. *Id.* at 55478.

Here, DEA presented evidence using the Tukey statistical model to determine a ballpark number of suspicious orders that an adequate SOM system might

have identified during the time period in the allegations both for the eight exemplar pharmacies and for Respondent's customer base at large for two frequently abused controlled substances: oxycodone and hydrocodone. The ballpark estimate found numerous potential suspicious orders for seven out of the eight exemplar pharmacies, and for the overall customers, it found that 7,252 sales of oxycodone and 4,948 sales of hydrocodone during this time period should have possibly been reported as suspicious to DEA.⁷⁰

The ballpark numbers constitute substantial evidence that there were far more suspicious orders that should have been identified, investigated, or reported than the mere three that Respondent reported during the time period. Even taking into consideration all of the criticism levied on DEA's modeling by Respondent's expert, he himself admitted that the data run during the beginning of 2018 produced similar results to the quantity that Respondent was reporting under the new system, which, in a little over a year, amounted to 3,915 suspicious orders. As such, the Agency agrees with the ALJ that the three suspicious order reports filed during the relevant timeframe "barely scratched the surface," RD, at 140, and finds it clear that the Government has proven by substantial evidence that Respondent failed to investigate or report potentially thousands of suspicious orders of oxycodone and hydrocodone to DEA. *Supra* section III.E.

Furthermore, the *Southwood* decision explained that even *after* a suspicious order is reported to DEA, a distributor must conduct some due diligence and only ship the order "if it is able to determine that the order is not likely to be diverted into illegal channels." *Masters Pharmaceuticals*, 861 F.3d 206 (2017) (citing *Southwood Pharm., Inc.*, 72 FR at 36500). Here, it is undisputed that Respondent submitted three suspicious order reports to DEA during the relevant time period. The GS testified that Respondent shipped these orders without documenting any resolution of the suspicious circumstances that caused Respondent to report them to DEA. Tr. 294. Thus, the Agency finds substantial record evidence that Respondent's lack of documentation of its investigation into and resolution of these red flags,

⁶⁸ DEA sent a letter in December 20, 2007, warning distributors that a SOM system "rely[ing] on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders." GX 4, at 2.

⁶⁹ Suspicious orders meeting the definition in 21 CFR 1301.74(b) must be reported to DEA, and Respondent did not argue otherwise. *See, e.g.*, Tr. 732, 1024; RX 20.001, at 1. There is additionally no record evidence that Respondent investigated these suspicious orders and resolved them at any time.

⁷⁰ It is noted that the ballpark numbers that G.R. testified to support a conclusion that Respondent failed to identify, resolve, or report suspicious orders under the criteria in § 1301.74(b) to DEA—not whether Respondent failed to conduct customer due diligence generally.

coupled with its shipping of the suspicious orders, demonstrates additional violations of Respondent's regulatory obligations to provide effective controls and procedures to guard against diversion of controlled substances.

4. Customer Due Diligence and Red Flags

It is inherent in the obligation under 21 CFR 1301.71(a) to maintain "effective controls" against diversion that "a registrant has an affirmative duty to protect against diversion by knowing its customers and the nature of [their controlled substances] sales." *Holloway Distributing*, 72 FR 42118, 42124 (2007).⁷¹ Therefore, a distributor is required to act on "information which raise[s] serious doubt as to the legality of [the customer's] business practices," also referred to as red flags,⁷² indicative of diversion. *Masters Pharm., Inc.*, 80 FR at 55477 (alteration in original) (quoting *Southwood Pharm., Inc.*, 72 FR at 36498). A distributor must also "conduct a reasonable investigation to determine the nature of a potential customer's business before it sells to the customer." *Id.* Furthermore, a distributor has a continuing obligation to perform due diligence of a customer throughout the distributor's relationship with that customer. *Id.* at 55477. *Masters* clarified that "although a distributor's investigation of the order (coupled with its previous due diligence efforts) may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags indicating that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order." *Id.* at 55478.

The record evidence and testimony from multiple experts in this case, the Pro Compliance Reports themselves,

⁷¹ See also *Holloway Distributing*, 72 FR 42118, 42124 (2007) (finding that a distributor of List I chemicals' "policy—which is fairly characterized as 'see no evil, hear no evil'—is fundamentally inconsistent with the obligations of a DEA registrant").

⁷² It is noted that Agency Adjudications have used the term "red flag" as early as 1998 and federal courts have used the term as early as 1986. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 FR 79188, 79195 n.23 (2016), *pet. for rev. denied*, 881 F.3d 823 (11th Cir. 2018). In general, a red flag is any "circumstance that does or should raise a reasonable suspicion as to the validity of a prescription [or order]." *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy*, 83 FR at 10896 n.31 (quoting *Hills Pharmacy, L.L.C.*, 81 FR at 49839). Red flags are, in essence, "warning signs" or "suspicious circumstances" that alert the registrant that something is not right. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 FR at 79195 n.23.

and prior DEA decisions have all clearly demonstrated that such suspicious circumstances, or red flags, include a pharmacy that: dispenses a high volume of narcotics;⁷³ dispenses the trinity drug cocktail;⁷⁴ dispenses disproportionately more controlled substances than non-controlled substances;⁷⁵ fills prescriptions for a high volume of patients who pay for prescriptions in cash;⁷⁶ fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers;⁷⁷ and orders excessive quantities of a limited variety of controlled substances.⁷⁸ See *supra* section III.C. A distributor fails to maintain effective controls against diversion when the distributor continues to distribute controlled substances to a pharmacy that exhibits red flags of diversion without resolving those red flags. *Masters Pharm., Inc.*, 80 FR at 55457 (faulting the distributor for supplying controlled substances "while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensing of controlled substances"); *cf. Top RX Pharmacy*, 78 FR 26069, 26082 (2013) (applying a similar principle to pharmacies filling prescriptions that contain red flags of abuse or diversion); see also *Novelty Distributors, Inc.*, 73 FR 52689, 52699 (2008) (applying a similar principle to list I chemical distributors under 21 U.S.C. 823(h) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for

⁷³ *Masters Pharm., Inc.*, 80 FR at 5548–81 n.168 (explaining where a distributor had information that 50 percent of the prescriptions filled by a pharmacy were for controlled substances, while the average pharmacy only fills about 20 percent, the distributor "had substantial information which raised a strong suspicion as to the legitimacy of [the pharmacy's] dispensing practices"); GX 3, at 3.

⁷⁴ *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 FR at 79194 ("The combination of a benzodiazepine, a narcotic and carisoprodol is 'well known in the pharmacy profession' as being used 'by patients abusing prescription drugs.'" (quoting *E. Main St. Pharmacy*, 75 FR 66149, 66163 (2010))).

⁷⁵ *Masters Pharm., Inc.*, 80 FR at 55456; GX 3, at 3.

⁷⁶ *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 FR at 79194 ("[A]ny reasonable pharmacist knows that a patient that (sic) wants to pay cash for a large quantity of controlled substances is immediately suspect." (quoting *E. Main St. Pharmacy*, 75 FR 66149, 66158 (2010))).

⁷⁷ GX 3, at 3.

⁷⁸ *Masters Pharm., Inc.*, 80 FR at 55421; GX 3, at 3.

legitimate purposes.")).⁷⁹ A distributor has an obligation to guard against diversion, and as such, must resolve red flags of diversion presented by its customers or decline to ship the controlled substance. 21 U.S.C. 823(b), (e); 21 CFR 1301.71(a).

When a customer demonstrates red flags of diversion, the distributor must report a suspicious order to DEA unless the distributor conducts a due diligence investigation, which "must dispel all red flags indicative that a customer is engaged in diversion." *Masters Pharm., Inc.*, 80 FR at 55478. "Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the [DEA] must be informed." *Id.*; see also *id.* at 55479 n.164 (same).

