DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–03]

OakmontScript Limited Partnership; Decision and Order

On October 20, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to OakmontScript Limited Partnership (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC proposed the revocation of Respondent's DEA Certificates of Registration Nos. RO0504680 and RO0527082 (hereinafter, CORs or registrations) and the denial of any pending application to modify or renew the registrations and any applications for any other DEA registrations pursuant to 21 U.S.C. 823, 824, 958, and other federal laws, because Respondent's ''registration[s are] inconsistent with the public interest,'' as that term is defined in 21 U.S.C. 823(b), (d), and (e); 824(a); and 958(c). *Id.*

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was conducted from March 8–12, 2021, at the DEA Hearing Facility in Arlington, Virginia, with the parties and their witnesses participating through video-teleconference.*[A] On June 11, 2021, Administrative Law Judge Paul E. Soeffing (hereinafter, ALJ) issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD). Neither party filed exceptions to the RD.

Having reviewed the entire record, I agree with the ALJ's Recommended Decision and I adopt it with minor modifications, as noted herein.*[B]

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge *[C] [1]

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

The Allegations

The Government alleges that the Respondent's CORs should be revoked because OakmontScript exported controlled substances prior to obtaining its exporter COR, exported controlled substances it was not approved to export, demonstrated a lack of candor about controlled substances it was exporting, falsified a copy of its distributor DEA registration, distributed controlled substances to an individual not registered with the DEA, exported controlled substances to fulfill prescriptions for underage patients, and failed to keep complete and accurate records.

The Evidence

Stipulations of Fact

The Government and the Respondent have agreed to the below stipulations, which I recommend be accepted as fact in these proceedings: [2]

(1) OakmontScript Limited Partnership (''OakmontScript'') [was] registered with the DEA as a distributor licensed to handle controlled substances within Schedules II–V under DEA COR No. RO0504680 (''Distributor COR'') at 1500 District Ave., Burlington, MA 01803–5069. DEA COR No. RO0504680 was first issued on October 7, 2016. [Respondent surrendered both registrations on December 22, 2021, therefore terminating these registrations.*[D] Omitted.]

(2) OakmontScript is registered with the DEA as an exporter licensed to handle controlled substances within Schedules II–V under DEA COR No. RO0527082 (''Exporter COR'') at 1500 District Ave., Burlington, MA 01803–

*[A] [This footnote has been relocated from RD n.1.] OakmontScript filed its Request for Hearing *pro se,* represented by Jufang (''Shirley'') Shi, its President and Chief Pharmacist. In the Order for Prehearing Statements issued by the tribunal on November 19, 2020, the tribunal advised the Respondent of its right under 21 CFR 1316.50 to seek representation by a qualified attorney at the Respondent's own expense. ALJ Ex. 3 at 1. At the Prehearing Conference held on January 5, 2021, this tribunal reiterated to the Respondent's representative the Respondent's right to obtain counsel. The Prehearing Ruling also discussed the Respondent's right to obtain counsel. ALJ Ex. 7 at 1 n.1.

*[B] I have made minor, nonsubstantive, grammatical changes to the RD and nonsubstantive conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits in brackets, and I have included specific descriptions of the modifications in brackets or in footnotes marked with an asterisk and a letter. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[C] I have omitted the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] [Footnote relocated, *see supra* n.*A.]

[2] The parties agreed to the following stipulations at the Prehearing Conference held on January 5, 2021. ALJ Ex. 7 at 2–3. The parties did not file any further Joint Stipulations.

*[D] On January 3, 2022, I was notified by the Office of Administrative Law Judges that Respondent had surrendered its distributor and exporter registrations by submitting two DEA–104 surrender forms signed by Respondent's representative, Jufang Shi. Pursuant to DEA regulations, Respondent's registrations terminated on the day of the surrender, and Respondent is no longer authorized to distribute or export controlled substances under federal law. 21 CFR 1301.52 (''[T]he registration of any person . . . shall terminate, without any further action by the Administration, if and when such person . . . surrenders a registration.'') On January 20, 2021, the Government filed a letter informing me of Respondent's surrender. However, notably the Government did not request that I dismiss this matter.

Although Respondent's registrations have terminated, the Agency has discretion to adjudicate this Order to Show Cause to Finality. *See Jeffrey D. Olsen, M.D.,* 84 FR 68,474, 68,479 (2019) (declining to dismiss an immediate suspension order as moot when the registrant allowed the subject registration to expire before final adjudication); *Steven M. Kotsonis, M.D.,* 85 FR 85,667, 85,668–69 (2020) (concluding that termination of a DEA registration under 21 CFR 1301.52 does not preclude DEA from issuing a final decision on an order to show cause against that registration and stating that the Agency would assess such matters on a case-by-case basis to determine if a final adjudication is warranted or if the matter should be dismissed); *The Pharmacy Place,* 86 FR 21,008, 21,008–09 (2021) (adjudicating to finality a registration terminated under 21 CFR 1301.52 in order to create a final record of allegations and evidence related to the matter); *Creekbend Community Pharmacy,* 86 FR 40,627, 40,628 n.4 (2021) (same).

As in *The Pharmacy Place* and *Creekbend,* I have evaluated the particular circumstances of this matter and determined that the matter should be adjudicated to finality. 86 FR at 21,008–09; 86 FR 40,627, 40,628 n.4. As my predecessor identified in *Olsen,* ''[b]ecause nothing in the CSA prohibits an individual or an entity from applying for a registration even when there is . . . a history of having a registration suspended or revoked. . . . having a final, official record of allegations, evidence, and the Administrator's decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.'' 84 FR at 68,479. Here, absent a final adjudication, there would be no final record of the allegations and evidence from this matter. (*Contrast with Kotsonis* in which the plea agreement and judgment from the respondent's concurrent criminal case provided a final record on which the Agency could rely in any future interactions with the respondent. 85 FR at 85,667). Adjudicating this matter to finality will create an official record the Agency can use in any future interactions with Respondent's owners, employees, or other persons who were associated with Respondent. Moreover, as in *The Pharmacy Place* and *Creekbend,* ''adjudicating this matter to finality will create a public record to educate current and prospective registrants about the Agency's expectations regarding the responsibilities of registrant pharmacies under the CSA and allow stakeholders to provide feedback regarding the Agency's enforcement priorities and practices.'' 86 FR 21,008–09 (applying *Olsen,* 84 FR 68,479); 86 FR 40,627, 40,628 n.4 (same).

It is noted that I recognize the importance of the parties' ability to request dismissal of a case, even after it has been forwarded to me for final adjudication. However, because surrenders are unilaterally submitted by the Respondent, without explicit instructions from both parties, I cannot assume the intent of a surrender is to dismiss the case. In this case, I assume that the Government has determined that a final decision on the merits will further DEA's adjudicatory efforts and law enforcement goals, because its letter to me regarding the surrender significantly omits any indication otherwise.

5069. DEA COR No. RO0527082 was first issued on December 5, 2017. It will expire by its terms on December 31, 2021.[3]

(3) OakmontScript has a Controlled Substance Registration, #MA0092875, as a Drug Distributor for Schedules II–V with the Commonwealth of Massachusetts, Department of Public Health, Drug Control Program.

(4) Dr. Jufang ''Shirley'' Shi is OakmontScript's general partner, owner, and Resident Agent. She also serves as its Managing Director, President, and Chief Pharmacy Officer.

(5) Dr. Shi is New England Executive Care Limited Partnership's (''NEEC'') Resident Agent.

(6) Dr. L.W. is NEEC's General Partner. Dr. L.W. also has served as a consultant with OakmontScript. He has acted as OakmontScript's supervisory physician. He was employed by OakmontScript on an as-needed basis.

(7) On or about September 16, 2016, DEA conducted a pre-registration investigation of OakmontScript's then application for a distributor registration.

(8) On or about June 22, 2017, DEA conducted a pre-registration investigation of OakmontScript's then application for an exporter registration.

(9) On or about July 26, 2018, DEA conducted an on-site inspection for OakmontScript's Distributor COR at OakmontScript's registered location pursuant to a Notice of Inspection.

(10) In or around January, 2017, OakmontScript falsified a print out of its DEA Distributor COR in order to set up a customer account with another company, Pharmacy Buying Association (''PBA''). Specifically, OakmontScript's DEA registration was altered so that the word ''Distributor'' was replaced with the word ''Pharmacy'' under the Business Activity section of the registration.

(11) OakmontScript employed an intern from January 1, 2017, to February 2018.

(12) Diazepam (brand name ''Valium'') is a Schedule IV controlled substance benzodiazepine class drug, commonly used to treat anxiety, muscle spasms, and seizures.

(13) Briviact is the brand name for brivaracetam, a Schedule V controlled substance commonly used to treat seizures.

(14) Belviq is the brand name for lorcaserin, a Schedule IV controlled substance commonly used to control appetite.

(15) Lyrica is the brand name for pregabalin, a Schedule V controlled substance commonly used to treat nerve and muscle pain and seizures.

(16) Clobazam (brand names include ''Sympazan'' and ''Onfi'') is a Schedule IV controlled substance benzodiazepine class drug that is commonly used to control seizures.

(17) Lunesta is the brand name of eszopiclone, a Schedule IV controlled substance that is commonly used as a sedative.

The Government's Case

The Government's case consisted of testimony from three witnesses: (1) Diversion Investigator (''DI'') 1, (2) DI 2, and (3) DI 3. Below is a summary of the testimony of these witnesses.[4]

DI 1

DI 1 has been employed with the DEA for eighteen years. Tr. 35. For ten years, until 2010, she worked as a Registration Program Specialist in the New York Field Division where she reviewed applications and conducted background checks regarding registrants who applied for DEA registrations. Tr. 36–37. She currently serves as a DI in Boston where she does on-site inspections and educates applicants on the guidelines required by the Controlled Substances Act (''CSA''). Tr. 35, 37. She received a three-month training in Quantico and has worked on over eighty cases as a DI. Tr. 35, 37–38. She is familiar with DEA regulations and the CSA. Tr. 38.

In August 2016, DI 1 was assigned as the lead investigator to the Respondent's first DEA application as a distributor, which was ultimately assigned COR No. RO504680. Tr. 38–39, 43. On September 16, 2016, DI 1 coordinated with the Massachusetts Department of Health, through a Senior Investigator, to conduct an on-site inspection of OakmontScript. Tr. 44–45. During the inspection, DI 1 met with OakmontScript's Dr. Shi and L.W. Tr. 44–45. Dr. Shi informed DI 1 of her intention to potentially distribute controlled substances to international customers. Tr. 45–46. DI 1 explained to Dr. Shi that she would need to apply for a second DEA registration as an exporter, and to fill out a Form DEA–161, Application for Permit to Export Controlled Substances (''DEA Form 161''), and a Form DEA–236, Declaration of Exportation (''DEA Form 236''), which both apply to Schedule II–V controlled substances. Tr. 46–47. *But see* Tr. 94–95 (When questioned by the Respondent what schedule of controlled substances apply to a DEA Form 161, DI 1 stated ''I don't recall'' and when questioned regarding what controlled substances apply to a DEA Form 236 stated ''Schedule III through V.'').[5]

DI 1 had conversations with Dr. Shi explaining the term ''end-use statement,'' which is a statement that is provided by a pharmaceutical company or researcher stating the use of the drug. Tr. 47–49. DI 1 explained that an ''ultimate user'' is an individual that would use controlled substances for his or her own personal medical use and that some people use the term ''end user'' and ''ultimate user'' interchangeably. Tr. 49–50. DI 1 further explained that ''ultimate user'' and ''end user'' are different from the ''end-use statement,'' which is something that is ''more for a business . . . a company for research purposes'' and is documented in writing. Tr. 50.

DI 1 also discussed record-keeping requirements with Dr. Shi, including the requirement to create an initial inventory of controlled substances she has on site after her application is approved. Tr. 50. She explained that Dr. Shi needed to create a biennial inventory every two years, not to commingle records from her distributor registration and any future exporter registration, and to maintain records for two years. Tr. 50–51. As of April 28, 2017, DI 1's understanding was that OakmontScript had not exported any controlled substances, which was based on an email from OakmontScript stating ''we do not have any executed controlled items to report during last two quarters.'' Tr. 61; Gov't Ex. 4.

OakmontScript first applied for an exporter registration with the DEA in April of 2017. Tr. 60. At some point, OakmontScript submitted a second exporter application.[6] Tr. 62. Because the first exporter application was still pending action by DEA, DI 1 contacted Dr. Shi to inquire why she had filed a second exporter application, to which Dr. Shi responded that she wanted to import, not export. Tr. 62. Therefore, DI

[3] The parties agreed during the Prehearing Conference that since the filing of the Government's Prehearing Statement, DEA COR No. RO0527082 was renewed and [was] due to expire [again] on December 31, 2021.

[4] I do not make any findings of fact in these summaries. Any facts necessary for a disposition of this case are set forth in the Analysis section of this Recommended Decision.

[5] The tribunal admitted a blank DEA Form 236 with instructions as Government Exhibit 47. For ''Type of Declaration'' the form includes a check box for export of ''Non-narcotic substances in Schedules III or IV and all substances in Schedule V,'' but does not have a check box for Schedules I or II. Gov't Ex. 47 at 1. The instruction page for the form states that its purpose is ''[t]o obtain information regarding the importation of nonnarcotic substances in Schedules III, IV, and V and the exportation of nonnarcotic substances in Schedules III and IV and all substances in Schedule V.'' Gov't Ex. 47 at 2.

[6] OakmontScript first applied for an exporter registration for Schedules III, IV, and V in April 2017 and then later requested Schedule II. Tr. 114, 115, 117.

1 contacted DEA Headquarters and had the second exporter application converted into an importer application. Tr. 62–63. The second exporter application, which was converted to an importer application, was ultimately withdrawn. Tr. 63.

On June 22, 2017, Mr. L.U. sent DI 1 an email requesting that Schedule II be added to the existing exporter application and DI 1 added this request for Schedule II to the exporter application on OakmontScript's behalf. Tr. 74–76; Gov't Ex. 50. DI 1 and the Senior Investigator from the Department of Health conducted a pre-registration inspection of OakmontScript for its exporter application on June 22, 2017. Tr. 69–71. They discussed with Dr. Shi security and record-keeping requirements including creating an initial inventory and maintaining records for at least two years. Tr. 71–72. DI 1 also discussed the importance of maintaining the DEA Form 161s and DEA Form 236s as well as the enduse statements. Tr. 72–73. DI 1 also instructed Dr. Shi that records must be kept separate for separate registrations. Tr. 73. It was DI 1's understanding that OakmontScript had not exported or distributed any controlled substances. Tr. 70–71. At this inspection, DI 1 also noted that OakmontScript's safe was not connected to an alarm system, which was a security concern because OakmontScript was storing Schedule II drugs, which have a higher security standard. Tr. 77, 78.

On September 1, 2017, DI 1 went back to OakmontScript for a return visit to test the safe's alarm after being notified by OakmontScript that the alarm would be professionally installed on August 30th. Tr. 80–81, 83. On this visit, DI 1 found no issues with the alarm. Tr. 83. However, at this time, DI 1 noted that OakmontScript should obtain a larger-sized safe pending the approval of its exporter application, which she communicated to OakmontScript on September 6, 2017. Tr. 84–85. DI 1 had a third visit on September 22, 2017, when she observed that OakmontScript purchased a larger safe and DI 1 tested the security system. Tr. 85–86.

Sometime in October 2017, DI 1's supervisor informed her that OakmontScript added over 170 drug codes to its exporter application, which DI 1 thought to be an excessive amount of drug codes because OakmontScript had previously stated that it was only intending to export small amounts of Oxycodone. Tr. 86–87, 96–97, 100. DI 1 testified that a drug code ''is a code that's assigned . . . to a controlled substance for identification purposes for individuals or pharmaceutical companies who are engaging in manufacturing, exporting, importing or distributing controlled substances.'' Tr. 86. DI 1 brought this issue to Dr. Shi's attention on November 17, 2017, and Dr. Shi stated that she had to select the drug code for each controlled substance on the web page in order to move to the next screen in the application process. Tr. 87–88. DI 1 worked with Dr. Shi, walked her through modifying the application, and eventually Dr. Shi applied for five drug codes. Tr. 88–89.

On December 5, 2017, DEA COR No. RO0527082, an exporter registration, was assigned to OakmontScript. Tr. 90–91; Gov't Ex. 1B. DI 1 had no indication that OakmontScript had exported any controlled substances prior to this approval date. Tr. 91–92.

DI 1's testimony included a discussion of the investigation of OakmontScript's first DEA application as a distributor, COR No. RO0504680, OakmontScript's two applications for exporter registrations, OakmontScript's request to add Schedule II to its exporter application, and OakmontScript's withdrawn importer application.

Throughout her testimony, DI 1 was generally consistent, genuine, and credible.[7] As a public servant, DI 1 has no personal stake in the revocation of the Respondent's registrations. There was no indication during her testimony that she had any animus against OakmontScript or any of its employees. I therefore find her testimony to be entirely credible and it will be afforded considerable weight.

DI 2

DI 2 received a bachelor's degree in political science from the College of Charleston and worked as a paralegal for several years prior to joining the DEA. Tr. 124. She received a twelve-week training in Quantico when she became an investigator. Tr. 125.

She has been employed as a DI for the DEA for approximately three years and works in the Boston Field Office. Tr. 124. As a DI, she ensures that DEA registrants are abiding by the DEA rules and regulations and the CSA to ensure there is no diversion of controlled substances from the point of manufacture to the end user. Tr. 125, 126. She has worked as a lead investigator on approximately twenty to thirty investigations. Tr. 125–26.

DI 2 first became familiar with OakmontScript on July 26, 2018, when she met Dr. Shi to conduct an inspection regarding OakmontScript's distributor registration.[8] Tr. 126–27, 128. DI 2 conducted an alarm test, performed a closing inventory, and reviewed OakmontScript's records. Tr. 130. DI 2 noted two issues with OakmontScript's record-keeping: (1) Commingling records by keeping some of its distributor records with its exporter records[9] and (2) a lack of any transfer documents showing the transfer of controlled substances between the distributor and exporter registrations. Tr. 131–33, 136. After she identified these issues, she discussed them with Dr. Shi and Dr. Shi stated that she understood and would not commingle records in the future. Tr. 133.[10] As to the transfer documents, Dr. Shi created a template form that she stated she would use in the future. Tr. 133. DI 2 was not aware that OakmontScript had any inconsistencies with its records relating to exports and did not receive any documents indicating that OakmontScript had exported controlled substances before receiving its exporter registration. Tr. 134.

DI 2's testimony was limited to a one-time inspection of OakmontScript's distributor registration. As a public servant, DI 2 has no personal stake in the revocation of the Respondent's registrations. There was no indication during her testimony that she had any animus against OakmontScript or any of its employees. I therefore find her testimony to be entirely credible and it will be afforded considerable weight.

DI 3

Background

DI 3 received her bachelor's degree in business administration in 2015. Tr. 143. Prior to working with the DEA, she was working with the Department of the Army in California, where she mainly conducted background investigations. Tr. 143. She was then promoted to a headquarters position in Detroit, Michigan, where she worked until 2017,

[7] DI 1 explained to Dr. Shi that she would need to apply for a second DEA Registration as an exporter, and to fill out a DEA Form 161 and a DEA Form 236, which both apply to drug schedules II–V. Tr. 46–47; *but see* Tr. 94–95 (When questioned by the Respondent what schedule of controlled substances apply to a DEA Form 161, DI 1 stated, ''I don't recall,'' and when questioned regarding what controlled substances apply to a DEA Form 236, she stated, ''Schedule III through V.'') [I find these statements to be confusing and inconsistent, but not to detract from the overall credibility of DI 1].

[8] Dr. Shi consented to this inspection. Tr. 128–29; *See* Gov't Ex. 6.

[9] DI 2 noted that OakmontScript was required to do an inventory for its distributor registration and its exporter registration and keep separate records for each registration. Tr. 138–39.

[10] DI 2 did not ''believe [Dr. Shi] knew about the commingling but once corrected, she understood.'' DI 2 further believed that Dr. Shi thought that transfer documents were only required for Schedule II drugs. Tr. 133–34.

when she was hired by the DEA. Tr. 143. She received a twelve-week training in Quantico at the DEA Academy and had six months of on-the-job training with a field investigator. Tr. 144–45. She received her master's degree in public policy in February 2021. Tr. 143.

DI 3 currently works as a DI for the DEA in the New England Field Division, in Boston, Massachusetts. Tr. 141–42. She has been a DI for three years. Tr. 142. As a DI, she investigates the diversion of controlled substances from licit channels to illicit channels by conducting investigations including completing accountability audits, reviewing records, testing security, and conducting on-site inspections. Tr. 143–44. She has led approximately seventy investigations and assisted on thirty. Tr. 145. She is familiar with the CSA and her job is to ensure public safety. Tr. 145, 766.

OakmontScript Assignment

DI 3 became familiar with OakmontScript in fiscal year 2019 when she was assigned to conduct an in-depth cyclical investigation of OakmontScript's exporter registration. Tr. 145–46. DI 3 reviewed OakmontScript's articles of limited partnership, with a date of organization of May 27, 2016, which indicate that Dr. Shi is the general partner and resident agent of OakmontScript. Tr. 146–49. Dr. Shi had explained to DI 3 that OakmontScript's business model was to procure controlled substances to export to foreign pharmaceutical companies for reverse engineering, so the companies can break down the controlled substance to recreate it. Tr. 150, 151, 760.

New England Executive Care (''NEEC'') is an entity with a date of organization of May 10, 2018, with Dr. Shi listed as its resident agent and Dr. L.W. and Dr. Donghui Yu listed as the general partners and it has some type of relationship with OakmontScript. Tr. 152–54. DI 3 is still unclear what NEEC's business model is and its full connection to OakmontScript. Tr. 155. Dr. L.W. is a consulting physician for OakmontScript and reviews patients' medical records and possibly prescriptions to determine if the drug being exported is appropriate for the patients' treatment. Tr. 155, 620–21.

February 19, 2019 Inspection

DI 3, DI 1, and DI 4, conducted an inspection of OakmontScript on February 19, 2019, and began their investigation by showing Dr. Shi their credentials and presenting a Notice of Inspection, which Dr. Shi signed. Tr. 156–58; Gov't Ex. 7. They discussed recordkeeping and the DIs explained that they would be conducting a controlled substance accountability audit.[11] Tr. 159.

The initial inventory date was February 19, 2018, and based on OakmontScript's self-reporting that it did not have any substances on hand, the initial count was a zero balance. Tr. 167, 763. According to the closing inventory dated February 19, 2019, which was signed by DI 3, DI 4, and a representative from OakmontScript, OakmontScript did not have any of the eight controlled substances the DIs chose to audit on that date. Tr. 159–60; Gov't Exs. 8, 9.

DI 3 also discussed drug codes[12] with Dr. Shi and it is standard practice for her to discuss what drug codes a registrant is authorized to handle and whether the registrant is handling any other drug codes. Tr. 175–76, 597.[13] DI 3 had accessed the DEA registration system and made a list of drug codes that OakmontScript was authorized to handle, and asked OakmontScript what drugs codes it was handling.[14] Tr. 183; Gov't Ex. 11. Dr. Shi reported there were no other drug codes that OakmontScript was exporting or handling other than what DI 3 listed and that there were two drug codes OakmontScript was no longer handling. Tr. 189, 598, 889.

[11] The accountability audit is a fixed moment in time when the registrant has conducted a physical hand count of any controlled substances it has on hand and the DIs include anything the registrant has purchased or transferred. Tr. 165–66. The DIs then take a closing inventory based on what has been distributed, dispensed, etc. Tr. 166.

[12] A drug code, or Administrative Controlled Substance Code Number, is a four-digit code that is assigned to each controlled substance and certain DEA registrants are allowed to handle only specific drug codes for which they have been approved. Tr. 169, 868. For example, a DEA registrant who is an exporter is only able to purchase and export controlled substances for which it has an authorized drug code and cannot engage in exporting drugs for which it does not have the necessary drug code. Tr. 176–77. When exporting drugs, the registrant needs to report the drug codes in an export declaration, such as a DEA Form 236, to include the drug code, strength, quantity, shipping destination, shipping origin location, the anticipated date it is being released, the anticipated date it should arrive, and the drug's intended use. Tr. 178.

[13] Dr. Shi asked DI 3 questions during her direct examination that led to a discussion about drug codes OakmontScript had requested in December 2020. Tr. 880–88. These discussions are not part of the Order to Show Cause that is the subject of the proceedings before this tribunal.

[14] If a registrant wants to make a change to its registration, including adding or removing drug codes, it may request a modification of registration online or contact the local DEA office by email or phone, and adding drug codes can be approved at the field level, but may require further inspection. Tr. 273–74, 800, 874–75, 876. There is no uniform guidance on how the DEA handles a request for adding or removing a drug code. Tr. 879.

Although the closing inventory was good because ''it tied out to zero,'' there were issues with OakmontScript's recordkeeping, including a failure to take an initial inventory, and there were also issues with the alarm system. Tr. 190, 192. DI 3 discussed these issues with her group supervisor and her group supervisor asked her to return to OakmontScript to conduct an alarm test and conduct an expanded controlled substance accountability audit going back to December 5, 2017, which is when OakmontScript first received its DEA exporter registration. Tr. 192–93.

March 29, 2019 Inspection

On March 29, 2019, DI 3 completed another inspection with DI 5 and the audit did not show any discrepancies. Tr. 195–97. Dr. Shi provided a pack of additional documents to DI 3 and stated that she was having problems filing the DEA Form 236 for OakmontScript's exports. Tr. 198–201; Gov't Ex. 12. After reviewing these documents, DI 3 determined that OakmontScript was having issues with the DEA Form 236 because OakmontScript did not have the authority to export the controlled substances as it did not have the appropriate drug codes in its registration for most of the drugs. Tr. 201. Therefore, OakmontScript was unable to select the drug codes from the online drop-down box in the DEA Form 236. Tr. 201–02, 613. Despite being unable to fill out the DEA Form 236, Dr. Shi ''exported them anyways'' and she did not think ''it was a big deal.'' Tr. 204. Ultimately, DI 3 found that OakmontScript had violated the CSA by not filling out the DEA Form 236s, by exporting drugs prior to holding its exporter registration,[15] and exporting drugs it did not have authorization to handle. Tr. 205.

Follow-Up to March 29, 2019 Inspection

On April 23, 2019, DI 3 had a phone call with Dr. Shi and requested a detailed list of exports OakmontScript had conducted because it was apparent that OakmontScript had exported a lot more than what Dr. Shi had previously stated. Tr. 206. DI 3 also discussed a fraudulent DEA registration. Tr. 206. During this discussion, Dr. Shi stated that OakmontScript had conducted its first export in May or June of 2017. Tr. 206.

After the April 23, 2019 phone call, DI 3 and Dr. Shi had an email exchange in which Dr. Shi continued to provide conflicting information, so DI 3 asked

[15] DEA registrants are required to provide the proximate date of export and to provide return information within thirty days. Tr. 759–60; *See* Gov't Ex. 47; 21 CFR 1304.22(d).

for further clarifying information. Tr. 208–21. *See* Gov't Exs. 16, 17, 18, 19, 20. After reviewing the several documents Dr. Shi emailed, DI 3 noted several issues, including that OakmontScript was not keeping complete and accurate records related to its controlled substance transactions, was unable to complete the DEA Form 236s, and was creating shipping labels well in advance of dropping off the controlled substances with the common carrier for shipment. Tr. 222–24; Gov't Exs. 16, 17, 18, 19, 20 at 9 (Dr. Shi responded to an email from DI 3 and indicated that the shipping label for an export of Belviq was ''created on date of 10/13/2017, but drop-off on later date while waiting for receiving party get ready for custom clearance.'').

May 8, 2019 Inspection

DI 3 served two administrative subpoenas on OakmontScript with DI 5 on May 8, 2019, that were issued based on the serious violations that DI 3 discovered since conducting her initial inspection on February 19, 2019.[16] Tr. 235–40; Gov't Ex. 24.[17]

OakmontScript kept track of each controlled substance it exported or distributed by assigning a purchase order number, usually starting with ''OKS-'' and followed by a series of numbers. Tr. 242. At the inspection, Dr. Shi provided DI 3 a large packet that was divided into smaller bundles by invoice, that DI 3 later may have reordered chronologically, but she did not remove or add any pages to the stack. Tr. 243–48, 709, 794–95; *See* Gov't Ex. 26. DI 3 discussed with Dr. Shi OakmontScript's exports for direct patient use, including a shipment of clobazam that was potentially sent to an underage patient, a fraudulent DEA registration, and OakmontScript's relationship with NEEC. Tr. 256.

May 13, 2019 Inspection

On May 13, 2019, DI 3 and DI 5 performed another inspection. Tr. 268. DI 3 discussed various topics with Dr. Shi, including a detailed discussion of all the violations DI 3 uncovered. Tr. 268–69. Prior to this visit, DI 3 had also reached out to DEA Headquarters to verify whether OakmontScript had properly completed DEA Form 236s for its exports. Tr. 269–70; Gov't Ex. 48.

Alteration of Distributor Certificate of Registration

A registrant receives a hard-copy certificate of registration, which is an official government document, based on DEA approval to hold a registration, which includes the company's or individual's name, the registered location address, the registrant's DEA registration number, the business activity for which the entity is approved, and—for exporters, importers, and bulk manufacturers—the drug codes that they are approved to handle. Tr. 272–73.

DI 3 had been reviewing OakmontScript's case files and discovered that there was a report filed by the Kansas City District Office of the DEA, naming OakmontScript as fraudulently creating a DEA registration. Tr. 275. OakmontScript had altered its distributor registration to indicate that it was a pharmacy and submitted it to Pharmacy Buying Association (''PBA'').[18] Tr. 275. PBA has a DEA registration and DI 3 spoke to one of PBA's Regulatory Compliance Team Leaders, B.W., and received email correspondence from B.W. that noted PBA ''only sell[s] to pharmacies'' and it does not ''sell to other distributors.'' Tr. 275–78; Gov't Ex. 55. PBA also requires customers to send a copy of their state pharmacy license and a copy of their DEA registration when they send in their account application. Tr. 278; Gov't Ex. 55. B.W. further noted that OakmontScript sent PBA a DEA registration indicating it was a pharmacy and after PBA performed its due diligence, PBA discovered that the document was altered. Tr. 278; Gov't Ex. 55. PBA reported OakmontScript and denied OakmontScript's account. Tr. 278; Gov't Ex. 55.

The DEA registration OakmontScript provided to PBA listed its business activity as ''pharmacy,'' even though the COR of RO0504680 corresponded to OakmontScript's distributor registration. Tr. 286; Gov't Exs. 14, 55. Dr. Shi took responsibility for the falsified registration. Tr. 290–93.

On April 23, 2019, DI 3 discussed the falsified registration with Dr. Shi on the phone. Tr. 293. Dr. Shi stated that she had hired an intern and Dr. Shi instructed the intern to establish relationships with OakmontScript's competitors to determine how they conduct business. Tr. 293–94. After PBA refused to establish a relationship with OakmontScript, the intern altered the DEA registration to list OakmontScript as a pharmacy. Tr. 294; Gov't Ex. 14. During this phone call, Dr. Shi indicated to DI 3 that she had fired the intern as a result of this incident. Tr. 294. However, in an email dated April 24, 2019, Dr. Shi indicated that the intern moved back to China and her employment dates were January 1, 2017, to February 2018. Tr. 297; Gov't Ex. 20 at 13. The phone conversation and email were therefore in ''direct conflict'' and it appeared that the intern had not been fired for falsifying the registration. Tr. 297–98. Dr. Shi also texted information regarding this incident in May 2019 where she said if the incident regarding the falsified registration ''constitutes any offensive sort, 'I' should take responsibility. If any actions taken toward, please address to me directly.'' Tr. 300–01; Gov't Ex. 29.

DI 3 had a follow-up inspection on May 13, 2019, and asked Dr. Shi why the intern's employment dates seemed to span an additional year after the date of the fraudulent DEA registration. Tr. 301–02. Dr. Shi stated that she had ties with the intern's family, who she felt had pressured her to keep the intern employed. Tr. 302. Dr. Shi also explained that the intern had come to her and explained that PBA would not ''do business with them because they viewed OakmontScript as a competitor'' and Dr. Shi had told the intern to ''do whatever is needed'' and to ''[g]ive them basically whatever they want in order to establish this . . . client relationship with them.'' Tr. 303. DI 3 was never able to contact the intern to discuss this violation with her. Tr. 304. OakmontScript was not able to obtain controlled substances from PBA. Tr. 304.

In this instance, DI 3 found that Dr. Shi had exhibited a lack of candor [19] because Dr. Shi initially stated that the intern had been fired and later stated the intern had not been fired, but maintained a position at OakmontScript and actually left the country and her

[16] At the May 8, 2019, meeting, DI 3 also discussed the Letter of No Objection (''LONO'') and that she had learned from someone at DEA Headquarters that a LONO must come from a foreign national government and not from a provincial or state-level government. Tr. 889–91, 893, 895–96, 910–11, 1432–33. A LONO is provided by the importing country stating that it has no objection to a controlled substance being imported into that country. Tr. 910, 1431–32.

[17] The tribunal questioned DI 3 regarding markings on the administrative subpoenas. Tr. 790–91; Gov't Ex. 24. DI 3 stated that the various check and dash marks made on the front pages of the subpoenas were made by OakmontScript. Tr. 790. DI 3 further explained that when she had served the subpoenas, she had not made scanned copies that were hand-signed by the diversion program manager and these were copies that were provided by OakmontScript. Tr. 790–91.

[18] PBA is a distributor of controlled substances and non-controlled substances that only sells to pharmacies. Tr. 275, 1444; *See* Gov't Ex. 55.

[19] Upon direct questioning by the tribunal, DI 3 testified that Dr. Shi exhibited a lack of candor when she ''led me to believe that [the intern] had been fired for her actions related to that forged DEA registration'' and that in their conversation Dr. Shi did use the exact word ''fired.'' Tr. 792–93. DI 3 did not believe this was a simple mistake by Dr. Shi. Tr. 793.

position with OakmontScript because her visa had expired. Tr. 307, 788.

February 2020 Subpoena

DI 3 served another administrative subpoena on OakmontScript on February 28, 2020, and issued an administrative subpoena to NEEC after learning that Dr. L.W. was writing prescriptions for direct patient care at Dr. Shi's request.[20] Tr. 389–95; Gov't Exs. 37, 38.

In response to the subpoenas, David Schumacher sent a letter dated March 26, 2020, indicating he was an attorney representing OakmontScript and NEEC and that neither OakmontScript nor NEEC had any records that were responsive to the subpoena, but he did re-produce certain documentation to DI 3 and addressed certain questions DI 3 posed in a March 10, 2020 email. Tr. 397–98; Gov't Ex. 42. DI 3 followed up with questions to Mr. Schumacher in an April 14, 2020 email, and he subsequently sent an email to DI 3 on April 17, 2020, which responded to some of these questions. Tr. 402–03; Gov't Ex. 44. DI 3 sent her April 14, 2020, email to seek clarification regarding two identical prescriptions she identified for clobazam and what role they played in the export of this controlled substance. Tr. 405; Gov't Ex. 44.

Invoice OKS–00243 (Diazepam)

OakmontScript received diazepam, 10 milligram gel on May 16, 2017, from McKesson that appears to have been shipped by OakmontScript on June 10, 2017. Tr. 352–53, 366, 432; Gov't Exs. 12 at 14, 26 at 20.[21] However on other documentation, the shipping date is listed as May 18, 2017, and the client's name is listed as Par Pharmaceutical, an Endo International Company. Tr. 356, 1448; Gov't Ex. 17 at 3. In other documentation, the shipping date is listed as May 18, 2017, and the client is listed as Cangzhou People's Hospital. Tr. 357, 1449; Gov't Ex. 18 at 3. Furthermore, Dr. Shi sent an email to DI 3 on April 23, 2019, indicating that she was unsure of the exact date of export because the ''shipping label was not retrievable due to USPS system update'' and Ms. Liu has ''made edit in the date multiple times and she thought the proper date is on the date of payment. . . .'' Tr. 358–59, 386, 1449; Gov't Exs. 20 at 8, 28 at 22.[22] The ''ship to name'' is listed as H.H.[23] at Cangzhou People's Hospital in China and Dr. Shi's guess of the ''best possible date'' of shipment was the date of payment on May 18, 2017. Tr. 361–63, 1449–50; Gov't Ex. 21 at 9. The use was listed as ''for research'' and the ''bill to'' party was H.X.Z. at Par Pharmaceutical and the ship to party was Dr. H.H. at Cangzhou People's Hospital in China. Tr. 365, 435; Gov't Ex. 26 at 19.

One of the license transfer documents for this export indicates that the diazepam was transferred from OakmontScript's distributor registration to its exporter registration on May 7, 2018. Tr. 371–72, 435; Gov't Exs. 26 at 21, 28 at 77. A different license transfer document indicates that the date of transfer was May 20, 2017. Tr. 371, 436; Gov't Ex. 26 at 22.[24] Other documentation provided by OakmontScript states that the diazepam prescription was made based on a request from a family in China for Patient S.Z. and was shipped sometime in May 2019. Tr. 407–09; Gov't Ex. 44 at 1–2. OakmontScript was unable to complete a DEA Form 236 for this export.[25] Tr. 352–53; Gov't Exs. 12 at 14, 16 at 2.

DI 3 confronted Dr. Shi regarding this conflicting information at the on-site inspection on May 8, 2019. Tr. 363. Dr. Shi recalled that this diazepam had been shipped for direct patient use in China. Tr. 363–64. Dr. Shi stated that OakmontScript had to label the reason for export as ''research'' in order to get the shipment past Chinese Custom Officials and that the actual intended use of the diazepam was for direct patient use. Tr. 366, 1446.

DI 3 was also confused by documents provided by Dr. Shi because although they appeared to be the exact same documents—a prescription written in Chinese, a hospital's government licenses, and a doctor's medical license—these documents were provided in stacks for two different invoices. Tr. 380–83; Gov't Ex. 26 at 12–14, 30–32. Based on a translation that DI 3 ultimately obtained for these documents, DI 3 learned that both prescriptions were for diazepam. Tr. 383.

OakmontScript also failed to include a DEA Form 236 for this invoice, which it was required to do. Tr. 416–19. Furthermore, OakmontScript's distributor registration and exporter registration do not allow for OakmontScript to fill prescriptions, as such prescriptions may only be filled by a pharmacist. Tr. 420–23, 429; 21 U.S.C. 1306.06. OakmontScript also did not provide the information required under Section 3a or Section 3b of the DEA Form 236.[26] Tr. 418–19; Gov't Ex. 48. Based on the records, OakmontScript appears to have exported 10 milligrams of diazepam under invoice number OKS–00243 prior to obtaining its DEA exporter registration on December 5, 2017. Tr. 423–25, 1433, 1452.

Furthermore, invoice OKS–00243 did not provide the DEA registration of the doctor prescribing the controlled substance and the patient's home address. Tr. 430–31. *See* 21 CFR 1306.05(a).[27] DI 3 stated that this failure to provide the required information is a danger to the public because the information is needed to ensure registered practitioners are prescribing appropriately. Tr. 431.

Invoice OKS–00301 (Briviact)[28]

OakmontScript received 10 milligrams and 100 milligrams of

[20] As discussed *supra,* Dr. L.W. was listed as a general partner of NEEC. Tr. 154. Furthermore, based on Dr. Shi's statements, it was unclear to DI 3 as to what role NEEC was playing in OakmontScript's exports. Tr. 393–94.

[21] This McKesson invoice listed OakmontScript's address as 15 New England Executive Park. Gov't Ex. 26 at 20. Dr. Shi explained that this address and the 1500 District Avenue address (OakmontScript's current address) are the same address. Tr. 367. Dr. Shi stated that the whole area where OakmontScript is located got ''reorganized'' and OakmontScript's address changed, but OakmontScript never changed its physical location. Tr. 368.

[22] This was concerning for DI 3 because a registrant is required to know when it has conducted a transaction with a controlled substance and OakmontScript was unable to provide this information. Tr. 360.

[23] In the translated prescription, H.H. appears to be a doctor in China. Tr. 413; Gov't Ex. 45 at 4. DI 3 conducted a search within the DEA database and determined that Dr. H.H. did not have a DEA registration. Tr. 413–14.

[24] DI 3 indicated that ''it seems more likely . . . that this license transfer document from May 20, 2017, is the more likely of the two to be accurate,'' based on comparing the McKesson invoice that was dated in 2017. Tr. 436.

[25] This is noted as ''no XFER'' in the Excel spreadsheets in the documents provided by OakmontScript, which indicates that OakmontScript was not able to fill out a DEA Form 236 for a particular drug. Tr. 202.

[26] Section 3a of DEA Form 236 requires that, for exports, the exporter ''list the U.S. port of export (port name, city, state) from where the shipment departs the United States and the anticipated date it will depart.'' Gov't Ex. 47 at 1, 2. Section 3b of DEA Form 236 requires that, for exports, the exporter ''list the foreign port of import (port name, city, country) and the anticipated date it will arrive.'' Gov't Ex. 47 at 1, 2.

[27] The personal use exemption allows someone who is traveling across international boundaries to take a controlled substance with them and a third-party shipping a controlled substance overseas would not fall within a personal use exemption. Tr. 437–38.

[28] Throughout her testimony, DI 3 mentioned that there were several handwritten notes or post-it notes with writing on the certain documents, and that these notes were in the documents when they were presented to her by OakmontScript. Tr. 373. There was one instance, however, where DI 3 acknowledged that she had made a handwritten note. Tr. 375–76; Gov't 26 at 25. Specifically, she had written the word ''Par'' next to the ''Bill To'' line of this invoice. She also made handwritten notes in Government Exhibit 26 noting that the

Continued

Briviact on July 12, 2017, that were shipped in August 2017—four months prior to OakmontScript receiving its exporter registration. Tr. 440–57, 1433; Gov't Exs. 12 at 7, 20 at 8, 26 at 35–36, 27 at 2, 28 at 27.[29] However, in other documentation provided by OakmontScript, this OKS–00301 invoice is not included in what is supposed to be a list of all controlled substances OakmontScript has exported. *See* Gov't Ex. 18 at 3–4. In other documentation, the commercial invoice for invoice OKS–00301 indicates that this shipment occurred May 8, 2019, and the indicated use was listed as ''research.'' [30] Gov't Ex. 26 at 33, 34.