In upholding DEA's interpretation of the due diligence requirement in the *Masters* decision, the D.C. Circuit Court of Appeals stated:

As we have emphasized throughout this opinion, it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them. But if a distributor chooses to shoulder the burden of dispelling suspicion in the hopes of shipping any it finds to be non-suspicious, and the distributor uses something like the SOMS Protocol to guide its efforts, then the distributor must actually undertake the

⁷⁹ Respondent introduced testimony regarding whether Respondent could continue to ship during a due diligence investigation into customer-level red flags of diversion—arguing that there is a certain amount of discretion involved and that stopping shipments would disrupt the supply chain. See, e.g., Tr. 1049, 1050, 1042; 649. The record does not support a finding that Respondent did, in fact, adequately dispel all of the red flags on these customers at any time (before or after distributing), or that Respondent adequately documented purported resolutions of the red flags. The *Masters* decision cannot be read to intend to create a loophole in which a distributor could avoid reporting requirements and continue to ship orders of controlled substances while conducting lengthy investigations into red flags. Such an interpretation would not meet the requirement that a distributor maintain effective controls against diversion. To the extent that, as Respondent argues, there may be some discretion in the decision of when to ship, it is abundantly clear that a distributor cannot ship if it cannot determine that the "proposed transaction is for legitimate purposes." *Novelty Distributors 73 FR* at 52699, or without resolving "information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices." *Masters Pharm., Inc.*, 80 FR at 55477 (alteration in original) (quoting *Southwood Pharm., Inc.*, 72 FR at 36,498). Further, Respondent's supply chain argument is weakened by the fact that Respondent had a duty to and was purportedly running reports on prospective customers; therefore, it knew about many of the red flags in the eight exemplar pharmacies before engaging in business with them. See, e.g., GX 25, at 4 (Initial Risk Evaluation Report for Hephzibah Pharmacy LLC); RX 11, at 15 (powerpoint demonstrating turned down prospective accounts based on Pro Compliance Reports).

investigation. For example, when an employee uses the SOMS Protocol to confirm or dispel suspicion based on the amount of controlled medication the pharmacy is selling, the employee must request a ‘UR,’ *i.e.*, a document showing the pharmacy’s ‘actual dispensing[s] . . . of each drug.’ [*Masters Pharm., Inc.*] 80 FR [55418,] 55420 [(2015)]. Moreover, the investigating employee must ‘document’ customers’ explanations for suspicious orders, so that he or she can verify those explanations and make sure they are consistent over time. *Id.* at 55428 n.21. Additionally, if a customer’s explanation for its order is ‘inconsistent with other information the investigator has obtained about or from the customer, . . . the [investigator] must conduct ‘additional investigation to determine whether [its customer is] filling legitimate prescriptions.’ *Id.* at 55477. Finally, the investigation must dispel all of the ‘red flags’ that gave rise to the suspicion that the customer was diverting controlled substances. *Id.* at 55478. The Administrator recognized that, if investigating employees fail to take such basic steps, the SOMS (or similar protocol) does not function as an effective tool for dispelling suspicion.

Masters Pharm., Inc., 861 F.3d at 222–23. The D.C. Circuit made clear that all red flags must be resolved or the order must be reported to DEA as suspicious.

In this case, Respondent received numerous Pro Compliance Reports that raised multiple red flags for each of the relevant customers during the relevant time period. *See* GX 20–56; *supra* section III.D. The Pro Compliance Reports themselves clearly identify specific red flags in Respondent’s customers’ data and frequently recommend further discussions and onsite visits to resolve them. *See, e.g.*, GX 21, at 6; *supra* III.E. Although Respondent produced some minimal evidence consisting of phone logs for some of the exemplar pharmacies in the OSC, *see supra* n.12 and section III.D., which indicated a few instances over the several year timeframe where Respondent had engaged with these customers regarding red flags and/or suspicious orders, there is not adequate documentation as to how Respondent resolved the red flags, even as Respondent continued to fill these orders without reporting them to DEA. Moreover, the GS credibly testified that documentation was an essential component of due diligence. Tr. 298–99 (“[I]f you don’t document it how are you going to remember it, how are you going to be able to prove it happened”). The *Masters* decision further pointed out that documentation is essential in maintaining effective controls against diversion to ensure that customers are consistent in their explanations regarding red flags. *Masters Pharm., Inc.*, 80 FR at 55428 n.21. The D.C.

Circuit also affirmed the Agency’s position that if a distributor undertakes an investigation into its customer’s potential diversion, then it must document and “dispel all of the ‘red flags’ that gave rise to the suspicion that the customer was diverting controlled substances” to avoid the requirement to report the suspicious order to DEA. *Masters Pharm., Inc.*, 861 F.3d at 222–23.

Here, Respondent acknowledged the paucity of documentation in its records that might show that it had resolved red flags. *See, e.g.*, Tr. 720; GX 9, at 1–2. Contrary to Respondent’s argument (ALJ–89, at 101–03, paras. 272–75), the absence of documentation of resolving red flags does indeed constitute evidence that the red flags were never resolved. *See Masters Pharm., Inc.*, 861 F.3d at 218.⁸⁰ While Respondent did conduct some due diligence, such as by obtaining Pro Compliance Reports and by preparing its own monthly Market Basket Reports of its customers, ordering the reports without taking appropriate action based on the content of those reports does not come close to satisfying the regulatory obligation to conduct due diligence. These Pro Compliance Reports identify multiple red flags from Respondent’s pharmacy customers—demonstrating that Respondent was aware of these red flags—while the records it produced do not resolve them in any substantive way to demonstrate effective controls against

⁸⁰ To permit Respondent to escape any liability for its lack of adequate controls to protect against diversion merely because Respondent created a policy that did not require documentation of how those controls were exercised would nullify the purpose of the statutory and regulatory requirements. Further, the Agency agrees with the ALJ that Respondent’s intentional strategy of not presenting the testimony of any witness who was actually involved in Respondent’s purported resolution of red flags further undermines its argument that the red flags were actually resolved. *Id.* Finally, Agency decisions have frequently described the importance of documentation to meet DEA regulatory requirements in other contexts. *See Kaniz F. Khan-Jaffery, M.D.*, 85 FR 45667, 45686 (2020) (“DEA’s ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment.” (citing *Cynthia M. Cadet, M.D.*, 76 FR 19450, 19464 (2011))). In particular, the *Masters* decision affirmatively stated the requirement for distributors to document their resolutions of red flags and gave a rational basis for that requirement—ensuring that the information is memorialized for the resolution of future indicia of diversion. *Masters Pharm., Inc.*, 80 FR at 55,428 n.21. This basis is very apparent here where Respondent’s customer base is large and the shipments are numerous. As such, the Agency finds that Respondent’s failure to maintain adequate documentation indicates a violation of the requirements to maintain effective controls against diversion.

diversion. *See, e.g.*, GX 20–56 (the Pro Compliance Reports for the exemplar pharmacies). Respondent’s employees even noted occasions where information in the Pro Compliance Reports was specifically concerning to them or where they were aware of additional indicia of diversion or suspicious orders, yet these orders were neither reported to DEA nor is there record evidence to support a finding that Respondent resolved all of the red flags that gave rise to the suspicion. *See, e.g.*, Respondent’s employee’s comments, at GX 14, at 4 (“[T]his seems quite elevated to me. . . .????”) and 31 (“Henry will give the customer a warning about his Oxy purchases. Too much cash, too much growth. Will re-run and if no improvement will either restrict or cut off completely.”). The note documenting this interaction not only fails to offer any resolution of the suspicious circumstances or indicate any reporting to DEA, but also indicates that Respondent knew of the existence of a suspicious order and that the customer was given a warning—providing it with a chance to amend its behavior and further avoid detection from DEA. The regulations require resolution or reporting, not implementation of a “second chance” or “three strikes you’re out” program.

A distributor fails to conduct meaningful due diligence that satisfies its regulatory duties where it merely “accept[s] at face value whatever superficial explanation” the pharmacy offers and then fails to independently verify it. *Masters Pharm., Inc.*, 80 FR at 55457. Further, conducting due diligence but then failing to act on the findings is also inadequate. *See Southwood Pharm., Inc.*, 72 FR at 36500 (finding the distributor’s due diligence efforts to be inadequate where the distributor possessed information that customers were diverting controlled substances yet the distributor continued to provide them with controlled substances). Thus, as the GS credibly testified as an expert witness, the Agency finds that even though Respondent produced some due diligence files to DEA, Respondent seemed to “conduct due diligence and ignore the red flags that are in [its] face and continue to ship” without documenting the resolution of red flags or reporting to DEA, in violation of DEA regulations. Tr. 463; *see also* Tr. 80 (testimony of the Section Chief: “[Y]ou can ask for all these things, but you have to do something with it.”). As the evidence shows, Respondent continued to distribute controlled substances despite the red flags raised in its due

diligence files and without either adequately documenting an investigation or resolution of the red flags or refusing to ship and reporting the orders to DEA. As such, Respondent's due diligence was clearly insufficient to meet DEA's legal requirements. *See also* RD, at 120–128 (finding that Respondent did not either dispel all red flags for Folse, Bordelon's, Wallace, Pharmacy Specialties, Dave's Pharmacy, Hephzibah, Wellness, and Wilkinson or report the customers to DEA and refuse to ship).

5. Summary of Public Interest Factors

There is substantial record evidence that Respondent failed to adequately design a suspicious order monitoring system and failed to report suspicious orders to DEA. Further, Respondent failed to report controlled substance orders from customers displaying red flags of diversion and in such cases failed to either cease shipment, or, alternatively, to investigate, resolve, and document the resolution of the red flags. Thus, the Agency finds that Respondent failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels in violation of 21 CFR 1301.71(a). The Agency also finds that Respondent failed to adequately design and operate a system to disclose to the registrant suspicious orders of controlled substances and report those orders to DEA in violation of 21 CFR 1301.74(b). *See also* RD, at 138. These violations constitute failures to maintain effective controls against diversion under 21 U.S.C. 823(b)(1) and demonstrate negative experience in distribution under 21 U.S.C. 823(b)(4) and weigh strongly in favor of revoking Respondent's Certificates of Registration.

B. Respondent's Integrated Enterprise

DEA has requested revocation of both Respondent's registration at its distribution center in Shreveport, Louisiana, and Respondent's second registration in New Orleans (Jefferson Parish). Respondent argues that DEA has not "alleged any misconduct to have occurred at Respondent's Jefferson location or adduced any evidence or testimony at the hearing regarding Respondent's Jefferson registration." Resp Exceptions, at 49.

The Agency has frequently "treat[ed] two separately organized business entities as one integrated enterprise . . . based on the overlap of ownership, management, and operations of the two entities." *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care,*

L.L.C., 81 FR 79188, 79222 (2016) (citing *MB Wholesale, Inc.*, 72 FR 71956, 71958 (2007)). "[W]here misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy." *Superior Pharmacy I and Superior Pharmacy II*, 81 FR 31310, 31341, n.71 (2016). Further, the Agency may revoke a registration without misconduct attributable to that particular registration if the Agency finds that the registrant committed egregious misconduct under a second registration. *Roberto Zayas, M.D.*, 82 FR 21410, 21430 (2017) (revoking physician's DEA registration in Florida due to conduct attributed to a Texas registration that had expired).

When a practitioner registrant acts in a manner inconsistent with the public interest, in determining whether to revoke, DEA looks to whether the practitioner can be entrusted with a registration. *See, e.g. Arvinder Singh, M.D.*, 81 FR 8247, 8248 (2016). If a practitioner holding multiple registrations cannot be entrusted with one, then it would be difficult to justify entrusting the same practitioner with another in a separate location. Similarly, when a corporate entity is owned and operated by individuals who have acted inconsistently with the public interest and have misused one of their registrations, the Agency cannot ignore this fact when considering whether to entrust those same individuals with another registration. Furthermore, even if Respondent has not used the Jefferson registration for distribution, this fact does not prevent it from using its registration for distribution in the future.⁸¹ *See Suntime Pharmacy and Suntime Medical Equipment, LLC*, 85 FR 73753, 73766 (2020).

The lens through which Congress has instructed the Agency to assess each distributor registration is whether or not such registration is consistent with the public interest. 21 U.S.C. 823(b). In this case, if Respondent was allowed to simply shift its operations to an entity with the same ownership, then the effect of the violations found herein against Respondent would be a nullity and there would be nothing to prevent Respondent's Jefferson location from continuing to act inconsistently with the

public interest. It would be inconsistent with the intent of the CSA to permit such an easily implementable loophole, while it is consistent with Agency decisions to close the loophole by treating the two overlapping entities as one integrated enterprise for purposes of sanction.

Therefore, due to the uncontested commonality of ownership, management, and operations, *see* RD, at 154, the Agency finds that it is appropriate to treat Respondent's two registrations as one integrated enterprise.

V. Sanction

The Government has established a *prima facie* case to revoke Respondent's registration; therefore, the Agency will review any evidence and argument that Respondent submitted to determine whether or not Respondent has presented "sufficient mitigating evidence to assure the Administrator that [it] can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.*, 53 FR 21931, 21932 (1988)). "Moreover, because "past performance is the best predictor of future performance," *ALRA Labs, Inc. v. Drug Enft 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 459, 463 (2009) (quoting *Medicine Shoppe*, 73 FR 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.*, 72 FR at 23853; *John H. Kennedy, 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 respondent; 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).

A. Acceptance of Responsibility

1. Standing and Authority To Accept Responsibility

Respondent contends that it has unequivocally accepted responsibility

⁸¹ The ALJ noted that Respondent's exhibits demonstrate that it uses the Jefferson location to "secure controlled substances" and makes distributions out of its Shreveport facility. RD, at 156 (citing RX 1, at 15, 16).

for the proven misconduct and that Irelan, as its Controlled Substance Compliance Officer, was both authorized by Respondent and an appropriate person to accept responsibility on behalf of Respondent. Resp Exceptions, at 8. The Agency agrees that neither Agency regulations nor prior Agency decisions clearly preclude Irelan from accepting responsibility on behalf of Respondent and will therefore consider his acceptance of responsibility on its merits. Further, the Agency finds that the record supports that Mr. Irelan is responsible for preventing the reoccurrence of Respondent's compliance failures and accepts that Irelan obtained authority from Respondent to accept responsibility at the hearing. See Tr. 803 (Irelan is responsible for continued remedial measures), Tr. 1072–74;⁸² but see Tr. 804 (decisions also go through the chain of command and to the Board).

Ultimately, as explained above, the Agency has long stated that when the Government has presented a *prima facie* case, the burden shifts to the respondent to demonstrate why it can still be entrusted with a registration in spite of its misconduct and the Agency has emphatically emphasized the requirement that respondent unequivocally accept responsibility to establish that trust. See, e.g., *Jeffrey Stein, M.D.*, 84 FR 46968, 46972 (2019); see also *Leo R. Miller, M.D.*, 53 FR 21931, 21932 (1988) (describing revocation as a remedial measure “based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration”). For several reasons, Irelan's testimony has not adequately convinced the Agency that Respondent unequivocally accepts responsibility for its past misconduct.