OakmontScript did not file a DEA Form 236 for this invoice because it was unable to do so. Tr. 443, 456–57; Gov't Exs. 20 at 8, 48. Dr. Shi claimed that OakmontScript did not need to make a declaration to Customs and Border Control as the value of the shipment was less than $2500. Tr. 443; Gov't Ex. 20 at 8.[31]

Invoice OKS–00315–1 (Belviq)

OakmontScript received 10 milligrams of Belviq on September 18, 2017, which was shipped on November 1, 2017, and OakmontScript was not able to file a DEA Form 236 for this prescription. Tr. 457–70; Gov't Exs. 12 at 3, 20 at 8,[32] 26 at 38–39, 27 at 2, 28 at 6. However, Belviq is omitted from two Excel spreadsheets that were provided to DI 3 by Dr. Shi, which were supposed to include all of OakmontScript's exports. Gov't Ex. 17 at 2–3, 18 at 3–4. Also, a different invoice provided by OakmontScript is dated September 18, 2017. Gov't Ex. 26 at 37. Another commercial invoice is dated May 8, 2019. Gov't Ex. 26 at 40. Based on the November 1, 2017, shipping date, OakmontScript exported this Belviq product approximately one month before it obtained its exporter registration. Tr. 470, 1433.

Invoice OKS–00315–2 (Lyrica)

This invoice included several strengths of Lyrica: 25 milligram, 50 milligram, 75 milligram, 100 milligram, 150 milligram, 200 milligram, 225 milligram, and 300 milligram tablets. Tr. 470.

OakmontScript purchased Lyrica on September 12, 2017, from American Pharma Wholesale and it was shipped sometime between November 17 through 21 of 2017 to Changzhou Pharmaceuticals in China and OakmontScript did not file a DEA Form 236 because it was unable to do so.[33] Tr. 470–83, 895; Gov't Exs. 12 at 9–10, 26 at 41–43, 27 at 2, 28 at 8, 78, 48. However, in other documentation provided by OakmontScript, Lyrica is not listed as an export. Gov't Exs. 17 at 2–3, 18 at 3–4. Furthermore, in other documentation, the invoice is dated August 2017. Gov't Exs. 26 at 44, 28 at 31. This shipment of Lyrica was shipped approximately one month prior to OakmontScript receiving its exporter registration. Tr. 483, 1433.

Invoice OKS–00108 (Belviq XR)

OakmontScript received Belviq on July 20, 2017, and shipped the same quantity of Belviq XR 20 milligrams on December 1, 2017. Tr. 483–95; Gov't Exs. 12 at 3; 26 at 45, 47, 27 at 2, 28 at 5, 19 (the shipping date is listed as December 1, 2017), 76 (the date OakmontScript transferred the Belviq from its distributor to exporter registration is listed as November 29, 2017). However, in other documentation provided by OakmontScript, Belviq is not listed as an export. Gov't Exs. 17 at 2–3, 18 at 3–4. In other documentation provided by OakmontScript, the shipping label for this invoice was created on October 13, 2017, and the customer was listed as Jiangsu Alicorn Pharmaceutical Co. Ltd in China. Gov't Ex. 20 at 9. There are also various dates included in the ''Import Drugs Approval Notice'' including February 16, 2017 and February 15, 2018. Gov't Ex. 26 at 46; Tr. 489. The packing list that OakmontScript provided is dated May 8, 2019. Gov't Ex. 28 at 19. OakmontScript did not file a DEA Form 236 for this export. Tr. 494. Regardless of whether the shipment was exported on December 1, 2017 or October 13, 2017, this shipment would have been exported prior to OakmontScript obtaining its exporter registration. Tr. 495, 1433.

Invoice OKS–00650 (Lunesta)

OakmontScript received Lunesta in May 2018 and shipped the Lunesta to Disha Pharmaceutical Group on May 21, 2018. Tr. 499–535; Gov't Exs. 12 at 17, 17 at 3, 18 at 3, 28 at 94. The Lunesta was shipped to Mr. Z.Y. at an address in the United States in Kearny, New Jersey. Tr. 1455; Gov't Ex. 22 at 10–11. Another document for this export that is dated May 3, 2017, states that this shipment was shipped to P.Z. in New Jersey. Tr. 515, 522–23; Gov't Ex. 26 at 87.

Upon further investigation, DI 3 realized that this was a domestic distribution or distributing to a registrant in the United States, as opposed to an export. Tr. 508, 510, 529, 533, 904–05; Gov't Exs. 22 at 10–11, 26 at 88, 89, 92, 27 at 3, 28 at 66, 67, 68. OakmontScript did not fill out a DEA Form 236 for this export. Tr. 500–01.

A distributor is not permitted to distribute controlled substances to an ultimate user and there is no coincidental activity that permits a distributor to provide controlled substances to non-DEA individuals or persons or companies. Tr. 511–12, 723. Distribution occurs between registrants while dispensing would take place through a prescription being filled by a pharmacy after a practitioner prescribes a controlled substance. Tr. 513.

DI 3 discussed this invoice with Dr. Shi. Tr. 513–14. Dr. Shi stated that she was provided a business card showing that Mr. Z.Y. was an employee of Disha Pharmaceutical Group, a pharmaceutical company in China, and that he was getting ready to move to China and asked that the Lunesta be shipped to his home address in New Jersey, and paid via personal payment. Tr. 514, 516, 531, 534–35. This invoice indicates that the ''bill to'' party was Disha Pharmaceutical Group. Tr. 530–31; Gov't Ex. 28 at 44. Dr. Shi had explained that Larry Yu, a colleague she had met at a conference, had requested the Lunesta for RefDrug and asked Dr. Shi to send the Lunesta to Mr. Z.Y. to

scanned documents were a ''Hospital's Central Gov. License,'' ''Doctor's Medical License,'' and a ''Prescription.'' Tr. 380–81; *See* Gov't Ex. 26 at 12, 14.

[29] This exhibit is titled as ''Customer End-Use Certification.'' Gov't Ex. 28 at 27; Tr. 453. An exporter is expected to know what the controlled substances it is exporting are being used for and this form includes questions regarding this use. Tr. 453–54. This is not a form created by the DEA, but rather a form ''the industry has come up with'' in order to meet the standards set forth in the Code of Federal Regulations. Tr. 454.

[30] DI 3 discussed the fact that the Respondent asserted in its prehearing statement that there was an Excel macro that affected some of the dates on OakmontScript's documents. Tr. 574. In this instance, the document is dated May 8, 2019, which was the date of one of DI 3's inspections. Tr. 575. Therefore, this could account for the incorrect date listed in this invoice. DI 3 stated that she became aware of the macro issue after the May 8, 2019 inspection, but OakmontScript never specifically brought this to her attention during her investigation. Tr. 1439–40. If DI 3 had been made aware of this issue at the time, she would have worked with OakmontScript to obtain the most accurate records. Tr. 1440–41.

[31] An ultimate user is the individual who will be ingesting the controlled substance or providing it for a pet's use, while an end-use certification addresses what the controlled substance is being used for and if it is going to be re-exported. Tr. 454–55.

[32] In response to DI 3's email, Dr. Shi sent a reply email stating that per the DHL shipping label, the shipment was made by a custom broker, Hangzhou Junyuan Meditech, LLC and the end-user is Changzhou Pharmaceuticals with an address in China, but no export date was provided. Tr. 461–62.

[33] DI 3 later testified that OakmontScript did submit a DEA Form 236, but it was subsequently cancelled. Tr. 909.

have him provide it in China as Dr. Yu was not able to acquire it. Tr. 515–16.

Dr. Shi confirmed for DI 3 that OakmontScript had purchased this Lunesta with its distributor registration and then distributed it to Mr. Z.Y. at his home address in New Jersey, which DI 3 testified was improper. Tr. 517–18. Dr. Shi did not believe that this incident was a violation and stated that because Disha Pharmaceutical Group was the end-user of this controlled substance that it did not have to be licensed or registered with the DEA to obtain this controlled substance. Tr. 518. In contrast, DI 3 believed that Disha was not the end-user or ultimate user [34] because it was seeking the Lunesta in order to conduct research as opposed to using it for personal medical use. Tr. 518–19, 772–73.

DI 3 conducted searches to see whether certain parties in this transaction had a DEA registration. Tr. 545. She conducted a search for Mr. Z.Y., RefDrug, Inc., L.Y., P.Z., Disha Pharmaceutical Group, and the address in Kearny, New Jersey, and found no results for any active or inactive DEA registrations for any of these searches. Tr. 545–54. DI 3 also conducted a Google search of the Kearny, New Jersey, address and was not provided any information from OakmontScript that this was a freight forwarding facility. Tr. 555–56, 558.

Invoice OKS–00715 (Lyrica)

A variety of Lyrica strengths were shipped on November 21, 2018, to J.F. at YaoPharma. Tr. 558–72; Gov't Ex. 31 at 1–4, 27 at 3, 31 at 1, 3–4. However, other documentation provided by Dr. Shi indicates that the date is November 21, 2019. Gov't Ex. 12 at 12.[35] Dr. Shi also sent an email stating that the label for the Lyrica was created on November 21, 2018, and the drop-off date was December 4, 2018. Gov't Ex. 20 at 10. Other documents list the date as March 29, 2019. Gov't Ex. 31 at 3. Other documents list an invoice date of May 8, 2019. Gov't Ex. 26 at 102.[36] The date of the invoice was also listed as August 8, 2018. Gov't Ex. 28 at 48. OakmontScript did not file a DEA Form 236 for this export. Tr. 572–73; Gov't Ex. 48.

Invoice OKS–00753 (Briviact)

Briviact 50 milligram and 100 milligram, a Schedule V drug, was received on October 22, 2018, the shipping label was created on October 25, 2018, and it was shipped on November 2, 2018. Tr. 579–96; Gov't Exs. 12 at 8, 20 at 10. Other documentation provided by OakmontScript states that this was shipped on October 26, 2018. Gov't Exs. 17 at 2, 18 at 4. The commercial invoice is dated September 26, 2018 and the ''bill to'' and ''ship to parties'' are Y.P. at Zhejiang Le Pu Technology Limited Company in China. Gov't Exs. 26 at 106, 28 at 53.[37] In other documentation provided by OakmontScript, no shipping date is provided. Gov't Ex. 27 at 3–4. OakmontScript did not have the authority to export Briviact. Tr. 580–81, 599, 1434–35; Gov't Ex. 11. OakmontScript did not fill out a DEA Form 236 for this controlled substance. Tr. 596, 1435–36; Gov't Ex. 48.

DI 3 found Dr. Shi's statement regarding drug codes to demonstrate a lack of candor because she had specifically asked Dr. Shi if OakmontScript was handling other controlled substances outside those listed and Dr. Shi reported that she had not. Tr. 600, 724, 788.

Invoice OKS–00902 (Belviq)

Belviq, 10 milligrams was received by OakmontScript on January 30, 2019, transferred from its distributor license to its export license on February 14, 2019, and shipped on February 15, 2019, to Beijing HeMingTang Pharmaceutical Company Limited. Tr. 602–13; Gov't. Exs. 12 at 5, 18 at 4, 26 at 121, 27 at 4, 28 at 60, 82. However, other documentation provided by Dr. Shi listed a packing slip date of January 16, 2019. Gov't Ex. 26 at 119. Other documentation listed an invoice date of May 8, 2019. Gov't Ex. 26 at 122.[38] Other documentation lists the billing date from McKesson as January 16, 2019. Gov't Ex. 28 at 18. OakmontScript did not file a DEA Form 236 for the Belviq. Tr. 609, 1435–36; Gov't Ex. 48. OakmontScript did not have the authority to export Belviq at this time. Tr. 612, 1435; Gov't Ex. 11.

DI 3 believed Dr. Shi's previous statement regarding drug codes demonstrated a lack of candor because she had specifically asked Dr. Shi if OakmontScript was handling other controlled substances outside those listed and Dr. Shi failed to report that OakmontScript had recently exported Belviq. Tr. 613, 724, 788.

Invoice DIW–0019 and NEEC–0019 (Clobazam)

Clobazam is a Schedule IV controlled substance. Tr. 614; Gov't Ex. 10 at 4. OakmontScript received a shipment of clobazam on February 28, 2019, and shipped it on March 5, 2019, to Patient J.L.'s home address in China. Tr. 613–41, 673–723, 727–33, 907, 912; Gov't Exs. 12 at 21, 26 at 15–16, 27 at 4, 28 at 65.

However, in other documentation provided by OakmontScript, there is no indication that clobazam was shipped or it is not listed on the invoice. Gov't Exs. 17 at 2–3, 18 at 3–4. OakmontScript did not have the authority to export clobazam and DI 3 was unable to confirm that it was used for a legitimate scientific, research, or medical purpose. Tr. 612–13; Gov't Ex. 11. OakmontScript also did not fill out a DEA Form 236 for this invoice. Tr. 615, 1435–36; Gov't Exs. 26 at 16, 28 at 76, 48 at 1.

At the May 8, 2019 visit, DI 3 asked why there was a discrepancy and Dr. Shi stated that the request had come to export the clobazam for direct patient use. Tr. 617–18. During this conversation, Dr. Shi stated that she had ''begged'' Dr. L.W. for about a week to write a prescription to legitimize this export of controlled substances and although he initially said no, he ''eventually relented'' and wrote the prescription, but asked that Dr. Shi not ask him to write a prescription like that again. Tr. 619–20, 621, 673, 769, 912, 1456.

It was DI 3's understanding that Patient J.L. was treated at Boston Children's Hospital, had returned to China, and was now seeking an export of clobazam to China. Tr. 620. Dr. Shi never provided this prescription to DI 3. Tr. 621–22.[39]

[34] 21 U.S.C. 802(27) defines ''ultimate user'' as ''a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.''

[35] DI 3 discussed these issues with Dr. Shi on April 23, 2019, and Dr. Shi indicated that this was an incorrect date and the date should be listed as November 21, 2018. Tr. 564.

[36] This incorrect date could be related to the macro issue, but regardless, having these incorrect dates caused confusion for DI 3. Tr. 576–77.

[37] While this exhibit was being discussed, Dr. Shi objected and explained that this ''page of the shipping label is different. So it's our mistake to put the shipping label of 715 in here. So this shipping label should not be discussed with this, it's our fault to misplace this page.'' Tr. 591. This issue is discussed *infra,* during Dr. Shi's testimony.

[38] This could have also been related to the macro issue as the invoice was dated May 8, 2019, one of the dates DI 3 was present for an inspection.

[39] Other documentation provided by OakmontScript indicates that the prescription was transferred to a doctor's office in the United States, which would appear to be a domestic distribution, but during the May 8, 2019 conversation, Dr. Shi indicated that the controlled substance was directly exported to Patient J.L. in China, which she asserted a distributor is able to do. Tr. 624, 633, 641, 726, 915; Gov't Ex. 20 at 11.

Administrative Subpoenas

DI 3 and DI 6 met with Dr. L.W. in January or February of 2020. Tr. 674. Upon arriving, both DIs explained the reason for the visit, identified themselves, and showed their credentials. Tr. 674. Dr. L.W. indicated he would be fine to answer questions. Tr. 674. During the interview, Dr. L.W. indicated that he was a consulting physician for OakmontScript, was paid a monthly stipend, and received extra compensation each time he wrote a prescription for OakmontScript. Tr. 675. It was unclear what his position was with NEEC. Tr. 675. Dr. L.W. reviewed the material transfer document that indicated the clobazam, invoice NEEC–019, was shipped directly to him and he stated that he had never taken physical possession of the clobazam or any controlled substances. Tr. 676, 677, 730. *See* Gov't Ex. 26 at 16. Dr. L.W. told DI 3 that he wrote prescriptions for OakmontScript after OakmontScript provided him with medical records for foreign patients who were being treated for illnesses in other counties and he would determine whether the drug OakmontScript wanted to export was the appropriate drug for the treatment of those patients. Tr. 677. He further stated that he had never seen Patient J.L. and did not have any medical records for Patient J.L. Tr. 678, 682. He stated that he did not have authority to write prescriptions for patients located outside of the United States, nor does he have foreign medical licenses or overseas privileges as a practitioner. Tr. 678.

DI 3 served an administrative subpoena on Dr. L.W. that was dated January 2, 2020. Tr. 678–79; Gov't Ex. 35. Dr. L.W. later called DI 3 to discuss the subpoena she had served on him. Tr. 681. Dr. L.W. stated that he did not have a response to the subpoena and he had not written prescriptions for controlled substances for OakmontScript. Tr. 681–82; Gov't Ex. 36. DI 3 asked him to email her his official response and he sent DI 3 an email stating this. Tr. 681–82; Gov't Ex. 36.

On March 6, 2020, DI 3 had an email exchange with Attorney Schumacher, in response to the administrative subpoenas that were served on OakmontScript and NEEC. Tr. 690; Gov't Ex. 40. *See* Gov't Exs. 37, 38. Mr. Shumacher indicated that he had no response to the subpoenas. Tr. 687–706; Gov't Exs. 39, 40, 41, 42.

Regarding the clobazam prescription,[40] Mr. Schumacher indicated that the prescription had been initiated or authorized by Dr. G.T. from a hospital in China and that this physician did not have a relationship with OakmontScript or NEEC. Tr. 710–11; Gov't Ex. 44 at 1. DI 3 conducted a search for Dr. G.T. in the DEA registration database known as RICS or CSA2 to determine whether Dr. G.T. or his hospital ever had a DEA registration associated with them and the search turned up no results. Tr. 715–17, 722.

Regarding the clobazam, 019 invoice, DI 3 found that Dr. Shi demonstrated a lack of candor because she initially provided documents indicating the clobazam had been exported, but then later provided information that it was actually transferred domestically to a doctor's office in Massachusetts and Dr. Shi continued to provide conflicting information. Tr. 730–31. This lack of candor made it difficult for DI 3 to understand what had actually been exported. Tr. 731, 788–89.

OakmontScript did not provide return information or a DEA Form 236 for the exports discussed at the hearing including, invoice OKS–00243 (Diazepam), invoice OKS–00301 (Briviact), invoice OKS–00315/OKS–00315–1 (Belviq), invoice OKS–00315/OKS–00315–2 (Lyrica), invoice OKS–00108 (Belviq XR), invoice OKS–00715 (Lyrica), invoice OKS–00753 (Briviact), invoice OKS–00902 (Belviq), and invoice DIW–0019/NEEC–0019 (clobazam). Tr. 732–35.

Overall, DI 3's investigation of OakmontScript identified record-keeping issues including, not having an initial inventory,[41] exporting before receiving its exporter registration,[42] and commingling records.[43] During her investigation in 2019, DI 3 requested that Dr. Shi provide specific dates of export, which is the actual date the controlled substance left the registrant's registered location and the date that the controlled substance was released by a customs official, which must be recorded within thirty days after the registrant learns of the export or within ten days if the Administrator asks for it earlier. Tr. 759–60, 807. The manner in which OakmontScript was conducting business violated the CSA and DEA regulations, which made it a potential threat to public safety. Tr. 762, 786. Although Dr. Shi and OakmontScript provided information upon request, the information was consistently conflicting and not necessarily helpful to DI 3. Tr. 765. Even if part of the exportation process occurred after OakmontScript obtained its exporter registration on December 5, 2017, this would not have legitimized the export because OakmontScript's intent to export the controlled substances was there once it transferred them to the common carrier. Tr. 1442–44.

DI 3 effectively explained her interactions with OakmontScript employees, including Dr. Shi and Dr. L.W. As a public servant, DI 2 has no personal stake in the outcome of the instant investigation or in the revocation of the Respondent's registration. There was no indication during her testimony that she had any animus against OakmontScript or any of its employees. I therefore find her testimony to be credible and it will be afforded considerable weight.

The Respondent's Case

The Respondent's case-in-chief consisted of the testimony of four witnesses: (1) Yujing Liu, (2) DI 3,[44] (3) Donghui Yu, Ph.D., and (4) Jufang Shirley Shi. Below is a summary of the testimony of these witnesses.[45]

Yujing Liu

Yujing Liu graduated from Northeastern University in 2015 with a major in project management. Tr. 814–15. Ms. Liu has been working for OakmontScript since February 2018 and coordinates logistics for OakmontScript including monitoring and tracking shipments, and preparing documents to support the exporting process. Tr. 815–16, 844. Ms. Liu also maintains OakmontScript's records on exports in a computer system that she reviews for accuracy, but all OakmontScript employees have access to these records. Tr. 849–50. A commercial invoice is part of the documents that are required to show the sale price of the drug. Tr.

[40] DI 3 obtained a translation of the clobazam prescription. Tr. 713–16; Gov't Ex. 46.

[41] Tr. 735–41; Gov't Exs. 9, 13.

[42] DI 3 learned that OakmontScript had exported thirteen controlled substances prior to being granted its export license on December 5, 2017, which was counted based on each drug and strength. Tr. 864. DI 3 offered an example for the Briviact shipment, which was 10 milligrams and 100 milligrams, which would count as two separate controlled substances. Tr. 864–68.

[43] There were issues with recordkeeping as OakmontScript had commingled records. Tr. 739. For instance, OakmontScript was keeping inventories for both its distributor registration and its exporter registration on the same document and it was difficult to discern under which registration each transaction had occurred. Tr. 743–48, 782; Gov't Ex. 12. DEA registrants are also required to take a physical hand count of all controlled substances that they have on hand under that DEA registration and document the results, which OakmontScript failed to do prior to the March 29, 2019 inspection date. Tr. 749, 778; Gov't Ex. 12.

[44] The Respondent called DI 3 as a witness for its case-in-chief. Tr. 862–63. The testimony elicited from DI 3 by the Respondent is incorporated into the summary of DI 3's testimony discussed above.

[45] I do not make any findings of fact in these summaries. Any facts necessary for a disposition of this case are set forth in the Analysis section of this Recommended Decision.