2. Minimization and Characterization of the Misconduct

Here, Irelan accepted responsibility for Respondent failing to effectively apply its customer due diligence in assessing orders of controlled substances, Tr. 722–23, for Respondent failing to implement and maintain a suspicious order monitoring system

⁸² The ALJ did not admit RX 54; however, the Agency accepts that Irelan had authority to make compliance decisions and speak for Respondent in the proceeding.

“consistent with best practices for compliance,” Tr. 729, 731,⁸³ and for the fact that “[t]he reporting that was being done, there were three suspicious order reports to the DEA, and that was insufficient,” Tr. 731, 733. Irelan also testified that he accepted responsibility for Respondent shipping orders of controlled substances from January 2014 to May 2018 without resolving red flags and testified that he is responsible “for preventing reoccurrence of the company's past failures with respect to application of customer due diligence.” Tr. 807, 721.⁸⁴

In discussing his acceptance of responsibility for Respondent's failure to apply its customer due diligence, Irelan specifically testified that, based on his review of Respondent's records before May 2018, Respondent conducted “a tremendous amount of due diligence” on its customers. Tr. 704–05, 710. Irelan caveated that Respondent did not keep the due diligence documentation “in such a way as to make it . . . easily accessible.” Tr. 705 (referring to “notes on paper,” “notes . . . kept in a database” and “limited notes in our enhanced customer profile”). Nonetheless, the Agency finds that Irelan's statements claiming a “tremendous amount of due diligence” were aimed at minimizing the extent of Respondent's misconduct, which the Agency has previously weighed against a finding of unequivocal acceptance of responsibility. See *Ronald Lynch, M.D.*, 75 FR 78745, 78754 (2010) (finding that

⁸³ Compare Tr. 731 (Respondent's counsel asked whether the SOM system “was consistent with best practices and compliance” (emphasis added)). Whether or not this distinction from the previous statement was an error of speech, the Agency finds this statement to not differ significantly from the previous statement—in both, there was clearly a purposeful avoidance of taking responsibility for the full scope of Respondent's actions and an attempt to characterize the DEA regulations as being merely best practices as opposed to affirmative legal requirements.

⁸⁴ When Government Counsel asked him whether he accepted responsibility in several specific paragraphs of the OSC, Irelan either refused or testified that he was not in a position to answer. See RD, at 86. For a few of the paragraphs, Irelan's reservations seemed to be that Respondent conducted at least some additional due diligence on some of the eight pharmacies, but Irelan admitted that the due diligence was not properly applied. See, e.g., Tr. 832–33, 828–29. Given the contested nature of this part of the hearing, the Agency does not find these failures to accept responsibility to imply that Irelan has not accepted responsibility for the misconduct. See Resp Exceptions, at 24 (arguing that these were not proven allegations). However, the Agency does find, as explained herein, that Irelan's continual insistence on referring to all of the due diligence that Respondent was conducting—while not documenting it in a retrievable manner nor applying it to the orders—was clearly intended to minimize Respondent's misconduct.

Respondent did not accept responsibility after noting that he “repeatedly attempted to minimize his [egregious] misconduct”; see also *Michael White, M.D.*, 79 FR 62957, 62967 (2014)). Additionally, Irelan's insistence that Respondent was conducting this “tremendous amount” of due diligence “but it was not applied at the order level,” e.g., Tr. 828, not only minimizes the violation but fails to acknowledge its scope. At the end of the day, the fact that Respondent was not *applying* the due diligence to the orders (investigating/stopping/reporting) is possibly the most impactful aspect of Respondent's violation. If Respondent was conducting due diligence that was not documented or could not be retrieved such that it could be applied to the actual filling of orders, then Respondent was not exercising effective controls against diversion because employees filling future orders would not know if there were customer-level red flags or whether they were resolved.

Further, Irelan's statements regarding whether Respondent's monitoring systems were “consistent with best practices” also clearly minimized the scope of Respondent's misconduct and did not demonstrate a full grasp of the breadth of the misconduct alleged—which was that Respondent had violated DEA regulations,⁸⁵ not failed to implement “best practices.” Respondent's attempt to characterize the DEA regulations as being merely best practices as opposed to affirmative legal requirements both minimizes the severity of the violations and also demonstrates a failure to grasp of the significance of the requirements.

3. Scope of the Misconduct

The requisite acceptance of responsibility hinges on the respondent demonstrating an understanding both of the past misconduct and its extent. See *Jones*, 881 F.3d at 833. Here, the ALJ found that Irelan did not “acknowledge the scope of the Respondent's misconduct,” and therefore, his acceptance was equivocal. RD, at 151 (citing *Arvinder Singh, M.D.*, 81 FR at 8250–51).

As Respondent stated in its Exceptions:

Multiple United States Courts of Appeal have upheld DEA's acceptance of responsibility requirement as rational on the grounds that if a respondent “does not understand the extent of the past misconduct or its current responsibilities under the law,

⁸⁵ Even if Respondent chose its language to avoid drawing legal conclusions, the use of the term “best practices” was not sufficient to accurately describe the violations found herein and was clearly aimed at minimizing them. See *supra* n.83.

the DEA rationally could doubt that the [respondent] would faithfully comply in the future with its obligations under the CSA.” *Jones Total Health Care Pharmacy, LLC v. [Drug Enf’t Admin.]*, 881 F.3d 823, 833 (11th Cir. 2018); *accord MacKay v. [Drug Enf’t Admin.]*, 664 F.3d 808, 820 (10th Cir. 2011) (admittance of fault is relevant to Administrator’s consideration of whether a respondent will change its future behavior). As Respondent’s current Compliance Director, Mr. Irelan has assessed Respondent’s past controlled substance compliance failures and is responsible for preventing their reoccurrence.

Resp Exceptions, at 13.

In contrast to Respondent’s final statement above, there were a few times where Irelan’s limited involvement and knowledge of the misconduct indisputably impeded his ability to accept full responsibility, such as when, regarding Wellness Pharmacy, he was unable to state what due diligence “specifically was performed for that account.” Tr. 831. The Agency finds that Irelan’s admission that he had not familiarized himself with the specific due diligence performed by Respondent for the exemplar pharmacies demonstrates that he did not actually have the knowledge required to accept unequivocal responsibility on behalf of Respondent for the full extent of the violations found. Irelan’s assertion that Respondent did conduct a “tremendous amount” of due diligence is also inconsistent with his stated lack of knowledge regarding the amount of due diligence conducted for the limited number of customers included in the OSC’s allegations. It seems logical that in cultivating an understanding of Respondent’s violations in order to adequately accept responsibility, Irelan would have focused his review on the customers most relevant to the allegations. Therefore, Irelan does not seem to have been equipped to meet Respondent’s burden in accepting responsibility.

4. Trust in Respondent

Although the Agency does not challenge Irelan’s authority to act on behalf of Respondent in accepting responsibility, the burden is on *Respondent* to credibly and candidly demonstrate that it can be entrusted with a registration. Respondent chose to meet that burden by presenting Irelan’s testimony in lieu of a principal or an individual who had knowledge of the full scope of the violations. Although the Agency does not contest that Respondent *could* choose Irelan to accept responsibility on its behalf, that finding does not mean that Irelan was equipped to do so unequivocally.

It is noted that the Agency has long held that the misconduct of an entity’s principal is properly considered in determining whether to revoke the entity’s registration. *Chip RX, L.L.C., d/b/a City Ctr. Pharmacy*, 82 FR 51433, 51438 (2017) (citing *G & O Pharmacy of Paducah*, 68 FR 43752, 43753 (2003)). An essential element of Respondent’s showing of trust is that the registrant and its principals accept responsibility for their misconduct by acknowledging their wrongdoing. *Sun & Lake Pharmacy*, 76 FR 24533 (citing *Medicine Shoppe*, 73 FR at 387; *Jackson*, 72 FR at 23853; *Kennedy*, 71 FR at 35709). In this case, at least one of Respondent’s principals, Paul Dickson, Sr., bears at least some responsibility for the misconduct, and Irelan bears none. See Tr. 723.

Irelan opined that C.G. and Jacob Dickson, who were in charge of compliance during the relevant time period, were responsible for Respondent’s misconduct, but was not sure enough of the “dynamics” or “reporting process” to opine about whether Paul Dickson, Sr., carried any responsibility. Tr. 808–09. The extent of the misconduct is an important factor in the Agency’s ability to determine whether to entrust Respondent with a registration and Irelan’s inability to testify to the level of involvement and knowledge of Respondent’s principals in the misconduct demonstrates another reason why the Agency cannot deem his acceptance of responsibility to be adequate such that the Agency can entrust Respondent with a registration. In fact, Respondent’s submitted evidence includes testimony from the Hearing on the Motion for Temporary Restraining Order⁸⁶ in which Paul Dickson, Respondent’s president, testified that he was primarily responsible for development of Respondent’s SOM program and that he designed the system. RX 1, at 33. Paul Dickson further told the Court that in designing the system, he knew that he

“didn’t do a perfect job,” but that “it was the best that [he] could do. And [he] think[s] it’s dang good. And [he doesn’t] think a single person has gotten hurt by [their] drugs. [He] sure do[esn’t] know of one So [he] think[s] it works.” RX 1, at 57. These statements from the president of a family-owned and -operated company so strongly miss the point of the requirements of a DEA registrant that they further undercut the Agency’s ability to entrust Respondent with a registration. To equate a registrant’s compliance with an agency’s closed regulatory system with the consequence of knowing whether anyone was hurt “by [their] drugs” exhibits a stark misunderstanding of the regulatory requirement.

The Agency finds that Irelan’s inability to describe Paul Dickson’s involvement in the proven misconduct further demonstrates the inadequacy of Respondent’s acceptance of responsibility in this proceeding. In all, Irelan’s lack of understanding and recognition of the full scope of the misconduct and attempts to minimize the misconduct lead the Agency to conclude that Respondent’s acceptance of responsibility was equivocal and insufficient to ensure that Respondent can be entrusted with a registration.

B. Remedial Measures

When a registrant fails to meet the threshold showing of acceptance of responsibility, the Agency has stated that it need not address the registrant’s remedial measures. *Daniel A. Glick, D.D.S.*, 80 FR 74800, 74,810 (2015); see also *Ajay S. Ahuja, M.D.*, 84 FR at 5498 n.33; *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 FR at 79202; *The Medicine Shoppe*, 79 FR 59504, 59510 (2014). A registrant does not unequivocally accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195*, 77 FR 62316, 62346 (2012). Refusal to acknowledge the *full scope of misconduct*, even with remedial measures, is a risk to the public interest. *Arvinder Singh, M.D.*, 81 FR 8247, 8250–51 (2016) (emphasis added).

The ALJ characterized Respondent’s remedial measures as “impressive.” RD, at 152. The Agency similarly credits the efforts that the record reflects Respondent undertook to improve its compliance with DEA’s requirements after being served with the OSC. As the ALJ appropriately stated, the Agency has also made it abundantly clear that remediation alone is not adequate to avoid a sanction and that limited-to-no-weight is given to remedial measures when the effort is not made until after

⁸⁶ It is noted that the ALJ excluded pages 147 to 216 of this transcript as irrelevant, but allowed pages 1 through 146 because Respondent offered it as remedial, mitigation, or community impact evidence. ALJX 59, at 6 (citing ALJX 29, at 2, 4.) Although it is also noted that the hearing in which these statements were made was related to the public interest in the context of the ISO, the ALJ found, and the Agency agrees, that this evidence bears some relevance to the current inquiry. *Id.* Furthermore, Respondent argues in its Exceptions that “[t]his testimony is relevant evidence of Respondent’s credibility and good faith intent in working with DEA to stop diversion.” Resp Exceptions, at 31. For the reasons stated above, the Agency finds that, if anything, Paul Dickson’s remarks seem indignant that DEA is pursuing enforcement, seem aimed at minimizing the misconduct, and display a lack of understanding and respect for the regulatory requirements.

enforcement begins. *See Mireille Lalanne, M.D.*, 78 FR 47750, 47777 (2013) (quoting *Liddy's Pharmacy, L.L.C.*, 76 FR 48887, 48897 (2011) (“The Agency has recognized that a cessation of illegal behavior only when ‘DEA comes knocking at one’s door,’ can be afforded a diminished weight borne of its own opportunistic timing.”)); *see also Southwood Pharm. Inc.*, 72 FR at 36503 (giving no weight to respondent’s “stroke-of-midnight decision” to cease supplying suspect pharmacies with controlled substances and to employ a compliance officer).⁸⁷

Additionally, the ALJ found that, based on prior Agency decisions, he could give no weight to Respondent’s remedial measures given the lack of Respondent’s unequivocal acceptance of responsibility. RD, at 152.^{88 89} As the

⁸⁷ In its Exceptions, Respondent points to the factual distinctions between cited cases in the RD and the circumstances in this case and also points to numerous other settled cases that, in Respondent’s opinion, demonstrate that the sanction here is unfair. Resp Exceptions, at 25 and 33. However, “the issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent,” and it is the respondent’s burden to bear. *See, e.g., Stein*, 84 FR at 46,972. And contrary to Respondent’s arguments, the proposed sanction is supported by similar sanctions in other recent distributor adjudications where the Agency similarly found that respondents’ registrations were inconsistent with the public interest and that those respondents had not demonstrated that they could be entrusted with a registration. *See Southwood Pharm., Inc.*, 72 FR at 36487 (rejecting the ALJ’s sanction because it was “insufficient to protect the public interest. While [the Agency is] mindful of the corrective measures engaged in by Respondent, its sales of extraordinary quantities of controlled substances to entities which it had reason to know were diverting the drugs caused extraordinary harm to public health and safety.”); *see also Masters Pharm., Inc.*, 80 FR at 55501.

⁸⁸ Respondent repeatedly asserts that these adjudications are difficult to defend due to what it claims is an unfair system—that Respondent must accept responsibility prior to knowing what misconduct has been proven. Resp Exceptions, at 7. Respondent chose litigation strategies presumably based on the longstanding structure and content of Agency decisions in these adjudications and the Agency does not fault it for those decisions. In the end, Respondent had the burden to prove that it could be entrusted with a registration and it has failed to meet that burden. *See Masters Pharm., Inc.*, 861 F.3d 206 (D.C. Cir. 2017) (rejecting arguments that DEA’s structure of requiring acceptance of responsibility is unfair, because “under longstanding DEA precedent, once DEA presents enough evidence at hearing to show that a registered vendor or distributor of controlled substances has ‘committed acts inconsistent with the public interest,’ the ‘registrant must present[] . . . mitigating evidence’ including evidence that it has ‘accept[ed] responsibility for its actions and demonstrate[d] that it will not engage in future misconduct’” (quoting *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008)). Furthermore, the Agency’s finding on this issue does not hinge on whether Ireland has accepted responsibility for each proven allegation, but instead hinges on Ireland’s persistent minimization of the misconduct and further on Respondent’s overall failure to demonstrate that Respondent has unequivocally

Agency has consistently held, “past performance is the best predictor of future performance.” *Lesly Pompy, M.D.*, 84 FR 57749, 57761 (2019); *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 833 (11th Cir. 2018) (affirming refusal to consider remedial measures where registrant did not accept responsibility for its misconduct); *Pharmacy Doctors Enterprises, Inc. v. Drug Enf’t Admin.*, 789 F. App’x 724, 2019 WL 4565481, at *7–8 (11th Cir. Sept. 20, 2019) (same).⁹⁰

In this case, even if the Agency gave weight to Respondent’s remedial measures, the measures are outweighed by the fact that it has not adequately established that Respondent as an entity fully understands the scope of the misconduct such that it can be entrusted with regulatory compliance in the future.