834. A commercial invoice's ''Bill to Address'' and ''Shipping to Address'' are not always the same. Tr. 834–35. After creating the commercial invoice, Ms. Liu will save the document as a PDF because the Excel formula [46] of OakmontScript's working documents does not capture the accurate date. Tr. 854–58. When Ms. Liu provided export records to DI 3, she provided OakmontScript's internal documents from the Dropbox, which are the working templates, rather than the PDF versions. Tr. 831–32.

Ms. Liu knows how to fill out a DEA Form 236 and DEA Form 161, which is not difficult to do if the drug code is available or assigned to OakmontScript and the national level import permit is available. Tr. 817, 830, 859–61.

The exporting process includes many events, including tracking when the shipment passes Customs. Tr. 816, 844. It is difficult for Ms. Liu to track when Customs clears a shipment and she cannot record that date. Tr. 844–45. Instead of providing that exact date, OakmontScript records ''every step we did,'' which includes when Customs clears a controlled substance to leave the United States, but not when the controlled substance is released by the country it is being shipped to. Tr. 845–48. OakmontScript uses the date on the customer's import permit, which is the customer's deadline to receive the export and finish the customer clearance date. Tr. 848. OakmontScript uses the common carrier DHL, but can only track DHL shipments for three months because the DHL system only provides three months of history. Tr. 848–49. Therefore, if the shipment arrives with the client outside this three-month window, OakmontScript is not able to track the exact date the shipment arrives and although a client will tell OakmontScript when it receives a shipment, OakmontScript does not record this information. Tr. 849.

On cross-examination, Ms. Liu agreed with Government counsel that the dates of shipment for invoice OKS–00715, as recorded in the Respondent's documentation admitted as Government Exhibits 26 (showing a shipment date of May 8, 2019) and 31 (showing a shipment date of March 29, 2019) are incorrect, based on the Respondent's documentation admitted as Government Exhibit 27 (showing a shipment date of November 21, 2018). Tr. 856–58.

Throughout her testimony, Ms. Liu was generally consistent and credible. As an employee of OakmontScript, she has a personal stake in the outcome of the instant investigation as well as the revocation of the Respondent's registrations. Her testimony generally involved her job duties with OakmontScript. At one point, she also agreed with Government counsel that the dates of shipment for invoice OKS–00715 were incorrect, based on different documents providing conflicting dates. Overall, I found Ms. Liu's testimony credible.

Donghui Yu, Ph.D.

Donghui Yu has a Ph.D. in Pharmacology and her post-doctoral training was at Dana-Farber Cancer Institute and Harvard Medical School. Tr. 918. Her research focus was in oncology research and cancer drug development. Tr. 918. She was a teaching assistant at the School of Medicine in Beijing University, a Research Scientist at the Cubist Pharmaceutical, and an Investigator at Infectious Diseases at Novartis in Cambridge, Massachusetts. Tr. 918. During 2011 and 2015, she volunteered at Boston Children's Hospital by hosting weekly craft activities and saw children who had diseases that were still not cured.[47] Tr. 919. She worked in a health-related facility in Needham, Massachusetts, helping her husband, from 2012 through 2017. Tr. 1015–16.

Dr. Yu started working at OakmontScript in June 2017 and she enjoys working for OakmontScript because it gives her the opportunity to serve people in need in the medical and science field. Tr. 919, 930, 1015. She is the Executive Director and helps Dr. Shi train new employees by using OakmontScript's Standard Operating Procedure (''SOP''), and ensures that the Drug Supply Chain Security Act is implemented in the SOP and that OakmontScript is complying with the FDA and following the rules of other countries.[48] Tr. 921, 925, 932. She also ensures that the SOP is timely updated, the employees are trained properly, and all the procedures are followed in the SOP. Tr. 921, 923, 930. Client validation is a very important part of compliance and OakmontScript considers customer verification a top priority as the drug abuse epidemic was caused by controlled substances being distributed for a non-legitimate use. Tr. 922. OakmontScript invested in security including having a security system, a safe box, a door lock, an alarm, and temperature control in the warehouse where pharmaceutical products are being stored. Tr. 925–26.

In order to export controlled substances legally in the United States, the person conducting the export of the controlled substance must have a DEA registration. Tr. 1029–30. Dr. Yu agreed with Government counsel's statement that applying for a DEA registration is not the same thing as having a DEA registration. Tr. 1030. Furthermore, a registrant can only export controlled substances for which it has authorization to do so. Tr. 1030–34.

OakmontScript obtained its DEA export registration on December 5, 2017. Tr. 1030. Dr. Yu stated that before DI 2 performed her on-site inspection,[49] OakmontScript was not aware that to do an export, it needed to transfer the controlled substances from its distributor registration to its exporter registration. Tr. 1011. As a result, after DI 2's inspection, OakmontScript updated its export process SOP to include the ''license transfer document.'' Tr. 1011. When a new customer comes to OakmontScript, OakmontScript checks the customer's business card, makes sure it belongs to the company it claims, ensures that person is the company's legal representative, obtains the company's business registration, and checks the company's website. Tr. 923. If there is an export of controlled substances to a Chinese client, OakmontScript asks the client to provide its business authorization for controlled substance usage, development, or manufacture. Tr. 923. OakmontScript also requires clients to fill out a form that ''covers all the business, and the history, and their financial situation, so on, so on.'' Tr. 923. In cases where clients need a clinical trial registration, OakmontScript will ask them to provide their clinical registration in order to go through its clinical trial protocol and once OakmontScript makes sure it is for a legitimate use, OakmontScript enters this information in a specific Dropbox database. Tr. 924.

OakmontScript's company goal is to serve the clients and the public and to make sure every step of its SOP is executed properly. Tr. 926–27. Otherwise, it can impact public safety and OakmontScript always discusses and modifies the SOP when it finds a problem that is not perfectly described in the SOP. Tr. 927.

Dr. Yu is familiar with the CSA and DEA regulations and it would be wrong for a DEA registrant to fail to comply with these. Tr. 1023–25. However, what

[46] The Excel formula is a macro that populates the current date that the document is open. Tr. 857–58.

[47] Dr. Yu was connected to Patient J.L.'s parents when he had surgery at Boston Children's Hospital. Tr. 920.

[48] This includes working with a Chinese client and needing to comply with the Chinese National Medical Product Administration. Tr. 933.

[49] DI 2 performed her on-site inspection on July 26, 2018. Tr. 126–27.

is wrong or correct is defined by the DEA and not everything can be defined as black and white. Tr. 1024. For instance, some substances that are controlled substances in the United States are not controlled substances in China including Lyrica, Belviq, Briviact, and clobazam, while substances like caffeine, are not controlled in the United States, but are considered controlled substances in China. Tr. 936.

It is difficult for OakmontScript to obtain the LONO *[E] from other countries, particularly China, and instead the clients present the permits from the local province. Tr. 937. Dr. Yu noted that one example occurred with Belviq, OKS Invoice 00902. Tr. 1048–49. Because Belviq was not a controlled substance in China, OakmontScript was unable to obtain a LONO letter for the Belviq. Tr. 1049. In addition, OakmontScript did not complete a DEA Form 236 for this shipment of Belviq. Tr. 1049. Further, on the date that OakmontScript shipped clobazam, invoice number NEEC–019, it did not have a drug code for clobazam and did not submit a DEA–236. Tr. 1049–51. Finally, on the date that OakmontScript shipped Briviact, invoice number 753, it did not have a drug code for Briviact and did not file a DEA–236. Tr. 1051–53.

Dr. Yu's understanding of a drug code is that it is used for a controlled substance export only and is for controlled substance identification purposes as different dosage forms or formulations of drug substances could be assigned different drug codes. Tr. 970–71. This does not apply to Schedule V controlled substances, where only one drug code is assigned for different doses and populations. Tr. 971. The DEA field agents told OakmontScript that there were several ways to obtain new drug codes, including filling out an online application, emailing the local DI agent, and adding new drug codes when it renews its license. Tr. 972. OakmontScript is not a manufacturer and does not deal with controlled substance manufacturers in the United States. Tr. 982.

Dr. Yu discussed the macro issue that Ms. Liu had previously mentioned in her testimony, and noted that once OakmontScript realized this caused a potential problem, Dr. Yu corrected the template. Tr. 984, 1053–60. Dr. Yu would also create separate PDFs that list the correct date, and save them to the same folder. Tr. 1055–57. OakmontScript's SOP does not contain the ''concept of date of export'' as OakmontScript feels it ''is unable to define'' it. Tr. 986. Instead, OakmontScript ''just document[s] every step we handled'' because an ''export is really a process.'' Tr. 986. Therefore OakmontScript ''had nothing to present'' when DI 3 asked about a ''specific export time.'' Tr. 987. Although DI 3 used the shipping labels, OakmontScript did not believe the shipping label was proper to use as the export date. Tr. 987. Dr. Yu was ''frightened'' when DI 3 asked about the date of export at the February 19, 2019, inspection because she did not know the exact document to show her. Tr. 991–92. However, Dr. Yu later went on to confirm that the date of shipment is the date the controlled substance departed from the registered location. Tr. 1046.

There is a date of EEI [50] and all shipments need to claim EEI for the customs declaration for export. Tr. 988. The shipping label is created and OakmontScript prints out the label, but the package is not necessarily ready to be shipped. Tr. 988. OakmontScript then needs to send the shipping label to its clients to let them start the import process. Tr. 988. The most important part is ''custom clearance ticket obtaining'' and that process depends on how the country handles that and different city customs handle the speed differently, which could be a couple weeks to several months. Tr. 988–89, 990.

There is a date of custom clearance, which is a cutoff date in which OakmontScript has an obligation to help the customer finish before the due date, or the whole purchase becomes invalid. Tr. 989. If the DEA Form 236 is available, OakmontScript records that transaction date. Tr. 989, 1039–41. At the end of the transaction, OakmontScript receives verbal confirmation from the client that it received the product. Tr. 989. Ms. Liu generates the shipping labels and takes care of the customs clearance and EEI. Tr. 989–90.

It would be ideal to use the DHL database to record the export date, but this was not part of OakmontScript's SOP. Tr. 990. Doing this is not always practical because the DHL online system only displays the last ninety days and if the package is dropped off several weeks after the shipping label was created, then it may fall out of this ninety-day window and OakmontScript cannot track this package. Tr. 991. Other issues occur when a client picks its own private carrier to pick up the package and OakmontScript can only get verbal confirmation from the client that it received the package. Tr. 991. OakmontScript records the date the client verbally tells it the package was received. Tr. 989, 991.

Physicians can order medications from distributors without a prescription, which includes foreign physicians who, in the name of the patient, order medication from an exporter or distributor. Tr. 993. Distributors or exporters need to verify the doctor's medical license. Tr. 993. As a DEA-registered distributor and exporter, OakmontScript is able to fill medical orders to serve hospitals, physicians, and other entities domestically and foreign research organizations. Tr. 993–94. Specifically, as it relates to the clobazam prescription, OakmontScript's client included the Chinese medical doctor, the hospital, and also pharmacists who ''have the medical history based on Boston Children's Hospital.'' Tr. 994. Without a legal prescription from a local hospital or physician, the controlled substance would not be permitted to enter the receiving country. Tr. 994. The foreign prescription has two functions: (1) Showing the medical necessity of the patient and (2) providing evidence to show when the controlled substance is imported at the Chinese border, acting as an import permit. Tr. 994–95.

For Patient J.L., the doctor's instruction is required to show that the patient was not hospitalized and instead had a chronic condition. Tr. 995. Per the doctor's instruction, OakmontScript contacted the patient and learned from his family that he was no longer in the hospital. Tr. 995–96, 1071. It is OakmontScript's practice to send controlled substances directly to patients if it receives a doctor's order to do so. Tr. 1066–67, 1070.

During the February 19, 2019, inspection, DI 3 told OakmontScript that it needed to fill out a DEA Form 236 for controlled substances Schedules III, IV, and V prior to shipping, and after receiving the approved DEA Form 236, it needed to wait for fourteen days to start shipping, which was new information to Dr. Yu. Tr. 996, 1025–26, 1028. Dr. Yu was not sure if this is what the regulation stated and was unable to confirm this is what the regulation actually required. Tr. 996–97, 1025–28. *See* 21 CFR 1312.27(a).[51]

*[E] Although LONO was not defined in the RD, it is believed to reference a Letter of No Objection.

[50] Dr. Yu did not provide the full term for this acronym, however, DI 3 defined this during her testimony as ''Electronic Export Information.'' Tr. 480.

[51] The regulation states that DEA Form 236 must be filed with DEA ''not less than 15 calendar days

As a scientist, Dr. Yu believes it is important to keep complete and accurate records, and even though mistakes are possible, failing to keep accurate records can lead to further mistakes. Tr. 1017–18. Dr. Yu feels lucky to work at OakmontScript and finds it to be a good opportunity and the work OakmontScript does is meaningful to the whole pharmaceutical industry. Tr. 997–98. She and her colleagues work together every day to learn and grow, but sometimes they make mistakes and Dr. Shi takes full responsibility and never blames them. Tr. 998.

Overall, Dr. Yu provided consistent testimony. She testified regarding her employment and noted that client verification is a top priority for OakmontScript. As the Executive Director of OakmontScript, she has a direct stake in the outcome of this case and whether OakmontScript loses either of its registrations. It was evident throughout her testimony that Dr. Yu had a strong allegiance to Dr. Shi and that she had been thoroughly coached on her direct examination. Dr. Yu had nothing but positive things to say about Dr. Shi and even refused to provide a specific answer to a question because the answer was not ''black and white.'' Tr. 1024. At one point Dr. Yu testified that she was ''frightened'' when DI 3 asked about the date of export at the February 19, 2019, inspection because she did not know the exact document to show her. Tr. 991–92. However, Dr. Yu later went on to confirm on cross examination that the date of shipment is the date the controlled substance departed from the registered location. Tr. 1046. Such inconsistencies in her testimony, coupled with Dr. Yu's evident allegiance to Dr. Shi, does not allow me to fully credit Dr. Yu's testimony.

Jufang ''Shirley'' Shi

Background

Dr. Shi came to the United States to study as a graduate student in 1988. Tr. 1075. She received her Ph.D. in Pharmaceutical Sciences from Duquesne University in Pittsburgh, Pennsylvania, and a Pharm.D., and then worked in various industries as a scientist. Tr. 1076, 1280. She also taught pharmacodynamics and pharmacokinetics to pharmacy students at Northeastern University during 2005 and 2007. Tr. 1277–78. After fifteen years, she dedicated herself to becoming a clinical pharmacist and has been registered as a pharmacist in Massachusetts since 2008. Tr. 1076, 1276–77. She has contributed to technology that led to eight patents. Tr. 1076–77. She became a fellow in the American Society of Consultant Pharmacists (''FASCP'') after passing a pharmacist exam and the Certificate of Geriatric Pharmacotherapy (''CGP'') for which she needed to know how to apply a safe protocol to her client. Tr. 1278–79. She also worked in retail pharmacies and an institutional pharmacy, as well as hospitals. Tr. 1077–78. This included working for PharmMerica and Lahey Hospital. Tr. 1280–81. Based on these experiences, she ''decided to take some risk and to start a company'' to aid in the support of the ''global research need.'' Tr. 1078.

Dr. Shi started OakmontScript in May 2016 as the owner, chief pharmacist, and president. Tr. 1078–79, 1283–85. She is familiar with the CSA and DEA regulations including 21 CFR 1306.04, 1306.05(a). Tr. 1079, 1280–82. Dr. Shi needed to obtain a license from the state prior to receiving OakmontScript's ''federal license.'' Tr. 1080–81; Resp't Ex. 4. After receiving OakmontScript's DEA registration for Schedule III, IV, and V controlled substances, Dr. Shi requested to add Schedule II controlled substances and had updated its security system by adding a monitor and camera, updated the safe, and worked on updating the alarm system. Tr. 1082–84. Dr. Shi's thought process was to first obtain access to Schedule III, IV, and V controlled substances and later request the Schedule II drugs. Tr. 1084–91; Resp't Ex. 5, 6, 7.

Dr. Shi received the first state license as a distributor for Schedules III, IV, and V within a couple of months. Tr. 1086. After receiving the state license, it took less than a month for Dr. Shi to obtain the Federal distributor COR, on October 7, 2016. Tr. 1086–87. Dr. Shi then applied for the Schedule II DEA registration, for which the approval process took about eight months. Tr. 1088–89. During this time, Dr. Shi made sure OakmontScript was in compliance and she spent more time training her employees. Tr. 1088–89.

Exporter Registration

OakmontScript applied for its first exporter COR on April 26, 2017 and applied for its second exporter COR on May 10, 2017. Tr. 1091, 1286, 1289–91, 1308; Gov't Ex. 4 at 6–8. At the time OakmontScript submitted the second exporter application on May 2017, the first application filed in April 2017 was still pending. Tr. 1291. At some point in May 2017, DI 1 informed Dr. Shi that the applications were duplicates and Mr. L.U. and DI 1 discussed OakmontScript getting an importer COR. Tr. 1291–92. Dr. Shi recalls discussions regarding converting an exporter application to an importer application, but did not recall if it was ever done. Tr. 1293–95.[52] Regardless, Dr. Shi recalled withdrawing the May 2017 application in October 2017 and OakmontScript never obtained an importer registration. Tr. 1295–97. Dr. Shi felt that the April application was ''neglected'' by the DEA and the May 10 application was ''mistreated.'' Tr. 1093, 1493.[53] Although Dr. Shi has a ''great appreciation for'' DI 1, she ''feel very bad'' because her application had ''been mistreated.'' Tr. 1094. In an email to DI 1 dated April 28, 2017, Dr. Shi indicated that OakmontScript had not exported any controlled substances as of that date. Tr. 1287–88; Gov't Ex. 4 at 1.

An inspection took place on June 22, 2017, with DI 1 and a Senior Investigator from the Massachusetts Department of Health. Tr. 1297–98.[54] At that time, Dr. Shi stated that she had not distributed or exported controlled substances as of that date. Tr. 1298. DI 1 also told Dr. Shi ''everything that's required'' including the requirement to maintain initial and biennial inventories, DEA Form 161s, DEA Form 236s, and foreign documents or invoices. Tr. 1298–99. DI 1 also explained that records must be maintained for at least two years, records for the DEA registrations must be maintained separately according to business activity, and theft or loss of controlled substances must be reported immediately. Tr. 1299. Overall, DI 1 was able to help OakmontScript address issues and problems. Tr. 1353–54.

As of July 26, 2017, Dr. Shi was aware that OakmontScript's exporter application was still being reviewed by the DEA, but that it was ''coming any

prior to the anticipated date of release by a customs officer at the port of export.'' 21 CFR 1312.27(a).

[52] After several unsuccessful attempts by Government counsel to elicit a response regarding whether Dr. Shi was aware whether OakmontScript had converted one of its exporter applications to an importer application, the tribunal intervened and asked Dr. Shi to directly answer the Government's question and—even then—the tribunal needed to ask the question four times. Tr. 1294–95.

[53] This is not the first or only time Dr. Shi blamed the DEA or made disparaging comments about the DEA. Most notably, Dr. Shi made the following comments about the DEA in her closing statement: ''Despite all evidence showed to their face, I'm very concerned about DEA's manner of how to treat the public, how to treat a small business, and how to treat the people who have a bundle of knowledge while they obviously lack it.'' Tr. at 1497.

[54] Based on Dr. Shi's testimony on cross-examination, it appears that Dr. Shi was under the impression that DI 1's June 22, 2017, inspection was based on OakmontScript's request to add Schedule II drugs to its exporter application. Tr. 1308–10. However, Mr. L.U. had not yet made a request to add Schedule II to OakmontScript's exporter application when DI 1 scheduled the inspection. Tr. 1309–10.

time.'' Tr. 1300–01.[55] As of July 26, 2017, Dr. Shi did not recall receiving a DEA communication about OakmontScript's April 2017 exporter application being approved. Tr. 1305. While waiting for OakmontScript's exporter registration, Dr. Shi assured her staff the exporter registration ''should be coming any time, should be coming any minute. But it didn't come. And I thought it's coming any minute,'' because it was her experience with the DEA that it only took about a month for the DEA to process an application for registration. Tr. 1095. She continued to tell her staff that the registration ''should be coming any time'' and that they should ''start preparing'' because ''[i]t should come in any minute.'' Tr. 1096.

Dr. Shi put too much trust in Mr. L.U., her chief pharmacist, who was her previous boss, but she also shares in the responsibility for not following up regarding the exporter application and leading her ''people to believe the license coming any day.'' Tr. 1096–97, 1305. Dr. Shi ''made [the] assumption it should come in any minute'' and ''misled [her] people'' by saying the exporter registration was on the way and thus OakmontScript started taking orders for Schedules III, IV, and V controlled substances. Tr. 1097–98. Dr. Shi began instructing her employees in June 2017 to start working on preparing controlled substances to be exported. Tr. 1311. OakmontScript ultimately received its exporter registration on December 5, 2017, in the mail.[56] Tr. 1099; Gov't Ex. 4 at 6–8.