C. The Extent of the Misconduct

The record demonstrates that Respondent’s violations of the law were not isolated occurrences, but took place over the course of four years and involved multiple customers. *See Garrett Howard Smith, M.D.*, 83 FR at 18910 (collecting cases) (“The egregiousness and extent of [the] misconduct are significant factors in determining the appropriate sanction.”). In spite of its self-described status as a privately-owned company that has been in business for 177 years,⁹¹ Respondent

accepted responsibility and can be trusted with a registration.

⁸⁹ Respondent argues that Milione’s testimony regarding the August 2016 meeting with Paul Dickson, Sr., *supra* n.8, demonstrates Respondent’s “good faith and sincerity, which flatly contradict the ALJ’s intent-laden description of Respondent’s compliance as ‘cavalier’” and argues that this fact is relevant in considering Respondent’s likelihood towards recidivism. Resp Exceptions, at 30 (citing RD, at 156). The Agency cannot give this meeting or Paul Dickson’s sincerity during this moment in time the weight that Respondent requests it be afforded given that the evidence demonstrates that for approximately two years prior to this meeting and two years afterwards, Respondent was not complying with DEA regulations. Further, Respondent did not present the Agency with Paul Dickson’s testimony at this hearing to be able to weigh his credibility and sincerity either in 2016, when this meeting occurred, or at the time of the hearing. The transcribed testimony that Respondent did submit from Paul Dickson demonstrated that he believed his SOM system to be “dang good”—a statement with which the Agency emphatically disagrees. *See* RX 1, at 57.

⁹⁰ *See also Hills Pharmacy, LLC*, 81 FR 49815, 49847 (2016) (“[T]here is no need to consider Respondent’s remedial efforts as they are rendered irrelevant by its failure to acknowledge its misconduct.”); *Daniel A. Glick, D.D.S.*, 80 FR 74800, 74810 (2015) (“[S]ince the Respondent has not tendered an unequivocal acceptance of responsibility, under established Agency precedent, [it] is foreclosed from a favorable result in these proceedings and the issue of remedial actions is irrelevant.”).

⁹¹ *See also* RX 1, at 21 (estimating Respondent’s number of retail pharmacy customers at

maintained sparse documentation of its SOM procedures generally and maintained very little documentation of its resolution of red flags of diversion displayed by its customers or of individual suspicious orders. The record evidence demonstrates that Respondent attended two conferences, held a personal meeting with DEA, and received multiple letters in which DEA emphasized the critical importance of a distributor’s role in preventing diversion given the opioid crisis in the nation and reminded distributors of their obligations under the law. A letter from DEA dated September 27, 2006, stated “[G]iven the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.” GX 3, at 2. In spite of Respondent’s established knowledge regarding the criticality of its role in preventing “dangerous and potentially lethal consequences,” Respondent did not adequately resolve or document investigation into the numerous red flags indicating diversion that its own Pro Compliance Reports identified on the exemplar pharmacies and failed to report a multitude of suspicious orders to DEA.

D. Deterrence

Finally, both specific and general deterrence strongly weigh in favor of revoking Respondent’s registration. *See Daniel A. Glick, D.D.S.*, 80 FR at 74810. The record demonstrates that Respondent violated DEA regulations over a lengthy time period—failing to report a multitude of suspicious orders to DEA and depriving DEA of valuable information about pharmacies and practitioners who might have been engaging in diversion or violating their obligations as DEA registrants, thus contributing to the country’s devastating prescription drug abuse problem. Under these circumstances and on this record, a sanction less than revocation⁹² would

“approximately 600 primary . . . and another 200 secondary that fluctuates”) and 22–23 (“[O]nly competition are what’s called ‘the big three,’ the global companies”).

⁹² Respondent argues without support that a sanction short of revocation would serve the same deterrence goals and would prevent harm to the community that would result from closing Respondent. Resp Exceptions, at 28, 31. The Agency does not consider community impact in its decisions. *See infra* n.96. As Respondent notes, it is difficult to know what level of sanction would deter future non-compliance in the registrant community, but in Respondent’s case, where the violations were blatant, long-term, and impactful, the Agency finds, given the record before it, that revocation offers an appropriate deterrent effect.

send a message to the current and prospective registrant community that compliance with DEA regulations is not a condition precedent to maintaining a DEA registration and that a distributor can spend years insufficiently reporting suspicious orders and inadequately resolving red flags presented by its customers, so long as it finally invests in the procedures it should have had in place all along after it is caught and faces potential consequences.⁹³

Although Respondent has implemented remedial measures, it has not adequately demonstrated that its leadership can be entrusted to continue these measures and prevent reoccurrence of what happened prior to the issuance of the OSC, which amounted to a SOM system that was not designed or operated in a way that would adequately prevent diversion of controlled substances nor provide DEA with information critical to its mission. Respondent argues that the ALJ erred in finding that “the continued registration of a fully remediated registrant with an ‘impressive’ anti-diversion regime, along with evidence of good faith desire to prevent diversion, does not serve the public interest.”⁹⁴ Resp Exceptions, at

Furthermore, again, Respondent has not adequately established trust, *see supra* Section V.A.4, which is crucial to demonstrate the appropriateness of a sanction less than revocation under the Agency’s consideration of specific deterrence. Respondent also argues that the ALJ erred in its deterrence analysis by failing to consider the Government’s purported unwillingness to engage Respondent in settlement negotiations. Resp Exceptions, at 33–35. While a settlement agreement between the Government and a respondent may be a way to provide enforceable assurances of the respondent’s future compliance, the parties have not reached such a settlement here. Accordingly, and although the Agency has considered alternative sanctions as Respondent has requested, it has decided that revocation currently is the most appropriate sanction as explained herein.

⁹³ DEA decisions have demonstrated concern that giving weight to last minute remedial measures would show the regulated community that a registrant “can unlawfully distribute controlled substances until [it] gets caught, and as long as [it] then acknowledges wrongdoing and puts on evidence that [it] has reformed, [it] will get a slap on the wrist.” *David Ruben, M.D.*, 78 FR 38363, 38387 (2013); *see also Southwood Pharm., Inc.*, 72 FR 36487, 36504 (2007) (“A precedent which ignores how irresponsibly a registrant has acted and allows it to maintain its registration based on its claim of having reformed its business practices, could well prompt other registrants to ignore their obligations under the Act and sell massive quantities of controlled substances to diverters.”).

⁹⁴ Respondent argues that its “current conduct is the best evidence that its continued registration is consistent with the public interest.” Resp Exceptions, at 7. However, remediation is notably not an enumerated public interest factor under 21 U.S.C. 823(b). Remediation is a factor that the Administrator considers in reviewing the extent to which sanctions are appropriate and only after the Government has made a *prima facie* case demonstrating that the allegations support a finding that Respondent’s continued registration is not in

1. However, Respondent’s argument neglects to mention that remediation is irrelevant without continued trust. Respondent wants credit for “commission[ing] former top DEA officials to design their ideal anti-diversion system,” *id.*, because it believes that as long as it has invested the money now, it will prevent DEA from enforcing against it. There are several considerations other than remediation that the Agency uses in determining sanction as explained herein. The fact is that, under these circumstances and on this record, Respondent has not adequately convinced the Agency that it can be entrusted with a registration—its acceptance of responsibility did not prove that it or its principals understand the full extent of their wrongdoing, the effect that it had on the Agency and the American public, and the potential harm that it caused.⁹⁵ It was Respondent’s burden to prove that it could be entrusted to protect the public interest in maintaining a DEA registration—and it has failed to do so.

Having reviewed the record in its entirety, the Agency finds that Respondent cannot be entrusted with a DEA registration and orders that its registration be revoked. The Agency addresses collateral matters and additional issues raised in Respondent’s Exceptions before issuing a final Order.

VI. Motion To Reopen

On January 5, 2022, Respondent filed a Motion to Reopen the Administrative Record. Respondent seeks to introduce evidence of post-hearing conduct that it argues demonstrates acceptance of responsibility and successful

the public interest. *See, e.g., Samuel S. Jackson, D.D.S.*, 72 FR at 23,853.

⁹⁵ Respondent attached to its Exceptions the Department of Justice Office of the Inspector General (OIG) September 2019 Review of the Drug Enforcement Administration’s Regulatory and Enforcement Efforts to Control the Diversion of Opioids—claiming that the report is DEA’s motivation for pursuing “the harshest sanction” against Respondent. The report is dated September 2019—a month after the ALJ’s issuance of the RD. Furthermore, DEA subpoenaed Respondent as early as February 1, 2018; therefore, temporally, the OIG’s findings could not have motivated the Agency’s investigation into Respondent. Such allegations are a distraction from the issue at hand—Respondent failed to comply with its regulatory obligations and neither the Agency nor the country could possibly have the ability to know what might have happened had those suspicious orders been reported to DEA and to what extent diversion and abuse might have been prevented. What the Agency does know is that Respondent’s failures were monumental, and Respondent clearly misses the point in arguing that “had the Respondent more consistently reported suspicious orders with the DEA, it has been established that the reports would have been ignored.” Resp Exceptions, at 5.

remediation.⁹⁶ Although not specifically contemplated in the CSA or regulations, DEA decisions have repeatedly held that the Administrator may, in her discretion, order that the administrative record be reopened. The party moving to reopen, however, bears a heavy burden. *See INS v. Abudu*, 485 U.S. 94, 110 (1988); *see also Cities of Campbell v. FERC*, 770 F.2d 1180, 1191 (D.C. Cir. 1985) (“Reopening an evidentiary hearing is a matter of agency discretion and is reserved for extraordinary circumstances.” (citations omitted)); *Nance v. EPA*, 645 F.2d 701, 717 (9th Cir. 1981).

The Agency finds that Respondent has not met its burden to reopen the record. In all DEA administrative proceedings, there is inevitably at least some delay between the hearing and the final decision of the Administrator.⁹⁷ Allowing parties to reopen the record to introduce evidence of acceptance of responsibility and remedial measures taken during that delay would create a recursive loop further delaying the conclusion of proceedings to the detriment of the public interest. *See, e.g., Abudu*, 485 U.S. at 107; *Qoku v. Gonzales*, 156 F. App’x. 703, 705 (5th Cir. 2005). As the Supreme Court observed in *Vermont Yankee Nuclear Power Corp. v. NRDC*, “[a]dministrative consideration of evidence . . . always creates a gap between the time the

⁹⁶ Respondent also requests to reopen the record to introduce evidence of the impact revoking its registration would have on the community. Motion to Reopen, at 20–22. The Agency has consistently found that community impact is not a relevant consideration under the public interest factors. *E.g., Stephen E. Owusu, D.P.M.*, 87 FR 3343, 3351 n.21 (2022); *George Pursley, M.D.*, 85 FR 80,162, 80,188 n. 82 (2020); *Frank Joseph Stirlacci, M.D.*, 85 FR 45229, 45239 (2020). Accordingly, Respondent’s community impact evidence is not grounds to reopen the record. Further, Respondent made arguments that it should be allowed to introduce evidence that it concedes is not an independent basis to reopen the record but argues is properly admitted if the record is reopened. Reply ISO Motion to Reopen, at 12. Nonetheless, the Agency is not reaching a finding on the admissibility of this evidence because it is not granting Respondent’s Motion to Reopen.

⁹⁷ The delay between the hearing and the issuance of the final decision in this matter was longer than is typical for the Agency, but the proceedings were delayed partially at Respondent’s request. On March 9, 2020, Respondent wrote a letter to the then-Acting Administrator asking that the Agency postpone issuing a Final Order “to allow the COVID–19 crisis to abate or the parties to reach a final settlement” *See* Letter from Respondent. Respondent then requested yet another delay in its Motion to Reopen asking that the Administrator delay the issuance of a final order “until after [Respondent’s] new counsel has had an opportunity to resolve the matter with DEA’s Chief Counsel.” Motion to Reopen, at 4, n.4. Respondent cannot request to delay the proceedings and then claim that a failure to reopen the record is somehow prejudicial to Respondent because of its requested delay.

record is closed and the time the administrative decision is promulgated If upon the coming down of the order litigants might demand rehearings as a matter of law because some new circumstance has arisen, some new trend has been observed, or some new fact discovered, there would be little hope that the administrative process could ever be consummated in an order that would not be subject to reopening.” 435 U.S. 519, 554–55 (1978) (quoting *ICC v. Jersey City*, 322 U.S. 503, 514 (1944) (citing *Northern Lines Merger Cases*, 396 U.S. 491, 521 (1970))).

Respondent had the opportunity to, and did, introduce evidence related to its acceptance of responsibility and remedial measures at the hearing. That evidence was entered into the record and considered in the ALJ’s Recommended Decision and this Final Order.

VII. Lucia

The Agency has carefully considered Respondent’s Exceptions to the Recommended Decision, has addressed them throughout the record, and addresses the remaining herein.

In its Exceptions, Respondent notes that “as [it] has repeatedly and consistently objected, including at the hearing, this entire proceeding was unconstitutional.” (citing Tr. 20:23–22:17). Respondent contends that “[t]he presiding ALJ in this matter was unconstitutionally appointed when these proceedings began and unconstitutionally continued to preside over these proceedings after the Attorney General purportedly ratified his appointment.” (citing *Lucia v. Securities and Exchange Comm’n*, 138 S. Ct. 2044, 2055 (2018) (hereinafter, *Lucia*)). The Agency will note the factual sequence of events surrounding Respondent’s *Lucia* claims.

Respondent’s Prehearing Statement, filed on August 3, 2018, averred, “Respondent may file a motion before this Tribunal related to the constitutionality of the DEA’s administrative process given the U.S. Supreme Court’s recent decision in [*Lucia*].” ALJX 8, at 37. During the Prehearing Conference, Respondent’s attorney stated, “with regards to the *Lucia* case, this is obviously no disrespect intended to the Court but we do think that it’s a significant issue that should we proceed to hearing, we do want to address and I would like to file a motion about it.” The ALJ replied, “Well, if you’re going to file a motion about it, I obviously would need to take a look at it Apparently, if you file a motion, there’s a good chance you’ll wind up with a different Judge

I’m just putting you on notice that that’s what’s likely to happen.” Prehearing, Tr. 36. The ALJ ordered that “[y]ou obviously can file motions tomorrow if you want to but any motions I’m going to need to rule on I would like to have no later than October 23rd. . . .” Tr. 42–43.