OakmontScript's Export Process

Based on DI 3's request for an exact export date, Dr. Shi created a document to track various parts of the export process. Tr. 1126–27. First, OakmontScript verifies the clients and records their import permit and sometimes their research proposal. Tr. 1126. The next step is to go through the contract to make sure everybody agrees on fees and that all parties are satisfied with the arrangement. Tr. 1127. The third step is to go through the ''contract process'' which is needed to finish the exporting process so the customer does not have to go back and reapply. Tr. 1127. OakmontScript also checks with Customs and Border Protection to see what type of license it needs to file. Tr. 1127–28. The U.S. Custom and Border Protection (''CBP'') also has updates that OakmontScript cannot ''log into the process'' if the value of the reported drugs are less than $2500, and this number is currently even lower. Tr. 1128. Dr. Shi updates the SOP based on the rules and regulations from the CBP, FDA, and the local government regarding the exporting process. Tr. 1128–29.

OakmontScript then prepares the shipping label and the customer ticket, which usually takes about two to four weeks. Tr. 1129–30. Dr. Shi instructs her staff to record what things happen, as opposed to providing the ''right date'' and she does not ''want her people to have any concept about what is the right date'' as this is not how this industry operates. Tr. 1130, 1366–67, 1495, 1498–99. Dr. Shi noted that ''because we lack of the drug code . . . our export process foundation didn't lay out perfectly for my people'' as it relates to the DEA Form 236. Tr. 1130–31. Dr. Shi does not ''want to blame the government[ ] who didn't give'' her a drug code. Tr. 1132. OakmontScript was not able to fill out DEA Form 236s for the diazepam 243 invoice, the Briviact 301 invoice, the Belviq 315 or 315–1 invoice, the Lyrica 315 or 315–2 invoice, or the Belviq 108 invoice. Tr. 1355.

OakmontScript did not export controlled substances prior to receiving its exporter registration on December 5, 2017, because the exporting process is not based around a specific date, but rather a customer's need. Tr. 1133. Dr. Shi started telling her employees that by May 2017, they ''could start the business'' because ''the license [was] on the way.'' Tr. 1134. The ''right'' date does not apply to OakmontScript because sometimes projects get cancelled and then reinstated. Tr. 1135. It takes about six to twelve months for OakmontScript to ''work[ ] out each detail'' to complete an export. Tr. 1136. The customer gives OakmontScript a due date and states when it wants OakmontScript to finish it. Tr. 1136–37. The exact date of export is not when the shipping label is created and the export is not defined by the exact date of export. Tr. 1138, 1495.

Dr. Shi discussed using a ''buy and bill'' model and how OakmontScript has collaborated with other companies including Biologics, Accredo, McKesson, and Specialty Biologics. Tr. 1209. If the buy and bill model has problems, then OakmontScript will establish another channel by using its ''doctors to provide another channel to support'' patients. Tr. 1209–10.

OakmontScript must submit the DEA Form 236 about two weeks before the planned export, so OakmontScript needs to have the anticipated date of departure from the port of export. Tr. 1371–72. For its exports, OakmontScript has the information required by section 3b of the DEA Form 236, but the information is ''recorded differently.'' Tr. 1375; *See* Gov't Ex. 47. The foreign client provides a custom clearance ticket that is issued by the country, which provides a window of time in which the export must occur and can be as far as a year into the future. Tr. 1376–77. OakmontScript records the required DEA Form 236 section 3a information in the app because if OakmontScript does not record, then things ''cannot move forward'' and the logistical team uses ''that app to record everything.'' Tr. 1379. After ''things done,'' OakmontScript then downloads the information to the Dropbox. Tr. 1379–80. If the foreign clients do not call OakmontScript or report any problems, OakmontScript reports the due date for section 3b. Tr. 1380. Otherwise, OakmontScript's record will show any issues. Tr. 1380. OakmontScript records the anticipated arrival date in the app and will save a copy to the Dropbox ''once things finish.'' Tr. 1381. OakmontScript only provided ''a portion'' of the information to DI 3 based on her subpoena because ''it's Chinese so she cannot read anyway, then. And so I stopped our oversharing with her, right.'' Tr. 1381. DI 3, from the app, ''should see that . . . all [OakmontScript's] process is being recorded in the app.'' Tr. 1381. Dr. Shi did not tell DI 3 that OakmontScript was using the app, but ''screenshotted a portion of the . . . app.'' Tr. 1381–82.

Dr. Shi reviewed DEA regulations and conducted her own research to learn about drug codes because OakmontScript had ''no guidelines . . . no laws, no rules'' and was ''left without being able to support our community of the research.'' Tr. 1149–50. She reviewed the DEA's website and 21 CFR 1308.03. Tr. 1156–61. The DEA has a lot of resources and Dr. Shi wishes she was ''led to a better source'' regarding drug codes. Tr. 1161. Dr. Shi continues to study the law, rules, and regulations in order to understand and ''better to learn how to help the people in this situation.'' Tr. 1194.

OakmontScript's Interactions With DI 3

DI 3 initially told Dr. Shi that she wanted to help OakmontScript, but through this hearing, Dr. Shi learned that DI 3's duty was not to help her. Tr.

[55] Again, Government counsel made several attempts to get Dr. Shi to answer a specific question, in this case whether as of June 26, 2017, Dr. Shi was aware that OakmontScript's exporter application was still being reviewed. Tr. 1300–05. And again, the tribunal needed to interject and direct Dr. Shi to ''listen to this question very carefully and give a direct response.'' Tr. 1304.

[56] According to the Government's Certification of Registration History, the Respondent was assigned an exporter Certificate of Registration number on December 5, 2017. Gov't Ex. 1B.

1147. Dr. Shi disagrees with the Government's accusation that she lacked candor. Tr. 1167–71. During the inspection in ''the beginning,'' OakmontScript showed DI 3 two lists and when DI 3 asked if OakmontScript was handling any other drugs, Dr. Shi said ''thank you for asking,'' ''praised'' DI 3 for asking this question, and stated that she was having trouble with another list of drugs for which OakmontScript did not have drug codes. Tr. 1172.

Dr. Shi provided two lists to DI 3 for clobazam with one list listing the clobazam and the other not listing the clobazam because DI 3 had repeatedly told her ''I come in to help your business'' and Dr. Shi did not know what DI 3's ''true agenda'' was. Tr. 1172–73. Dr. Shi did not ''keep complete and accurate records'' based on DI 3's standards, ''so that should not be basis for lack of candor.'' Tr. 1173. Dr. Shi ''shared more than'' she should have and believed that DI 3 would take all of the information they had discussed and ''dialogue with'' her. Tr. 1174–76, 1351. Dr. Shi never provided updated records to DI 3 after Dr. Shi found errors in the spreadsheets Dr. Shi had previously provided. Tr. 1321–23.[57]

OakmontScript's Use of the WeChat App

OakmontScript uses an app [58] to communicate with foreign customers and uses this app to explain what is needed for an export. Tr. 1196–98. OakmontScript is not able to export to a hospital in bulk, such as tens of thousands of bottles. Tr. 1197. OakmontScript can only export if it has the name of a patient. Tr. 1197.

Dr. L.W. is part of the app and does not write prescriptions, but is there as a physician consultant and ''check'' for Dr. Shi as he ''know[s] the medical record,'' that a medication is being used for a legitimate purpose, and ensures that OakmontScript is delivering the treatment to the right patient. Tr. 1197–99.

OakmontScript will exchange documents with foreign clients through this app and will respond to clients with urgent issues. Tr. 1382–83.[59]

OakmontScript's Record-Keeping System [60]

OakmontScript keeps accurate and complete records for controlled substances in a database system so all records are readily retrievable as required by the DEA based on OakmontScript's SOP. Tr. 1248–49, 1250. These folders contain subfolders and capture any changes that are made to an order. Tr. 1249–50. Each file has a name with a label and a number and these numbers are then assigned to a specific team to complete that order. Tr. 1250–52. Dr. Shi also created a link that a party can access if she gives that person authority to open a file. Tr. 1260. On the date of DI 3's March 29, 2019, inspection, Dr. Shi's printer had ink problems, so she wanted to be able to electronically download files and give access to DI 3, but DI 3 stated that she would only accept paper copies. Tr. 1260–61.

OakmontScript maintains separate inventory records for Schedule II, III, IV, and V controlled substances. Tr. 1268. There are separate folders for Schedule II and then Schedules III through V, for the initial inventory, for the biennial inventory, for exports, and for the distributions. Tr. 1268–69.

Corrective Measures

At the June 22, 2017 meeting, DI 1 told Dr. Shi there was an issue with OakmontScript's alarm system and OakmontScript then took steps to fix the alarm issue. Tr. 1313–14. DI 1 came back at some point to check the alarm. Tr. 1315–16. During DI 1's return visit to check the alarm, she also informed Dr. Shi that OakmontScript would need to get a different safe. Tr. 1316. In mid-September 2017, OakmontScript notified DI 1 that it was going to install a new safe. Tr. 1316–17. The new safe was installed in late September or early October 2017. Tr. 1317. At some point, DI 1 came back to OakmontScript to check the new safe and DI 1 stated that it ''was okay.'' Tr. 1317–18.

In approximately November 2017, Dr. Shi recalls having a conversation with DI 1 regarding requesting excessive drug codes. Tr. 1324–25. DI 1 walked Dr. Shi through how to delete the excess codes, and Dr. Shi deleted the codes. Tr. 1324–28.

Dr. Shi did not review 21 CFR 1301.26 when shipping the diazepam invoice number 243 and clobazam invoice number 0019 overseas because it is ''a U.S. law'' and ''of course, I cannot base[ ] on that'' and if the DEA is able to provide ''such a law'' that shows this regulation is applied globally, she ''will be happy.'' Tr. 1365. Before a controlled substance leaves the United States, OakmontScript complies with United States law and then ''after border, [OakmontScript] comply[ ] whatever the law required upon'' OakmontScript by the recipient country. Tr. 1366.

Alteration of Distributor Certificate of Registration

Dr. Shi met the intern through the intern's grandmother who was also Dr. Shi's teacher. Tr. 1395. Around Christmastime of 2016, the intern started working for OakmontScript as Dr. Shi's intern. Tr. 1395. The intern altered OakmontScript's distributor Certificate of Registration by using Adobe Shop on her personal laptop. Tr. 1405–06. Once Dr. Shi learned that the intern had changed OakmontScript's registration to state it was a pharmacy, Dr. Shi immediately analyzed the situation, realized the intern made a mistake and was still only learning so it was ''not all her fault.'' Tr. 1397. *See* Gov't Ex. 14. Therefore, Dr. Shi did not fire the intern and instead moved her to a different position with OakmontScript making shipping labels, which is a ''more straightforward job.'' Tr. 1397.

When Dr. Shi did business with other partners, including PBA and its staff, they would say they wanted OakmontScript to submit a pharmacy license. Tr. 1409. Dr. Shi believed that the intern made a change to the registration based on lack of experience. Tr. 1410–11.[61] Dr. Shi hoped to create an account with PBA so OakmontScript could purchase drugs from PBA. Tr. 1411–12. Dr. Shi believes that PBA

[57] Again, Government counsel made several attempts to get Dr. Shi to answer a specific question, in this instance, whether Dr. Shi provided updated spreadsheets to DI 3. Tr. 1321–22. And again, the tribunal interjected and instructed that Dr. Shi answer the question posed by Government counsel, noting that the Government ''is asking you very direct questions and we need direct answers for clarity of the record on this. Please answer . . . and please respond directly to the question that's asked.'' Tr. 1322.

[58] This app is called ''WeChat.'' Tr. 1382.

[59] Dr. Shi reviewed an example of her use of the WeChat app. Tr. 1383–90; Gov't Ex. 26 at 23. Dr. Shi translated this conversation, which was predominantly in Chinese. Tr. 1384–85. Part of this included a woman explaining that there was a child in her family that had seizures and she wanted to help that child. Tr. 1384. Dr. Shi explained that this person needed to send her the patient record, doctor's information, doctor's prescription, and the doctor's and hospital's registration so Dr. Shi could establish an account with her. Tr. 1385. Dr. Shi then obtained more information from a doctor in China. Tr. 1386. This document was then ''dumped'' to the Dropbox once this Order was done. Tr. 1385–86.

[60] Dr. Shi noted that Government Exhibit 28, page 54, was misplaced and should actually be page 51 and with the other documents for invoice OKS–00715. Tr. 1391–92.

[61] Dr. Shi mentioned that OakmontScript has an ''all-in-one license'' from the state. Tr. 1396–97; 1409; ALJ Ex. 26 at 3–4. It is unclear what Dr. Shi believes the effect of this ''all-in-one-license'' is on its DEA registration. Regardless, it is clear that the intern altered OakmontScript's DEA distributor registration to state ''Pharmacy'' after B.W. indicated that PBA would only conduct business with pharmacies. Gov't Exs. 14, 55.

distributes to other distributors. Tr. 1412–13. Essentially, PBA told the intern that it needed some information about a pharmacy license associated with OakmontScript and the intern then used her laptop to edit the distributor registration to indicate it was a pharmacy registration, without specific instruction from an OakmontScript employee to do so. Tr. 1414–15.

The intern left OakmontScript in February 2018 for multiple reasons, including that her visa expired. Tr. 1398. Dr. Shi explained to DI 3 that she ''could have fired'' the intern, but thought this would be ''a little too much'' because it was only the intern's ''first week she ever entered the job.'' Tr. 1399–1400.

Dr. Shi testified that it is a serious issue to falsify a DEA registration based on the consequences, but this issue did not get ''somebody killed'' or cause ''some pandemic'' and the intern was allowed to bring her laptop and continue to access OakmontScript files after this issue, but was limited to the ''non-vendor'' part. Tr. 1417–18. Furthermore, in her closing statement, Dr. Shi stated ''this is not a controlled-substance-related issue,'' yet the DEA ''continued to maintain their limited understanding about controlled substances.'' Tr. 1496. Dr. Shi went on in her closing to state that OakmontScript ''did more than the minimum, we did 500 times more than what's required to address this incident.'' Tr. 1496.

Invoice OKS–00243 (Diazepam)[62]

Two of the documents provided by OakmontScript indicate that diazepam was shipped on May 18, 2017. Tr. 1311–12; Gov't Exs. 17 at 3, 18 at 3. Another document indicates that the diazepam was shipped on June 10, 2017. Tr. 1313;[63] Gov't Ex. 12 at 14. Dr. Shi had indicated that OakmontScript had not exported controlled substances at the June 22, 2017, meeting with DI 1, but both of these dates are prior to the meeting date with DI 1. Tr. 1313. Dr. Shi was not able to provide the date the diazepam was shipped because the USPS updated its online system sometime in 2017 and ''erased all the information'' during the upgrade. Tr. 1368–69.

Invoice OKS–00650 (Lunesta)

As it pertained to the Lunesta invoice, Dr. Shi testified that this transaction was an export and not a domestic distribution as claimed by the Government, because the address was the contact address for a company representative, Z.Y., who was taking this prescription to China and the company in China was the end-user. Tr. 1180–82, 1359. Dr. Shi had used ''common sense'' when sending this prescription because the representative of the company signed a contract with OakmontScript, the address was named on the PO contact,[64] it gave OakmontScript its import permit, and it signed the end-user certification. Tr. 1182. An ''end-user is the person who signed the end-user statement to give [OakmontScript] a certificate.'' Tr. 1183.

Dr. Shi noted this was an ''informal channel'' and ''since this incident and since DI 3 have point this out, [OakmontScript] no longer accept[s] informal channel of delivery for any order.'' Tr. 1182, 1183.

Subpoena Served on May 8, 2019[65]

Dr. Shi acknowledged that dates entered on OakmontScript's shipping labels are not actual shipping dates. Tr. 1342–43. Dr. Shi noted that ''[w]e have, we have of course, we have the date, we have all the records.'' Tr. 1344. After receiving the May 8, 2019 subpoena, Dr. Shi did not provide the specific information of the shipping date because it was ''not required. [DI 3] didn't, she didn't ask for it'' and DI 3 was ''so confused about what is the shipping date, she don't know what to ask.'' Tr. 1343–46. Furthermore, there is ''no such things as the export date . . . [the regulations] do not require the export date to be recorded. That's, that's actually pity . . . wrong information to ask.'' Tr. 1347. However, Dr. Shi provided export dates when DI 3 asked for them. Tr. 1347–48; Gov't Ex. 20 at 9.

Invoice OKS–00301 (Briviact)

Briviact was shipped on August 2, 2017. Tr. 1314; Gov't Exs. 12 at 7, 27 at 2.

Invoice OKS–00315–1 (Belviq)

OakmontScript shipped Belviq on November 1, 2017, based on the shipping label. Tr. 1318–19; Gov't Exs. 12 at 3, 27 at 2. However, the shipping label is an estimated time. Tr. 1319.

Invoice OKS–00315–2 (Lyrica)

Documentation provided by OakmontScript indicates that Lyrica was shipped on November 20, 2017. Tr. 1328–35;[66] Gov't Ex. 12 at 9–10.[67] However, other documentation provided by OakmontScript indicated that the Lyrica was shipped a day later, on November 21, 2017. Tr. 1339; Gov't Ex. 27 at 2. Dr. Shi does not know which document is incorrect and claims that regardless, it is ''one days apart. This is not like somebody get killed or something.'' Tr. 1340. Dr. Shi went on to say ''I know it's mistake. It's 20 or 21st.'' Tr. 1340. Moments later, Dr. Shi stated ''I can say both [dates] are correct, or I mean, both are incorrect . . . I also can say both are right. Because that's just the date.'' Tr. 1341. Dr. Shi stated OakmontScript did the best it could when entering these dates into the spreadsheets. Tr. 1341. OakmontScript has the exact date because in ''the record, we have every app, the people coming to pick up. And then, all those too.'' Tr. 1342. Regarding dates that OakmontScript's products were provided to the common carrier, Dr. Shi stated ''[w]e have the record. But I didn't give it to DI 3'' and ''whatever cannot be exact, I cannot provide to her because that complicated her understanding.'' Tr. 1349–50.

Invoice OKS–00108 (Belviq)

Some documentation indicates that the Belviq was shipped on December 1, 2017. Tr. 1351; Gov't Exs. 12 at 3, 27 at 2.

Invoices DIW–0019 and NEEC–0019 (Clobazam)

Patient J.L.'s family came into contact with Dr. Yu, who learned about Patient J.L.'s situation while doing community service at Boston Children's Hospital. Tr. 1195. When the family returned to China, they wanted to continue the therapy and they supplied

[62] This invoice indicates that OakmontScript's address is 15 New England Executive Park, which is the same as the 1500 District Avenue address, because after 2017, the District of Burlington was acquired and updated by a development company, National Development Corporation. Tr. 1393–94; Gov't Ex. 26 at 20.

[63] During Dr. Shi's response on cross-examination regarding the shipping date of this diazepam, the tribunal needed to interject and instruct Dr. Shi to ''[j]ust respond to the question please.'' Tr. 1312.

[64] It is unclear what Dr. Shi meant by ''PO contact.''

[65] The subpoena was admitted as Government Exhibit 24.

[66] Again, Government counsel made several attempts to get Dr. Shi to answer a specific question, in this instance, how Dr. Shi's employees would have filled out documents. Tr. 1331. And again, the tribunal interjected and instructed Dr. Shi to answer the ''straightforward question'' posed by Government counsel. Tr. 1331. The tribunal needed to interject again during this cross-examination regarding the Lyrica and instructed Dr. Shi that she needed ''to answer the question'' and to ''[l]isten carefully to the question.'' Tr. 1334.

[67] Dr. Shi was evasive in testifying that the ''ship to date'' was indeed the date the Lyrica was shipped. Dr. Shi continued to claim that there were several steps in the export process and this was likely the date the shipping label was created and this Lyrica would have been shipped ''approximately around'' November 20, 2017. Tr. 1338–39.

OakmontScript with the hospital discharge paper, the prescription from China, and the prescription from the United States. Tr. 1194–96.

As the founder and President of OakmontScript, Dr. Shi has the most at stake in this case involving the potential revocation of OakmontScript's CORs. Throughout her testimony, she was often evasive in answering the questions posed by opposing counsel to the point where Government counsel had to repeat questions multiple times and the tribunal even needed to intervene multiple times to instruct Dr. Shi to answer direct questions posed by the Government.[68] By her own admission, Dr. Shi purposely withheld documents that OakmontScript had in its possession and were requested in not one, but two administrative subpoenas that were served on OakmontScript. During her testimony, she condoned these actions and even when confronted with documents that provided conflicting export dates, she continued to be evasive and refused to admit there were errors. I therefore cannot make a wholly positive credibility finding with respect to Dr. Shi's testimony.

Analysis

The Government seeks revocation of the Respondent's distributor and exporter CORs based on its contention that the Respondent, through its employees, has committed acts that would render its registration inconsistent with the public interest as that term is defined in 21 U.S.C. 823(b), (d), and (e), 824(a), and/or 958. ALJ Ex. 1 at 1. The Government alleges that the Respondent's CORs should be revoked because it exported controlled substances prior to obtaining its exporter COR, exported controlled substances it was not approved to export, demonstrated a lack of candor to DEA investigators regarding its business activities, falsified a copy of its DEA distributor COR, distributed controlled substances to a non-DEA registered individual, exported controlled substances to fill prescriptions for underage patients, and commingled the records for its two registrations and otherwise failed to keep complete and accurate records.

Although the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Acting Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie* v. *DEA,* 419 F.3d 477, 481 (6th Cir. 2005). [Omitted for brevity.] While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Acting Administrator's ability to find facts on either side of the contested issues in the case, *Trawick* v. *DEA,* 861 F.2d 72, 77 (4th Cir. 1988), all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007).