On October 26, 2018, Respondent submitted a letter on the record alerting the Tribunal that it had commenced an action in the United States District Court for the Western District of Louisiana seeking an “injunction enjoining DEA and DOJ from requiring Morris & Dickson to appear in any administrative proceeding, including the upcoming hearing scheduled for November 13, 2018, unless and until a constitutionally valid administrative system has been established.” ALJX 26, at 1. On October 31, 2018, Respondent filed another letter with the Tribunal explaining that it did not file a motion with the ALJ because the Agency “has no authority to entertain a facial constitutional challenge” and that “[t]he Louisiana Court will resolve that question. Morris & Dickson simply provides this Tribunal notice of that filing and requests sufficient time to allow the Louisiana Court (and, if necessary, the Fifth Circuit Court of Appeals) to make its ruling.” ALJX 34, at 1–2.

On December 31, 2018, Respondent submitted a letter notifying the Tribunal that “[o]n December 28, 2018, the District Court in the Western District of Louisiana dismissed Respondent’s complaint without prejudice, finding that it did not have jurisdiction to hear Morris & Dickson’s claims” and attaching the decision. ALJX 47, at 1. The Decision stated that, although Respondent’s argument was “somewhat close,” “in light of the policy problem created by crafting a ‘constitutional claim’ exception to Congress’s ability to channel initial review through agencies, the Court finds that Morris & Dickson’s separation-of-powers claims are not ‘wholly collateral’ to the proceeding before Judge Dorman because they were raised in an attempt to delay or defeat administrative enforcement of the CSA.” *Id.* at 30.

On January 15, 2019, the ALJ issued an Order Lifting the Stay and Third Prehearing Ruling. ALJX 51. The Order stated that Respondent indicated during a telephonic conference on the previous day that it “w[ould] not seek to maintain the stay in this case pending its appeal to the United States Court of Appeals for the Fifth Circuit”⁹⁸ and that

⁹⁸ Respondent’s appeal to the United States Court of Appeals for the Fifth Circuit was dismissed by

“it w[ould] not file a motion seeking to recuse [the ALJ] from this case based on the Supreme Court’s decision in *Lucia*” *Id.* at 1.

The next time Respondent raised the *Lucia* issue was at the beginning of the hearing on May 13, 2019. Respondent’s lawyer made a self-described “statement of the record, simply,” Tr. 23, that “we respectfully renew for the record our objection to the hearing and proceeding.” Tr. 22. However, Respondent’s lawyer also agreed that Respondent was ready to go to hearing that day and made no further motions or requests for a new ALJ. Tr. 24.

On October 25, 2018, the Attorney General ratified the prior appointment of the DEA ALJs, including ALJ Dorman, and “approved their appointments as his own under the Constitution.” See Office of the Attorney General, Order No. 4.315–2018.⁹⁹ It is noted that, at the time that the hearing took place in this matter, ALJ Dorman’s appointment as an Administrative Law Judge had been ratified. Respondent never formally requested reassignment nor availed itself of the opportunity to request interlocutory review to the Administrator on any ruling of the ALJ or any *Lucia*-related issue pursuant to 21 CFR 1316.62. Had Respondent contested the matter formally with the Agency, the Agency would have assigned another ALJ, see Prehearing, Tr. 36, and saved significant Agency resources. The Agency further finds that ALJ Dorman’s appointment was ratified before the hearing. Due to Respondent’s calculated choice to preserve the matter for the record, Tr. 23, but not raise it in any way that the Agency might have had the capacity to address and remedy itself, the Agency considers the argument waived for purposes of finalizing this adjudication.

Having found that Respondent cannot be entrusted with a DEA registration, the Agency issues the following Order revoking Respondent’s DEA registrations.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(b), (e), I hereby revoke DEA Certificates of Registration Nos. RM0314790 and RM0335732 issued to Morris & Dickson, Co., LLC. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a)(4) and 21 U.S.C.

its own motion. See *Morris and Dickson v. William Barr, et al.*, No. 19–30043, 2019 WL 3230978 (5th Cir. Apr. 1, 2019).

⁹⁹ Although not considered material to this Decision, a copy of this Order will be included in the administrative record for future reference.

823(b), (e), I hereby deny any pending application of Morris & Dickson, Co., LLC to renew or modify these registrations, as well as any other pending application of Morris & Dickson, Co., LLC. This Order is effective August 28, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on May 19, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023-11369 Filed 5-26-23; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Information Collection Activities; Comment Request

AGENCY: Bureau of Labor Statistics, Department of Labor.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments concerning the proposed revision of the "Current Population Survey (CPS)." A copy of the proposed information collection request can be obtained by

contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before July 31, 2023.

ADDRESSES: Send comments to Erin Good, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room G225, 2 Massachusetts Avenue NE, Washington, DC 20212. Written comments also may be transmitted by email to *BLS_PRA_Public@bls.gov*.

FOR FURTHER INFORMATION CONTACT: Erin Good, BLS Clearance Officer, at 202-691-7628 (this is not a toll free number). (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The CPS has been the principal source of the official Government statistics on employment and unemployment for over 75 years. The CPS is a monthly sample survey of 60,000 eligible households. The labor force information gathered through the survey is of paramount importance in keeping track of the economic health of the Nation. The survey is the only source of monthly data on total employment and unemployment. The Employment Situation news release contains data from this survey and is designated as a Principal Federal Economic Indicator (PFEI). Moreover, the survey also yields data on the characteristics of persons not in the labor force. The CPS data are used monthly, in conjunction with data from other sources, to analyze the extent to which, and with what success, the various components of the American population are participating in the economic life of the Nation.

The labor force data gathered through the CPS are provided to users in the greatest detail possible, in conjunction with the demographic information obtained in the survey. In brief, the labor force data can be broken down by sex, age, race, ethnicity, marital status, family composition, educational level, veteran status, certification and licensing status, disability status, and other characteristics. Through such breakdowns, one can focus on the employment situation of specific population groups as well as on general trends in employment and unemployment. Information of this type can be obtained only through demographically oriented surveys such as the CPS.

The basic CPS data also are used as an important platform on which to base the data derived from the various

supplemental questions that are administered in conjunction with the survey. By coupling the basic data from the monthly survey with the special data from the supplements, one can get valuable insights on the behavior of American workers and on the social and economic health of their families.

There is wide interest in the monthly CPS data among Government policymakers, legislators, economists, the media, and the general public. While the data from the CPS are used in conjunction with data from other surveys in assessing the economic health of the Nation, they are unique in various ways. Specifically, they are the basis for much of the monthly Employment Situation report, a PFEI. They provide a monthly, nationally representative measure of total employment, including farm work, self-employment, and unpaid family work; other surveys are generally restricted to the nonagricultural wage and salary sector, or provide less timely information. The CPS provides data on all job seekers, and on all persons outside the labor force, while payroll-based surveys cannot, by definition, cover these sectors of the population. Finally, the CPS data on employment, unemployment, and on persons not in the labor force can be linked to the demographic characteristics of the many groups that make up the Nation's population, while the data from other surveys often have limited demographic information. Many groups, both in the government and in the private sector, are eager to analyze this wealth of demographic and labor force data.

II. Current Action

Office of Management and Budget clearance is being sought for a revision of the Current Population Survey. BLS is seeking approval to remove two questions that collected information about the impact of the COVID-19 pandemic on where people worked. These questions, which ask about telework or work at home in February 2020, have been included on the CPS since October 2022 to measure the impact of the COVID-19 pandemic on the labor force. BLS feels that enough time has passed since the onset of the pandemic and its impact on how people work. These questions would not provide meaningful data going forward.

III. Desired Focus of Comments

The Bureau of Labor Statistics is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the