[Omitted for brevity.] It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this Recommended Decision are entitled to significant deference, *see Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this Recommended Decision constitutes an important part of the record that must be considered in the Acting Administrator's decision, *see Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Acting Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Public Interest Determination: The Standard

The Government seeks revocation of the Respondent's DEA CORs based on its allegations that continuation would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(b), (d), and (e). The CSA provides that the Agency may suspend or revoke a registrant's COR ''upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). The Government specifically alleged that the Respondent violated the law regarding its distributor registration by: (1) Falsifying its distributor registration, (2) displaying a lack of candor regarding this falsified registration, (3) domestically distributing Lunesta, a controlled substance, to a non-registrant in May 2018, and (4) commingling records. The Government further alleges that the Respondent violated the law regarding its exporter registration by: (1) Exporting controlled substances prior to obtaining its exporter COR, (2) exporting controlled substances it was not approved to export, (3) exporting controlled substances to fill foreign prescriptions for underage patients, and (4) failing to keep complete and accurate records of controlled substances it had exported.

The Government bears the burden of proving that the Respondent's continued registration would be inconsistent with the public interest. 21 CFR 1301.44(e). Where the Government has met its burden by making a *prima facie* case for revocation (or some other sanction), the burden of production then shifts to the registrant to show that, given the totality of the facts and circumstances in the record, revocation (or any other sanction) would not be appropriate. *Southwood Pharm., Inc.,* 72 FR 36487, 36498, 36504 (2007) (citing *Gregory D. Owens, D.D.S.,* 67 FR 50461, 50464 (2002)).

Any additional facts necessary for a disposition of this case are set forth in the balance of this Recommended Decision.

Distributor Registration

As to its distributor COR, the Government alleges that the Respondent violated the CSA and its implementing regulations by: (1) Altering its distributor registration to state that it was a pharmacy and then representing to another DEA registrant that it was a pharmacy by presenting the altered DEA COR, (2) displaying a lack of candor regarding this falsified registration, (3) domestically distributing Lunesta (eszopiclone, a schedule IV controlled substance) to a non-registrant in May 2018, and (4) commingling its distributor records with records pertaining to its exporter registration. The Government seeks the revocation of the Respondent's distributor COR based on its allegations that the Respondent's continued registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(b) and (e).

The CSA provides that ''[a] registration . . . to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 . . . inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4).

Congress has provided the following factors to be considered in the public interest analysis as it relates to

[68] *See supra* at 36 n.52, 37 n.55, 40 n.57, 44 n.63, 45 n.66, 45 n.67.

distributors of controlled substances, as set forth in 21 U.S.C. 823(b) and (e):[69]

(1) Maintenance of effective control(s)[70] 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 [the registrant] 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), (e). The factors are considered in the disjunctive, and the Agency may give each factor the weight it deems appropriate in determining whether to revoke a registrant's registration. *Masters Pharm., Inc.,* 80 FR 55418, 55472–73 (2015) (citing *Green Acre Farms, Inc.,* 72 FR 24607, 24608 (2007); *ALRA Labs., Inc.,* 59 FR 50620, 50621 (1994)). Moreover, the Agency is ''not required to make findings as to all of the factors.'' *Masters Pharm., Inc.,* 80 FR at 55473 (quoting *Hoxie,* 419 F.3d at 482).

Factor One: Maintenance of Effective Controls Against Diversion of Particular Controlled Substances Into Other Than Legitimate Medical, Scientific, and Industrial Channels

Evidence properly considered under Factor One of the public interest analysis for a distributor registrant includes the adequacy of the registrant's recordkeeping. *CBS Wholesale Distrib.,* 74 FR 36746, 36749 (2009) (citing *Holloway Distrib., Inc.,* 72 FR 42118, 42123 (2007); *Rick's Picks, L.L.C.,* 72 FR 18275, 18278 (2007); *John J. Fotinopoulos,* 72 FR 24602, 24605 (2007)). Although the Government failed to allege a specific public interest factor for this allegation, I find that the commingling of records allegation should be analyzed under Factor One.

21 CFR 1304.21(c) requires that ''[s]eparate records shall be maintained by a registrant for each independent activity and collection activity for which he/she is registered or authorized, except as provided in § 1304.22(d).'' Therefore, as OakmontScript possesses both an exporter and distributor registration, it must maintain separate records for each registration. 21 CFR 1304.21(c). ''Recordkeeping, reporting and security requirements are also more rigorous for those who manufacture and distribute controlled substances.'' *Wedgewood Vill. Pharmacy,* 71 FR 16593, 16594 (2006).

On September 16, 2016, DI 1 conducted an on-site inspection of OakmontScript with a Senior Investigator with the Massachusetts Department of Health regarding OakmontScript's distributor registration. Tr. 44–45. At this time, DI 1 instructed Dr. Shi that OakmontScript needed to ensure it did not commingle records from its distributor registration with any future exporter registration. Tr. 51.

On July 26, 2018, a second DI, DI 2, conducted an inspection of OakmontScript's distributor registration and noted that OakmontScript was commingling records by keeping some of its distributor records with its exporter records. Tr. 129–33, 135–36. After she identified this issue, she discussed it with Dr. Shi, who indicated that she understood and stated that OakmontScript would not commingle records in the future. Tr. 133. DI 2 did not ''believe [Dr. Shi] knew about the commingling but once corrected, she understood.'' Tr. 133.

A third DI, DI 3 noted that there were issues with recordkeeping as OakmontScript had commingled records. Tr. 739. For instance, OakmontScript was keeping inventories for both its distributor registration and its exporter registration on the same document and it was difficult for DI 3 to discern under which registration each transaction had occurred. Tr. 743–48, 782; Gov't Ex. 12. DI 3 specifically noted that it was difficult to discern if the Lunesta invoice OKS–00650 was a distribution or export as the spreadsheet provided by OakmontScript had both CORs listed on the spreadsheet. Tr. 746–47; Gov't Ex. 12 at 17.

As discussed, prior to DI 3's most recent inspections, OakmontScript had been told by two DI investigators that it needed to maintain separate inventories for its distributor and exporter registrations. Tr. 51, 131–36. Despite this, when DI 3 performed her initial inspection on March 29, 2019, the only records OakmontScript provided for the biennial inventory included commingled records that contained information for both its distributor and exporter registrations. Tr. 351, 739, 744–49; Gov't Ex. 12. In fact, DI 3 was only able to discern invoice OKS–00243 was an export after reviewing the license transfer document for this export. Tr. 747–48; Gov't Ex. 26 at 21. However, another spreadsheet provided for this export at the March 29, 2019, inspection did not indicate this was an export or that the diazepam had been transferred from OakmontScript's distributor license to its exporter license. Tr. 747; Gov't Ex. 12 at 14.

I therefore find that OakmontScript commingled records that were provided to DI 3 at the March 29, 2019 inspection, after being put on notice of this not once, but twice. This commingling of OakmontScript's distributor and exporter records makes it difficult, if not at times impossible, to discern whether a particular controlled substance was distributed or exported.[71]

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegation 21.b is *sustained.* [Based on Respondent's failure to maintain complete, accurate, and separate records, in accordance with federal law, I find that Factor One weighs against Respondent.]

Factor Five: Such Other Factors as May Be Relevant to and Consistent With the Public Health and Safety

The Government has alleged that Factor Five is relevant to the public interest analysis regarding the Respondent's distributor COR. ALJ Ex. 1 at 4, 5 ¶ 13.[72] Although the Government failed to explain under which factor the lack of candor allegation falls, the tribunal finds that the allegations regarding the Respondent's lack of candor fall squarely within the purview of Factor Five. *See John V. Scalera,* 78 FR 12092, 12093, 12100 (2013) (considering under Factor Five, the respondent's lack of candor based on lies made to DEA investigators and false testimony under oath at the hearing). Further, the DEA has consistently held that ''[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest'' and that a registrant's ''lack of candor and failure to take responsibility for his [or her] past legal troubles . . . provide substantial evidence that his

[69] Subsection (b) applies to distributors of controlled substances in schedule I or II and subsection (e) applies to distributors of controlled substances in schedule III, IV, or V.

[70] 21 U.S.C. 823(b) uses the term ''control,'' whereas 21 U.S.C. 823(e) uses the term ''controls.'' The origin of the variance appears typographical, not substantive. The text of subsections (b) and (e) is otherwise identical.

[71] Although it appears that OakmontScript attempted to rectify this issue, any attempts to do so were made after the March 29, 2019 inspection. *See* Gov't Ex. 28 at 83–97 (several of these inventory forms indicate that the forms were recreated on April 25, 2019). Dr. Shi provided these documents to DI 3 via email on May 10, 2019. Tr. 781. *See* Gov't Ex. 28.

[72] The Government alleged that Factor Five applied to the Respondent's violation of 21 U.S.C. 843(a)(3), but did not provide its reasoning as to why this violation should be reviewed under Factor Five. ALJ Ex. 1 at 4–5 ¶ 13.

registration is inconsistent with the public interest.'' *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010) (quoting *Hoxie,* 419 F.3d at 483); *see also Mark P. Koch, D.O.,* 79 FR 18714, 18736 (2014) (assessing the respondent's candor); *Ronald Lynch, M.D.,* 75 FR 78745, 78754 (2010) (same); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995) (same).

A lack of candor may properly be considered by the DEA as something that threatens public health and safety. *Annicol Marrocco, M.D.,* 80 FR 28695, 28705 (2015). ''Because of the authority conveyed by a registration and the extraordinary potential for harm caused by those who misuse their registrations, DEA places significant weight on an applicant/registrant's candor in the proceeding.'' *Alan H. Olefsky, M.D.,* 76 FR 20025, 20031 (2011). A registrant's dishonesty under oath downplays the registrant's acceptance of responsibility and shows that the registrant ''cannot be entrusted with a registration.'' *Rose Mary Jacinta Lewis, M.D.,* 72 FR 4035, 4042 (2007). The degree of candor displayed by a registrant during a hearing is ''an important factor to be considered in determining . . . whether [the registrant] has accepted responsibility'' and in formulating an appropriate sanction. *Hills Pharmacy, LLC,* 81 FR 49815, 49845 (2016) (citing *Michael S. Moore,* 76 FR 45867, 45868 (2011)).

Additionally, the Respondent's falsification of its COR should be considered under Factor Five. For example, in another case where the registrant was put on notice that her registration was being improperly used to order controlled substances, her failure to take prompt and reasonable action to investigate the misuse constituted additional conduct that threatened public health and safety. *Lewis,* 72 FR at 4041–42 (citing 21 CFR 1301.71(a)). Further, DEA can consider under Factor Five evidence that a registrant was aware that his DEA registration was being improperly used and took no action to stop its improper use. *Kevin Dennis, M.D.,* 78 FR 52787, 52800 (2013). Even if the ''Respondent did not obtain possession of the controlled substances . . . misconduct can still be actionable as an attempt to obtain controlled substances by fraud or misrepresentation.'' *Jana Marjenhoff, D.O.,* 80 FR 29067, 29068, 29069. *See* 21 U.S.C. 843(a)(3), 846.

Finally, the Respondent's domestic distribution of Lunesta to a non-registrant should be considered under Factor Five. In a similar situation, a previous Acting Administrator examined a pharmacy's distribution of a controlled substance to a non-registered location under Factor Four of 21 U.S.C. 823(f). *Sewanee Pharmacy,* 55 FR 29279, 29281 (1990). Section 823(f)(4), defines Factor Four as ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances'' and roughly corresponds with section 823(e) Factor Two, except that section 823(e)(2) omits ''Federal'' and only includes ''compliance with applicable State and local law.'' As distribution of a controlled substance to a non-registered location is a violation of Federal law, it does not fit within the parameters of Factor Two. Nor does it fit within the definitions of Factors One, Three, or Four of section 823(e). Thus, it is properly considered under Factor Five. *See Perry County Food & Drug,* 80 FR 70083, 70112 (2015) (where DEA applied the analogous Factor Five ''such other conduct'' in the context of a pharmacy registrant where the violations at issue were ''not covered by application of the other four public interest factors.'').

Falsified Registration Certificate

The Government alleges that the Respondent violated 21 U.S.C. 843(a)(3), which states that ''[i]t shall be unlawful for any person knowingly or intentionally . . . to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.'' 21 U.S.C. 843(a)(3). The Government alleges that the Respondent violated 21 U.S.C. 846 which states, ''[a]ny person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.'' The Government alleges that OakmontScript violated these statutes and that such conduct constitutes conduct that is inconsistent with the public health and safety, in violation of 21 U.S.C. 823(b)(5) and (e)(5).[73] ALJ Ex. 1 at 4–5 ¶ 13.

Dr. Shi met the intern through the intern's grandmother, who was also Dr. Shi's former teacher. Tr. 1395. The intern started working for OakmontScript as Dr. Shi's intern in January 2017 and her responsibilities included establishing relationships with OakmontScript's competitors to determine how they conduct business. Tr. 293–94, 1395. Dr. Shi hoped to create an account with PBA so OakmontScript could purchase drugs from PBA. Tr. 1411–12. Dr. Shi told the intern to ''do whatever is needed'' and to ''[g]ive [PBA], basically, whatever they want in order to establish this . . . client relationship with them.'' Tr. 303. When Dr. Shi conducted business with companies, including PBA, these companies would sometimes request OakmontScript to submit a copy of a pharmacy license as some distributors will only work with pharmacies. Tr. 275, 1409. Dr. Shi was ''too busy'' to help the intern so she told the intern to ask Mr. L.U. what letter to send to PBA. Tr. 1414.

After PBA requested that OakmontScript submit a pharmacy registration, the intern altered OakmontScript's distributor COR No. RO0504680 by using Adobe Shop on her personal laptop. Tr. 1405–06; Gov't Ex. 14. Without being told to do so, she modified the business activity of the distributor registration to indicate it was a pharmacy registration. Tr. 1414–15. Even though Dr. Shi was ''on the email chain being cc'ed'' regarding this application to PBA, she testified that she did not notice the altered registration document which was an attachment. Tr. 1415. During the tribunal's questioning of Dr. Shi, Dr. Shi agreed that the intern had changed the business activity from ''distributor'' to ''pharmacy'' and this altered registration was sent to PBA in order to open an account with PBA. Tr. 1396.

While DI 3 was reviewing OakmontScript's case files, she discovered a report filed by the Kansas City District Office of the DEA, naming OakmontScript as fraudulently creating a DEA registration. Tr. 275. PBA holds its own DEA registration and DI 3 spoke to one of PBA's Regulatory Compliance Team Leaders, B.W., via email correspondence that noted PBA ''only sell[s] to pharmacies'' and it does not ''sell to other distributors.'' Tr. 275–78; Gov't Ex. 55. PBA also requires potential customers to send a copy of their State pharmacy licenses and a copy of their DEA registrations when they submit their account application. Tr. 278; Gov't Ex. 55. B.W. further noted that OakmontScript sent PBA a DEA registration indicating it was a pharmacy and after PBA performed its due diligence, PBA discovered that the document had been altered. Tr. 278; Gov't Ex. 55. PBA reported OakmontScript and denied OakmontScript's request to open an account. Tr. 278; Gov't Ex. 55.

On April 23, 2019, DI 3 and Dr. Shi discussed this issue on the phone. Tr. 293. DI 3 learned that after PBA initially refused to establish a relationship with OakmontScript, the intern altered the

[73] Although the Government failed to provide why the Factor Five, ''catch-all'' provision applies in this instance, I agree that this allegation would fall under a Factor Five Analysis as the Respondent has violated Federal law.

DEA registration to list OakmontScript as a pharmacy. Tr. 294; Gov't Ex. 14. During this phone call, Dr. Shi indicated that she ''could have fired'' the intern, but thought this would be ''a little bit too much'' because it was only the intnern's ''first week she ever entered the job.'' Tr. 1399–1400. In an email that Dr. Shi sent to DI 3 on April 24, 2019, Dr. Shi indicated that the intern's employment dates were January 1, 2017 to February 2018 and that the intern had moved back to China. Tr. 297; Gov't Ex. 20 at 13. Dr. Shi also texted information regarding this incident to DI 3 in May 2019 and she said if the incident regarding the falsified registration ''constitutes any offensive sort, 'I' should take responsibility. If any actions taken toward, please address to me directly.'' Tr. 300–01; Gov't Ex. 29 at 3. OakmontScript ''does not contest that this incident occurred'' and, in fact, the parties have stipulated to the basic facts. ALJ Ex. 26 at 2; ALJ Ex. 7 at 3, Stipulation 10.

It was DI 3's understanding from the April 23, 2019, phone call that the intern had been fired. Tr. 294–95. Therefore, when on the following day DI 3 received the email from Dr. Shi that the intern had indeed not been fired for falsifying the registration, she understandably viewed her phone conversation with Dr. Shi on April 23 and the email from Dr. Shi on April 24 to be in ''direct conflict.'' Tr. 297–98.

Because Dr. Shi had ties with the intern's family, she felt pressure to keep the intern employed. Tr. 302. The intern left OakmontScript in February 2018 for multiple reasons, including that her visa expired. Tr. 1398. DI 3 was never able to contact the intern to discuss the registration falsification incident with her. Tr. 304.

As the Government noted in its post-hearing brief, although OakmontScript was not able to establish a customer relationship with PBA and therefore was unable to purchase any controlled substances, ''had [OakmontScript] been successful'' in opening an account, (ALJ Ex. 27 at 17), ''OakmontScript [would] have had the capacity to order controlled substances'' from PBA. Tr. 304. In its post-hearing brief, the Respondent asserts that ''[t]his concern . . . is misplaced'' because OakmontScript has established ''multiple accounts with other trading partners'' and ''in its five years of operation, never suffered any losses, theft, inventory discrepancies, or other incidents relating to controlled substances'' and therefore OakmontScript ''has proven itself to be a trustworthy DEA registrant and true to its professional obligations.'' ALJ Ex. 26 at 2–3. To the contrary, OakmontScript's falsification of a DEA registration displays the antithesis of trustworthiness. As DI 3 testified, ''DEA registrants hold a public trust position'' and because controlled substances that are used improperly can be dangerous, ''DEA registrants have to be licensed and registered with the proper authorities.'' Tr. 305. *See* 21 U.S.C. 822(a).

Furthermore, the fact that the ''Respondent did not obtain possession of [any] controlled substances'' is irrelevant and her misconduct is still ''actionable as an attempt to obtain controlled substances by fraud or deception.'' *Marjenhoff,* 80 FR at 29069.

As both parties stipulated to the registration being falsified, and based on Dr. Shi's own admission that she was aware that the intern had altered OakmontScript's distributor registration to reflect that it was a pharmacy, it is uncontroverted that OakmontScript falsified a copy of its DEA registration. I therefore find that the intern working for OakmontScript, altered OakmontScript's distributor COR by using a computer program to change the registration so that the word ''Distributor'' was replaced with ''Pharmacy'' under the ''Business Activity'' section of the registration. I further find that this registration was altered in an attempt for OakmontScript to establish a relationship with PBA to ultimately obtain controlled substances from PBA, which is in violation of Federal law, specifically 21 U.S.C. 846.

Accordingly, in review of the evidence of record, including stipulations of the parties,[74] [I find that Respondent's submission of a falsified registration to PBA represented an attempt to obtain controlled substances outside of the CSA's closed regulatory system, and as such, is conduct that is not ''consistent with the public health and safety'' under Factor Five.] *[F]

Lack of Candor

The Government alleges that Dr. Shi exhibited a lack of candor as it relates to this allegation. When Dr. Shi learned that the intern had altered OakmontScript's registration to list its business activity as a pharmacy, Dr. Shi ''analyzed the situation.'' Tr. 1397. Dr. Shi believed that the intern made this error because she was ''a new intern'' and due to her ''lack of experience.'' Tr. 1410–11. Because this was ''not all her fault,'' Dr. Shi did not fire the intern and instead ''changed her to a different position'' and moved her to a ''more straightforward job.'' Tr. 1397.

During her testimony, DI 3 indicated that during the April 23, 2019, phone call Dr. Shi had informed her that she had fired the intern, but DI 3 later learned that the intern remained employed at OakmontScript for an additional thirteen months after this incident. ALJ Ex. 1 at 5 ¶ 14; Tr. 297–98, 307, 788. Dr. Shi sent an email the next day, on April 24, 2021, to DI 3 indicating that the intern was employed from January 1, 2017 through February 2018 and left the United States because her work visa expired. Tr. 297.

Based on the testimony of the parties, I do not find that Dr. Shi exhibited a lack of candor. I do not find that DI 3 was being disingenuous regarding her testimony that ''it was [her] understanding that [the intern] had been fired due to the fraudulent DEA registration'' in January 2017 and that she had been ''led . . . to believe that [the intern] had been fired'' based on this incident. Tr. 295, 297–98, 793. Rather, I find that it is more likely there was a miscommunication between DI 3 and Dr. Shi as opposed to a lack of candor.

As discussed *supra,* only one day after DI 3's and Dr. Shi's phone conversation regarding this incident, Dr. Shi sent an email to DI 3 responding to DI 3's request for more information regarding the intern and stating that the intern was employed until February 2018, when her visa expired. It does not make sense that Dr. Shi would claim to have fired the intern, and the very next day, put in writing that she continued the intern's employment for over another year, until the intern's visa expired. Moreover, DI 3's email does not reference any conversation she had with Dr. Shi from the previous day that the intern was fired. Dr. Shi was consistent in her testimony regarding this allegation and admitted she may have stated that she ''could have fired'' the intern while speaking with DI 3. Tr. 1399. Dr. Shi was also adamant and consistent in her testimony that the intern had ''made that mistake'' and instead of firing the intern, which Dr. Shi believed would be ''a little bit too much,'' she was using this as a ''training opportunity'' and despite this being a ''huge risk,'' Dr. Shi kept the intern as a staff member and instead moved her

[74] *See* Stips. 10 and 11.

*[F] I agree with the ALJ that there was evidence on the record to support the conclusion that Respondent violated 21 U.S.C. 846 by attempting to establish a relationship with PBA in order to obtain controlled substances by fraud. However, because there is considerable other evidence on the record that demonstrates that Respondent's registration is inconsistent with the public interest, I do not find that it is necessary for me to determine whether Respondent has violated 21 U.S.C. 846. I may consider this conduct under Factor Five without finding a violation of this statute.

to a different part of OakmontScript. Tr. 1397, 1400–01. Based on these circumstances, I do not find a lack of candor by Dr. Shi regarding statements she made about how the intern's employment with OakmontScript came to an end.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegation 14 is *not sustained* to the extent that Dr. Shi exhibited a lack of candor in her statements made to DI 3 on April 23, 2019.*[G]

Distribution of a Controlled Substance to a Non-Registrant [75]

The CSA's general criminal provision is contained in 21 U.S.C. 841(a), and in relevant part states: ''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance . . . .'' 21 U.S.C. 841(a)(1). ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA'' to prevent abuse and diversion of controlled substances. *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). A vital component of the CSA's closed regulatory system requires that any person who handles controlled substances must obtain a registration from the DEA. *Wedgewood Vill. Pharmacy,* 71 FR at 16594 (citing 21 U.S.C. 822).

''Distribute'' is defined as ''to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.'' 21 U.S.C. 802(11). ''The term 'distributor' means a person who so delivers a controlled substance or a listed chemical.'' 21 U.S.C. 802(11). A distributor can only distribute to another DEA registrant who holds the appropriate authority to handle that controlled substance. 21 U.S.C. 822(a). A distributor is not permitted to distribute controlled substances to an ultimate user and there is no coincidental activity that permits a distributor to provide controlled substances to non-DEA individuals or persons or companies. *See* 21 CFR 1301.13(e)(1) (distributing to a non-registered person is not listed as a coincident activity).

Although OakmontScript's records have inconsistent information regarding the Lunesta invoice OKS–00650 shipment, I find that the most likely scenario is that OakmontScript received Lunesta in May 2018 and shipped the Lunesta to Mr. Z.Y. at an address in the United States of [omitted for privacy], Kearny, New Jersey [ ] in May 2018. Tr. 499–535, 1455; Gov't Exs. 12 at 17, 17 at 3, 18 at 3, 22 at 10–11.

Dr. Shi also indicated the following in an email dated April 30, 2021:

> Lunesta was shipped on *May 21, 2018* to Mr. [Z.Y.] at his USA address. Mr. [Z.Y.] is an executive member of the company. At the time of this purchase request, he still in US division while he was planning to move to China Disha Pharmaceutical group. The shipping logistics was arranged such: OakmontScript shipped his US address, and then his China Disha Pharma carried out the rest of shipping from NJ to China. Disha pharma is a manufacturer, they are not required to have DEA license, and they are the end user.
>
> Lunesta is not controlled drug in China.
>
> Mr. [Z.Y.] now in China Disha Pharma Group, as a director.

Gov't Ex. 22 at 10 (emphasis in original).

After reviewing OakmontScript's records, DI 3 initially believed this transaction was an export, but upon further investigation, realized that this was a domestic distribution or a distribution to a registrant in the United States. Tr. 508, 510, 529, 533–34; Gov't Exs. 22 at 10–11, 26 at 88, 89, 92, 27 at 3, 28 at 66, 67, 68.

DI 3 discussed this invoice with Dr. Shi on May 8, 2019, when she conducted another inspection of OakmontScript. Tr. 513–14. Dr. Shi stated that L.Y., a colleague Dr. Shi had met at a conference, requested that Dr. Shi send the Lunesta to Mr. Z.Y. prior to Mr. Z.Y. going to China as Dr. Yu was not able to acquire it. Tr. 515–16. Mr. Z.Y. then provided her a business card showing that he was an employee of Disha Pharmaceutical Group, a pharmaceutical company in China. Tr. 534. Mr. Z.Y. was planning to move to China, and asked that the Lunesta be shipped to his home address in New Jersey, and paid via personal payment. Tr. 514, 516, 531, 534–35. This invoice indicates that the ''bill to'' party was Disha Pharmaceutical Group. Tr. 530–31; Gov't Ex. 28 at 44. At some time in May 2019, DI 3 discussed with Dr. Shi that this was improper. Tr. 518.

OakmontScript purchased this Lunesta with its distributor registration and then mailed it to Mr. Z.Y. at his home address in New Jersey. Tr. 517–18. Disha was not the end user or ultimate user because it was seeking the Lunesta in order to conduct research as opposed to using it for personal use. Tr. 518–19, 772–73. *See* 21 U.S.C. 802(27) (defining ''ultimate user'' as ''a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.'').

DI 3 conducted a search of the DEA registration database for Mr. Z.Y., Disha Pharmaceutical Group, and the address in Kearny, New Jersey and discovered that none of them have any active or inactive DEA registrations. Tr. 545–54. There is also no indication that the Kearny, New Jersey, address could be a freight forwarding facility.[76] Tr. 555–56, 558.

Dr. Shi testified that this transaction was an export and not a domestic distribution as claimed by the Government, because Mr. Z.Y. was taking this prescription to a company in China, Disha Pharmaceutical, which was the end-user. Tr. 1180–82, 1359. Dr. Shi also asserts that an end-user or ultimate user [77] is the person who signed the end-user statement to give OakmontScript a certificate. Tr. 1183. In fact, OakmontScript created a license transfer document, transferring the Lunesta from OakmontScript's distributor license to its exporter license. Gov't Ex. 26 at 93.

*[G] The ALJ stated that OSC Allegation 14 was ''SUSTAINED IN PART to the extent that Dr. Shi maintained the intern's employment for an additional thirteen months after the falsification occurred and the intern left OakmontScript because her work visa expired, rather than being fired.'' RD, at 58. However, it is unclear what allegation the ALJ is sustaining. Paragraph 14 of the OSC alleges that Respondent exhibited a lack of candor during the investigation by initially indicating that the intern was fired. The ALJ found that there was no lack of candor related to this charge. Based on the ALJ's interpretation of the evidence and testimony, I do not find any additional allegations in paragraph 14 to sustain.

[75] Although the Government failed to allege a specific public interest factor, I find that this best fits under Factor Five as it is a violation of Federal law.

[76] A freight forwarding facility is defined as:

> A separate facility operated by a distributing registrant through which sealed, packaged controlled substances in unmarked shipping containers (*i.e.,* the containers do not indicate that the contents include controlled substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer controlled substances from any location the distributing registrant operates that is registered with the Administration to manufacture, distribute, or import controlled substances, or, with respect to returns, registered to dispense controlled substances, provided that the notice required by § 1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved. For purposes of this definition, a distributing registrant is a person who is registered with the Administration as a manufacturer, distributor (excluding reverse distributor), and/or importer.

21 CFR 1300.01(b).

[77] DI 3 explained that these terms are synonymous. Tr. 773.

OakmontScript did this even before it likely received the Lunesta shipment. *See* Gov't Ex. 26 at 89, 90 (The packing slip from McKesson for the distribution to OakmontScript is dated May 9, 2018, while the license transfer document is dated May 7, 2018.)

Although Dr. Shi indicates that OakmontScript no longer uses this ''informal logistical arrangement,'' Dr. Shi continues to believe this was a proper way to export controlled substances. ALJ Ex. 26 at 12. OakmontScript references 21 U.S.C. 822(c)(2)[78] as an exception that allowed Mr. Z.Y. to transport the Lunesta to China. *Id.* As Dr. Shi noted in her testimony, Mr. Z.Y. is an employee of Disha, Tr. 1180–82, not of a ''common or contract carrier or warehouse.'' 21 U.S.C. 822(c)(2). Therefore, OakmontScript would not meet this exception. Furthermore, OakmontScript did not provide any documentation to DI 3 that indicated Mr. Z.Y. had actually delivered the Lunesta to Disha Pharmaceutical in China. Tr. 1455–56.

I find that OakmontScript shipped Lunesta to an address in Kearny, New Jersey, United States, which makes this a domestic distribution as opposed to an export. I also find that the Lunesta was shipped to Mr. Z.Y. at his home address in Kearny, New Jersey, Mr. Z.Y. did not possess a DEA registration, and this transaction did not meet any exceptions provided by the regulations.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 16 and 17 are *sustained.* [Additionally, I consider this violation under Factor Five to weigh against Respondent's continued distributor registration based on Respondent's unlawful domestic distribution of a controlled substance.]

[Summary of the Public Interest Factors for Respondent's Distributor Registration

I find that the Government has proven that Respondent failed to maintain complete, accurate, and separate records for its distributor registration; that Respondent submitted a falsified pharmacy registration to PBA in an attempt to obtain controlled substances outside of the CSA's closed regulatory system; and that Respondent unlawfully distributed a controlled substance domestically. Accordingly, I find that Factors One and Five weigh strongly in favor of revoking Respondent's distributor registration.]

Exporter Registration

As to its exporter COR, the Government alleges that the Respondent violated the CSA and its implementing regulations by: (1) Exporting controlled substances prior to obtaining its exporter COR, (2) exporting controlled substances it was not approved to export, (3) exporting controlled substances to fill prescriptions for underage patients, and (4) commingling its exporter records with records pertaining to its distributor registration and otherwise failing to keep complete and accurate records of controlled substances it exported. The Government seeks the revocation of the Respondent's exporter COR based on its allegations that the Respondent's continued registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 958.

The CSA, as codified at 21 U.S.C. 958, provides that ''[t]he Attorney General may . . . revoke or suspend a registration under subsection (a) or (c) of this section,[79] if he determines that such registration is inconsistent with the public interest . . . .'' 21 U.S.C. 958(d)(2).

Congress has provided the following factors to be considered in the public interest analysis, as set forth in 21 U.S.C. 823(d), which relates to exporters of schedule III, IV, and V controlled substances pursuant to 21 U.S.C. 958(c)(1):

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

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

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

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

21 U.S.C. 823(d).

As with the public interest factors applicable to the Respondent's distributor registration, these factors are considered in the disjunctive, and the Agency may give each factor the weight it deems appropriate in determining whether to revoke a registrant's registration. *Edmund Chein, M.D.,* 72 FR 6580, 6593–94 (2007) (quoting *ALRA Labs., Inc.,* 59 FR at 50,621). Moreover, and also in alignment with determinations applicable to other categories of registrants, the Agency is ''not required to make findings as to all of the factors.'' *Chein,* 72 FR at 6594 (quoting *Hoxie,* 419 F.3d at 482).

Factors One and Five: Maintenance of Effective Controls Against Diversion and the Existence in the Establishment of Effective Controls Against Diversion

In engaging in the public interest analysis regarding an exporter, the Deputy Administrator has noted that, ''[b]oth factors one and five inquire into whether [a registrant] has effective controls against diversion.'' *Chein,* 72 FR at 6594. At issue in *Chein,* and considered under these factors, was the Respondent's failure to provide compliant initial and biennial inventories, an essential recordkeeping responsibility. *Id.* Likewise, other recordkeeping requirements are at issue in the instant case, namely accurate recording of documentation regarding dates of transfer, dates of export and the identity of purchasers. Finally, as discussed in the portion of this Recommended Decision dealing with the Respondent's distributor registration, the commingling of records is a recordkeeping issue that falls within the maintenance of effective controls factor. *See supra* at 50.

DEA registrants are required to keep complete and accurate records related to controlled substances. 21 U.S.C. 827(a) and (b); 21 CFR 1304.21(a). The Deputy Administrator has stated, including in the context of an exporter, that ''[a]ccurate inventories are essential to conduct accountability audits and to determine whether diversion has occurred.'' *Chein* at 72 FR at 6594. Registrants must ensure that inventories

[78] 21 U.S.C. 822:

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

[79] Subsection (c) applies to exporters of schedule III, IV, or V controlled substances and states that ''[i]n determining the public interest, the factors enumerated in paragraphs (1) through (6) of section 823(d) of this title shall be considered.'' 21 U.S.C. 958(c)(1).

Subsection (a) applies to exporters of schedule I or II controlled substances and states that ''[i]n determining the public interest, the factors enumerated in paragraph (1) through (6) of section 823(a) of this title shall be considered.'' Although the Respondent is registered to export schedule II controlled substances, the Government made no allegations regarding the Respondent's exporter registration and schedule II controlled substances, thus sections 958(a) and 823(a) are not relevant to the instant proceedings.

of controlled substances in Schedules III, IV, and V are ''readily retrievable.'' 21 CFR 1304.04(f)(2). ''DEA regulations define the term 'readily retrievable' to mean 'that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records *in a reasonable time.*''' *Chein,* 72 FR at 6593 (emphasis in original)(citations omitted). ''While what constitutes 'a reasonable time' necessarily depends on the circumstances, under normal circumstances if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request.'' *Id.*

OakmontScript failed to keep complete and accurate records, did not record an initial inventory for its exporter registration, and did not keep separate records for its exporter and distributor license.[80] [I find that Factors One and Five weigh against Respondent's continued exporter registration based on these recordkeeping violations.]

Inaccurate Records [81]

Invoice OKS–00243 (Diazepam)

OakmontScript received diazepam, 10 milligram gel on May 16, 2017 from McKesson. Tr. 356–57; Gov't Ex. 18 at 3. OakmontScript provided documentation to DI 3 that indicates this diazepam was exported on both May 18, 2017 and June 10, 2017. Tr. 352–53, 366. Tr. 356, 1448; Gov't Exs. 17 at 3, 18 at 3.[82] OakmontScript provided documentation to DI 3 that indicates Par Pharmaceutical, an Endo International Company, was the recipient. Tr. 356, 1448; Gov't Ex. 17 at 3. In other documentation, the recipient is listed as Cangzhou People's Hospital in China. Tr. 357, 1449; Gov't Ex. 18 at 3.

When questioned regarding the exact export date of the diazepam, Dr. Shi sent an email to DI 3 on April 23, 2019 indicating that she did not know the exact date of export because the ''shipping label was not retrievable due to USPS system update'' and Ms. Liu has ''made edit in the date multiple times and she thought the proper date is on the date of payment . . . .'' Tr. 358–59, 386, 1449; Gov't Exs. 20 at 8, 28 at 22. In this response email, the ''ship to name'' is listed as H.H. at Cangzhou People's Hospital in China and Dr. Shi's guess of the ''best possible date'' of shipment was the date of payment on May 18, 2017. Tr. 361–63, 1449–50; Gov't Ex. 21 at 9. In other documentation provided by Dr. Shi at the May 8, 2019 inspection, the use was listed as ''for research'' and the ''bill to'' party was H.X.Z. at Par Pharmaceutical and the ship to party was Dr. H.H. at Cangzhou People's Hospital in China. Tr. 365; Gov't Ex. 26 at 19.

One of the license transfer documents for this export indicates that the diazepam was transferred from OakmontScript's distributor registration to its exporter registration on May 7, 2018. Tr. 371–72, 435; Gov't Exs. 26 at 21, 28 at 77. A different license transfer document indicates that the date of transfer was May 20, 2017. Tr. 371–72, 436; Gov't Ex. 26 at 22. Other documentation provided by OakmontScript states that the diazepam prescription was made based on a request from a family in China for Patient S.Z. and was shipped sometime in May 2019. Tr. 407–09; Gov't Ex. 44 at 1–2. OakmontScript was unable to complete a DEA Form 236 for this export.[83] Tr. 352–53; Gov't Exs. 12 at 14, 16 at 2.[84]

DI 3 confronted Dr. Shi regarding this conflicting information at the on-site inspection on May 8, 2019. Tr. 363. Dr. Shi recalled that this diazepam had been shipped for direct patient use in China. Tr. 363–64. Dr. Shi stated that OakmontScript had to label the reason for export as ''research'' in order to get the shipment past Chinese Custom Officials and that the actual intended use of the diazepam was for direct patient use. Tr. 366, 1446.

DI 3 was also confused by documents provided by Dr. Shi because although they appeared to be the exact same documents—a prescription written in Chinese, a hospital's government licenses, and a doctor's medical license—these documents were provided in stacks for two different invoices. Tr. 380–83; Gov't Ex. 26 at 12–14, 30–32. Based on a translation that DI 3 ultimately obtained for these documents, DI 3 learned that both prescriptions were for diazepam. Tr. 383.

Invoice OKS–00753 (Briviact)

OakmontScript provided DI 3 with documents that indicated that Briviact 50 milligram and 100 milligram, was received on October 22, 2018, the shipping label was created on October 25, 2018, and was shipped on November 2, 2018. Tr. 579–96; Gov't Exs. 12 at 8, 20 at 10, 26 at 103, 105, 28 at 16. Other documentation provided by OakmontScript indicated that this Briviact was shipped on October 26, 2018. Gov't Exs. 17 at 2, 18 at 4. In other documentation provided by OakmontScript, no shipping date is provided. Gov't Ex. 27 at 3–4. OakmontScript did not fill out a DEA Form 236 for this controlled substance. Tr. 596, 1435–36; *See* Gov't Ex. 48.[85]

Invoice OKS–00315–2 (Lyrica)

OakmontScript provided documentation to DI 3 indicating that a variety of Lyrica strengths were shipped on November 21, 2018, to J.F. at YaoPharma. Tr. 558–72; Gov't Ex. 31 at

[80] The analysis regarding the commingling of records is the same as discussed above. *See supra* at 50–51.

[81] On the last day of the hearing Dr. Shi indicated that she ''want[ed] to see if we can submit our record, which I'll look at in the app.'' Tr. 1429. She further stated that she needed ''to check back because some of the things that happened three or four years ago, if I can retrieve it'' and that ''[a]t this point, I don't have any evidence ready to present and I didn't prepare additional.'' Tr. 1429. To be clear, Dr. Shi had several opportunities to submit any additional records that had not previously been provided to DI 3 at the February 19, 2019 inspection, including the inspections DI 3 conducted in March 29, 2019, May 8, 2019, May 13, 2019, and February 28, 2020. OakmontScript also could have provided these records as an exhibit with its Prehearing Statement, Amended Prehearing Statement, Supplemental Prehearing Statement, Hearing Exhibits, or even offered them during the hearing, if it could have demonstrated good cause. As noted by Dr. Shi, she ''has the records'' but decided not to give them to DI 3 and also did not prepare them for the hearing.

[82] As noted *supra,* this McKesson invoice listed OakmontScript's address as 15 New England Executive Park. Dr. Shi explained that this address and the 1500 District Avenue address (OakmontScript's current address) are the same address. Tr. 367. Dr. Shi stated that the area where OakmontScript is located got ''reorganized'' and although OakmontScript's address changed, its physical location never changed.

[83] This is noted as ''no XFER'' in the spreadsheets, which indicates that OakmontScript was not able to fill out a DEA Form 236 for a particular drug. Tr. 202.

[84] Although the OSC did not include any allegations regarding the Respondent's failure to complete DEA Form 236 for controlled substances that it exported, the Government did include these allegations in its Prehearing Statement. *See* ALJ Ex. 5 at 43. Where an allegation is not included in the OSC, but the Government includes the allegation in its Prehearing Statements, adequate notice is provided to a respondent. *Jose G. Zavaleta, M.D.,* 78 FR 27431, 27439 (2013) (Where the Government did not allege material falsification on the respondent's application in the OSC, but did raise the issue in its Supplemental Prehearing Statement, the respondent was on notice that the issue would be considered at the hearing); *Treasure Coast Specialty Pharmacy,* 76 FR 66965, 66967 (2011) (The respondent's argument that it was denied due process because the Government had not alleged lack of state authority in the OSC was rejected, because the scope of the proceedings before the Administrative Law Judge was not defined by the OSC ''but rather by the Government's prehearing disclosures'' as well); *John Stafford Noell,* 59 FR 47359, 47361 (1994) (Notice of allegations were adequate where they were not included in the OSC, but they were contained in the Government's Prehearing Statement).

[85] The allegation specific to this invoice was made on page 29 of the Government Prehearing Statement (''GPHS''). ALJ Ex. 5 at 29.

1–2, 27 at 3, 31 at 1, 4. However, other documentation provided by Dr. Shi indicates that this Lyrica was exported on November 21, 2019. Gov't Ex. 12 at 12.[86] Dr. Shi also sent an email stating that the label for the Lyrica was created on November 21, 2018, and the drop-off date was December 4, 2018. Gov't Ex. 20 at 10. Other documents list the date as March 29, 2019. Gov't Ex. 31 at 3. Other documents list an invoice date of May 8, 2019. Gov't Ex. 26 at 102.[87] The date of the invoice was also listed as August 8, 2018. Gov't Ex. 28 at 48. OakmontScript did not file a DEA Form 236 for this export. Tr. 572–73.[88]

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 20.a.a, 20.a.b, 20.a.c, 20.a.d, 20.b, 20.c.e, and 20.c.f[89] [related to Respondent's failure to keep complete and accurate records] are *sustained*. [I find that Factors One and Five weigh against Respondent's continued exporter registration based on these recordkeeping violations.]

Lack of Initial Inventory

Pursuant to 21 CFR 1304.11, ''[e]very person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable'' and ''[i]n the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.'' 21 CFR 1304.11(b).

On September 16, 2016, DI 1 conducted an on-site inspection of OakmontScript with a Senior Investigator with the Massachusetts Department of Health. Tr. 44–45. DI 1 explained that OakmontScript was required to create an initial inventory of controlled substances OakmontScript has on site. Tr. 50. DI 1 and the Senior Investigator conducted a pre-registration inspection of OakmontScript for its exporter application on June 22, 2017. Tr. 69–71. They discussed with Dr. Shi that OakmontScript was required to create an initial inventory and maintain records for at least two years. Tr. 71–72.

DI 3, DI 4, and DI 1 conducted an inspection of OakmontScript on February 19, 2019. Tr. 156–58. They discussed recordkeeping and the DIs explained that they would be conducting a controlled substance accountability audit. Tr. 159. Although the closing inventory for the accountability audit was good because ''it tied out to zero,'' there were issues with OakmontScript's recordkeeping, including a failure to take an initial inventory, which OakmontScript was unable to produce. Tr. 190, 736, 763. Specifically, during the February 19, 2019 inspection, OakmontScript informed DI 3 ''that they had forgotten to take the initial inventory when they received the export registration.'' Tr. 735–36. DI 3 discussed these issues with her group supervisor and her group supervisor asked her to return to conduct an expanded controlled substance accountability audit going back to December 5, 2017, when OakmontScript first received its DEA exporter registration. Tr. 192–93.

I find that OakmontScript failed to record an initial inventory for its exporter registration, which is a violation of 21 CFR 1304.11(b). This is also particularly concerning because OakmontScript has a distributor license and was aware of these requirements. Furthermore, both DI 1 and DI 2 had explained to Dr. Shi that an initial inventory was required once OakmontScript's exporter application was approved.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegation 21.a is *sustained*. [I find that Factors One and Five weigh against Respondent's continued exporter registration based on Respondent's failure to conduct an initial inventory.]

Factor Six: Such Other Factors as May Be Relevant to and Consistent With the Public Health and Safety

The Government alleges that Factor Six is relevant to the public interest analysis regarding the Respondent's exporter COR. ALJ Ex. 1 at 7.[90]

The Respondent's exporting of controlled substances prior to having an exporter COR, its exporting of controlled substances for which it did not have approved drug codes and its exporting to fill individual prescriptions do not fall under any of the first five factors that are to be considered in determining the public interest for an exporter and thus are appropriately addressed under Factor Six. *See Perry County Food & Drug,* 80 FR at 70,112 (DEA applied the analogous Factor Five ''such other conduct'' in the context of a pharmacy registrant where the violations at issue were ''not covered by application of the other four public interest factors.'').

Additionally, as discussed in the portion of this Recommended Decision dealing with the Respondent's distributor registration, the lack of candor is an issue that falls within the category of ''such other factors as may be relevant to and consistent with the public health and safety.'' [91] *See supra* at 52–53.

Pre-Registration Exports

The CSA requires that in order to export a controlled substance a person must be properly registered to do so. 21 U.S.C. 957(a) specifically states: ''No person may . . . export from the United States any controlled substance . . . unless there is in effect with respect to such person a registration issued by the Attorney General under section 958 of this title . . .'' Further, DEA regulations state that ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1301.13(a). These requirements have been applied in DEA decisions. *Chein,* 72 FR at 6592 (citing 21 U.S.C. 957(b), and 21 CFR 1301.13(a)). Additionally, another regulation applying specifically to exports states that ''[n]o person shall in any manner export, or cause to be exported from the United States any controlled substance . . . unless and until such person is properly registered under the Act . . .'' 21 CFR 1312.21(a).

The parties stipulated that the Respondent's exporter COR was first issued on December 5, 2017. Stipulation 2. Moreover, it is established by the Certification of Registration History for the Respondent's exporter registration that the COR number was assigned on December 5, 2017. Gov't Ex. 1B. Therefore, there is no dispute that the Respondent first had DEA authority to export controlled substances on December 5, 2017.

Invoice OKS–00243 (Diazepam)

The testimony by both DI 3 and Dr. Shi, as well as the documentation

[86] DI 3 discussed these issues with Dr. Shi on April 23, 2019, and Dr. Shi indicated that this was an incorrect date and the date should be listed as November 21, 2018. Tr. 564.

[87] This incorrect date could be related to the macro issue, but regardless, having these incorrect dates caused confusion for DI 3. Tr. 576–77.

[88] The allegation specific to this invoice was made on page 22 of the GPHS. ALJ Ex. 5 at 22.

[89] It appears that the Government had formatting issues when identifying various paragraphs of the OSC.

[90] The Government failed to state why Factor Six is applicable and only specifically stated that Factor Six applied to the allegation that OakmontScript filled prescriptions for underage patients in China.

[91] For other categories of registrants, the ''such other factors'' or ''such other conduct'' is listed as Factor Five. *See, e.g.,* 21 U.S.C. 823(b) & (e) (applicable to distributors) and 21 U.S.C. 823(f) (applicable to practitioners).

admitted at the hearing, provided conflicting dates for the export of this diazepam. The dates in the documentation and discussed by both witnesses are May 18, 2017 and June 10, 2017. Tr. 352–53, 356, 357, 366, 424–25, 432, 1311–12, 1313, 1448, 1449; Gov't Exs. 12 at 14, 17 at 3; 18 at 3; 26 at 20. Dr. Shi admitted she did not know the date of export because of a USPS system update that resulted in the loss of shipment information for this invoice. Tr. 358–59, 386, 1449; Gov't Exs. 20 at 8, 28 at 22. However, there was no testimony or other documentation that suggested an export date other than May 18, 2017 or June 10, 2017. Indeed, at the hearing, Dr. Shi offered testimony that ''the best possible date'' of shipment was May 18, 2017, despite telling DI 1 during her June 22, 2017, pre-registration inspection that she had not exported any drugs. Tr. 361–63, 1313, 1368–69, 1449–50; Gov't Ex. 21 at 9.

Based on the testimony and admitted exhibits, it is evident that this diazepam was exported on either May 18, 2017, or June 10, 2017. Regardless of which date the diazepam was actually shipped, both dates are approximately six to seven months before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00301 (Briviact)

DI 3 testified that this Briviact was shipped on August 2, 2017. Tr. 440. The documentation that DI 3 received from the Respondent also indicates an export date of August 2, 2017. Gov't Ex. 12 at 7, 26 at 36, 27 at 2. Furthermore, correspondence from Dr. Shi states the shipping label was created on August 2, 2017. Gov't Ex. 20 at 8. Dr. Shi confirmed the August 2, 2017 date in her testimony at the hearing. Tr. 1313–14.

Based on the testimony and admitted exhibits, this Briviact was exported on August 2, 2017. This date is approximately four months before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00315 (Belviq)

DI 3 testified that this Belviq was shipped on November 1, 2017. Tr. 459. The documentation that DI 3 received from the Respondent also indicates an export date of November 1, 2017. Gov't Ex. 12 at 3, 26 at 38–39, 27 at 2. In her testimony, Dr. Shi confirmed the November 1, 2017 date in the documentation she provided to the Government as reflected in Government Exhibits 12 and 27, but also testified it was an estimated date.[92] Tr. 1318–20.

Based on the testimony and admitted exhibits, this Belviq was exported on November 1, 2017. This date is approximately one month before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00315/OKS–00315–2 (Lyrica)

DI 3 testified that this Lyrica was shipped on November 20, 2017. Tr. 471. Some documentation that DI 3 received from the Respondent also indicates an export date of November 20, 2017. Gov't Ex. 12 at 9–10. Other documentation that DI 3 received from the Respondent provides a date of November 17, 2017 (Gov't Ex. 28 at 32), November 19, 2017 (Gov't Ex. 28 at 78), or November 21, 2017 (Gov't Ex. 27 at 2). Dr. Shi acknowledged the date on Government Exhibit 12, but stated that ''[i]t's just the date we entered'' before later agreeing that her employees enter the dates on which events actually occurred.[93] Tr. 1330, 1331.

Based on the testimony and admitted exhibits, this Lyrica was exported sometime between November 17 and 21, 2017. November 21, 2017, is approximately two weeks before the Respondent's registration as an exporter was issued on December 5, 2017.

I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Invoice OKS–00108 (Belviq XR)

DI 3 testified that this Belviq was shipped on December 1, 2017. Tr. 484. The documentation that DI 3 received from the Respondent also indicates an export date of December 1, 2017. Gov't Ex. 12 at 3, 26 at 47, 27 at 2. Dr. Shi confirmed the December 1, 2017, shipping date for this Belviq in Government Exhibits 12 and 27 in her testimony at the hearing. Tr. 1351–52.

Based on the testimony and admitted exhibits, this Belviq was exported on December 1, 2017. This date is four days before the Respondent's registration as an exporter was issued on December 5, 2017. I therefore find that the Respondent exported this controlled substance when it was not properly registered to do so in violation of 21 U.S.C. 957(a) and 21 CFR 1312.21.

Faced with the fact that the Respondent exported controlled substances pursuant to the above-referenced invoices prior to being registered as an exporter, the Respondent makes the argument that it had applied for the registration, had been inspected by DEA, passed the security measures, and that the registration would be forthcoming at any time.[94] Tr. 1303. It should be noted that in her testimony, Dr. Shi emphasized numerous times that she felt her registration would be coming ''any minute.'' Tr. 1095:4–5, 1096:8, 1097:4, 23, 1303:20–21, 23. Also, tellingly, Dr. Shi admitted that she ''misled my people, say this export license on the way.'' Tr. 1097. Dr. Shi then went on to admit that she ''prepared my business, say that license should be coming'' which led to ''schedule 3, 4, 5 being processed and we started taking order.'' Tr. 1097–98. Dr. Shi further admitted ''I didn't do my part.'' Tr. 1098.

In *Chein,* the Deputy Administrator stated the following:

> DEA has recognized that acting with a 'good faith belief that [one is] properly registered with DEA . . . is a mitigating factor in determining the public interest,' . . . DEA has recognized this defense in only two situations. The first is where a person had previously held a registration for the activity and believed it to be still valid pending an appeal of a final order of revocation. *See Stanley Alan Azen, M.D.,* 61 FR 57893, 57895–96 (1996). The second is where an applicant applied for a registration and received from DEA controlled substance order forms that were imprinted with a new DEA number. *See Howard,* 62 FR at 32660. *Howard* is therefore properly understood as a case involving reliance on an affirmative act of the government.

[92] Dr. Shi did not offer an alternative date in her testimony.

[93] Again, Dr. Shi did not offer any alternative date for a shipment of the drugs for this invoice.

[94] The Respondent also argued that DEA had ''neglected'' and ''mistreated'' its application with the result that its exporter registration ''didn't come in on time.'' Tr. 1093–94, 1493. To the extent that the Respondent is making an argument that its exporter application was mishandled, [which was not supported by any record evidence], there is no exemption from registration because one has submitted an application which was subsequently mishandled. *Chein* 72 FR at 6589 (quoting *Dennis Robert Howard, M.D.,* 62 FR 32658, 32661 (1997) (''there is no 'good faith' exemption from liability in administrative proceedings'' under the CSA)).

Chein, 72 FR at 6589 (alterations in original).[95]

Neither of the mitigating factors discussed in *Chein* is present in this case. First, the Respondent had never previously held a valid exporter registration. Second, the Respondent did not receive documentation regarding a new registration number and, in fact, Dr. Shi admitted that although she thought ''the registration would be coming any day,'' she did not receive the registration. Furthermore, the Respondent's expectation that she would shortly receive her registration or that she had met all the requirements for the registration are not a substitute for having actually been issued a valid registration by DEA.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 7.a, 7.b, 7.c, 7.d, and 7.e are *sustained.* [I find that Factor Six weighs against Respondent's continued exporter registration based on Respondent's repeated exporting of controlled substances prior to obtaining a registration.]

Exporting Without the Required Drug Code

In addition to the requirement in 21 U.S.C. 957 that a registrant have a registration to export controlled substances, the CSA also requires that a registrant shall not ''export controlled substances other than those specified in the registration.'' 21 U.S.C. 958(b). DEA has explained that ''[t]he mechanism by which a controlled substance is specified in a registration is through the use of its Administration Controlled Substance Code Number.'' [96] Changes in Administration Controlled Substances Code Numbers, Final Rule, 52 FR 5951 (1987); Gov't Ex. 53. As DI 1 further explained in her testimony, these ''drug codes'' are used for ''identification purposes'' for certain types of registrants, including exporters. Tr. 86. The regulations also require that ''[a]pplicants for import and export permits must include the appropriate code number on the application . . . .'' 21 CFR 1308.03(a).

Both DI 1 and DI 3 explained the use of the drug codes to Dr. Shi and assisted her in having the appropriate drug codes associated with the Respondent's exporter registration. Tr. 86–89, 96–97, 100, 175–76, 183, 597. However, the Respondent later expanded the types of controlled substances it was exporting and Dr. Shi testified that the Respondent lacked the necessary drug codes. Tr. 1130–31.

The CSA also requires that appropriate export documentation be completed. For nonnarcotic controlled substances in schedule III or IV and controlled substances in schedule V, 21 U.S.C. 953(e) requires certain documents, including ''such export permit, notification, or declaration as the Attorney General may by regulation prescribe.'' 21 U.S.C. 953(e)(2). Regulations implementing this section require that the registrant complete and file a DEA Form 236. 21 CFR 1312.21(b), 1312.27(a), 1312.28(a); Tr. 996, 1025, 1028; *See* Gov't Ex. 47.

As to DEA Form 236 requirements, Dr. Shi testified that DI 1 covered the DEA–236 requirements at the June 22, 2017 inspection. Tr. 1298–99. Dr. Yu testified that DI 3 provided the Respondent with instructions regarding the DEA Form 236 during the February 19, 2019 inspection. Tr. 996, 1025. However, Dr. Shi acknowledged in her testimony that the Respondent's DEA–236 forms ''didn't get filled because lack of drug code.'' Tr. 1131.

Invoice OKS–00753 (Briviact)

The Respondent shipped Briviact to China under this invoice on either October 26, 2018 or November 2, 2018. Tr. 579–96; *Compare* Gov't Exs. 17 at 2 and 18 at 4 *with* Gov't Ex. 20 at 10.

DI 3 testified that the drug code for Briviact is 2710. Tr. 581; Gov't Ex. 10 at 3. DI 3 testified that the Respondent was not authorized to handle Briviact under its exporter registration because it did not have drug code 2710 associated with that registration. Tr. 581, 1434–35; Gov't Ex. 11. On cross-examination, Dr. Yu agreed that on the date of shipment for this controlled substance, the Respondent did not have a drug code for Briviact. Tr. 1052. Therefore, the uncontested evidence is that the Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b).

Furthermore, DI 3 testified that the Respondent did not fill out a DEA Form 236 for this controlled substance.[97] Tr. 596–97, 1435–36. There is also no record of the Respondent completing a DEA–236 in the documentary evidence that DI 3 obtained, which lists the DEA–236 forms that the Respondent filed with DEA. Gov't Ex. 48. In response to the Government's allegations, the Respondent provided no evidence that it successfully completed a DEA Form 236 for this export. Therefore, the evidence leads to the inescapable conclusion that the Respondent did not complete the required DEA Form 236, in violation of 21 U.S.C. 953(e) and 21 CFR 1312.21, 1312.27 and 1312.28.

Invoice OKS–00902 (Belviq)

The Respondent shipped Belviq to China under this invoice and, according to most of the evidence, the date of shipment was February 15, 2019. Tr. 602–13; Govt. Exs. 18 at 4, 26 at 121, 27 at 4, 28 at 60.

DI 3 testified that the drug code for Belviq is 1625. Tr. 602; Gov't Ex. 10 at 2. DI 3 testified that the Respondent was not authorized to handle Belviq under its exporter registration because it did not have drug code 1625 associated with that registration. Tr. 612, 1435; Gov't Ex. 11. On cross-examination, Dr. Yu agreed that on the date of shipment for this controlled substance, the Respondent did not have a drug code for Belviq. Tr. 1049. Therefore, the uncontested evidence is that the Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b).

Furthermore, DI 3 testified that the Respondent did not fill out a DEA Form 236 for this controlled substance.[98] Tr. 609. There is also no record of the Respondent completing a DEA–236 in the documentary evidence that DI 3 obtained, which lists the DEA–236 forms that the Respondent filed with DEA. Gov't Ex. 48. In response to the Government's allegations, the Respondent provided no evidence that it successfully completed a DEA Form 236 for this export. Therefore, the evidence leads to the inescapable conclusion that the Respondent did not complete the required DEA Form 236, in violation of 21 U.S.C. 953(e) and 21 CFR 1312.21, 1312.27 and 1312.28.

Invoice DIW–0019 and NEEC–0019 (Clobazam)

The Respondent shipped clobazam to China on March 5, 2019. Tr. 613–41, 673–723, 727–33, 907, 912; Gov't Exs. 26 at 15–16, 27 at 4, 28 at 65.

[95] In a footnote, the Deputy Administrator declined to extend the good faith defense, citing a threat to public safety. *Chein,* 72 FR at 6589, n.16.

[96] The DEA Controlled Substances Code Numbers (''drug codes'') assigned to each controlled substance are listed in the regulations at 21 CFR 1308.11–.15. The tribunal also admitted Government Exhibit 10, which lists the drug codes for each controlled substance and according to DI 3 is the ''DEA drug code book'' that is arranged by DEA Drug Code Number. Tr. 181–82.

[97] Although the OSC did not include any allegations regarding the Respondent's failure to complete DEA Form 236s for controlled substances that it exported, the Government did include these allegations in the GPHS. ALJ Ex. 5 at 9, 11–12. The allegation specific to this invoice was made on page 29 of the GPHS. ALJ Ex. 9 at 29.

[98] The allegation regarding the Respondent's failure to complete a DEA Form 236 that is specific to this invoice was made on page 30 of the GPHS. ALJ Ex. 9 at 30.

DI 3 testified that the drug code for clobazam is 2751. Tr. 614; Gov't Ex. 10 at 4. DI 3 testified that the Respondent was not authorized to handle clobazam under its exporter registration because it did not have drug code 2751 associated with that registration. Tr. 615, 1435; Gov't Ex. 11. On cross-examination, Dr. Yu agreed that on the date of shipment for this controlled substance, the Respondent did not have a drug code for clobazam. Tr. 1049–50. Therefore, the uncontested evidence is that the Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b).

Furthermore, DI 3 testified that the Respondent did not fill out a DEA Form 236 for this controlled substance.[99] Tr. 615, 1435–36. There is also no record of the Respondent completing a DEA–236 in the documentary evidence that DI 3 obtained which lists the DEA–236 forms that the Respondent filed with DEA. Gov't Ex. 48. In response to the Government's allegations, the Respondent provided no evidence that it successfully completed a DEA Form 236 for this export. Therefore, the evidence leads to the inescapable conclusion that the Respondent did not complete the required DEA Form 236, in violation of 21 U.S.C. 953(e) and 21 CFR§ 1312.21, 1312.27 and 1312.28.

Based on my review of the testimony by DI 3 and by the Respondent's witnesses, as well as the documentary evidence, the Respondent did not have the required drug codes for the Briviact (Invoice OKS–00753), Belviq (Invoice OKS–00902), and clobazam (Invoice OKS–DIW–0019/NEEC–0019) listed under these invoices and consequently did not have the authority to export them. Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 9.a, 9.b, and 9.c are *sustained*.

In addition, I find that the Respondent did not complete the required DEA Form 236 for any of these three exports. Accordingly, in review of the evidence of record, including stipulations of the parties, the additional allegations from the GPHS (ALJ Ex. 5 at 9, 29, 30, 37) that the Respondent failed to file DEA–236 forms regarding invoices OKS–00753, OKS–00902, and DIW–0019/NEEC–0019 are *sustained*. [I find that Factor Six weighs against Respondent's continued exporter registration based on Respondent's repeated exporting of controlled substances that it was not authorized to export and Respondent's repeated failure to fill out required DEA forms.]

Lack of Candor Regarding Exports

Although the Government failed to explain under which factor the lack of candor allegation regarding the Respondent's exporter registration falls, as with the tribunal's previous discussion of the lack of candor allegation regarding the Respondent's distributor registration, the tribunal finds that the allegations regarding the Respondent's lack of candor appropriately fall under Factor Six. I incorporate by reference the discussion, *supra* at 52–53, regarding the legal standard that applies to a lack of candor finding.

On February 19, 2019, DIs conducted an on-site investigation of the Respondent pertaining to its exporter registration. Tr. 156–57; *See* Gov't Ex. 7. DI 3 testified that as part of that inspection she reviewed the drugs that the Respondent was authorized to handle and inquired of Dr. Shi as to whether the Respondent was handling any other drug codes. Tr. 159, 169, 175–76. DI 3 testified that the drug codes that the Respondent was authorized to export as of February 19, 2019, are listed in Government Exhibit 11, which she created sometime after her inspection by using her notes from the inspection and the DEA registration system. Tr. 184–87. DI 3 testified that these are the drug codes that she asked Dr. Shi about during the February 19, 2019 inspection. Tr. 188. DI 3 explained that she read through the list of drugs and stated the controlled substance name and ''asked if there were any additional drug codes that OakmontScript was handling or exporting at the time'' and that Dr. Shi stated there were no other drug codes. Tr. 189, 597–98. In her testimony, Dr. Shi admits that she had a conversation with DI 3 about drug codes and that she showed DI 3 two lists. Tr. 1172. The first list was a list for which the Respondent had drug codes.[100] Tr. 1172. After DI 3 asked whether the Respondent was handling any other drugs, Dr. Shi showed DI 3 another list and explained ''I really have trouble with another, the list of the drugs which we don't have drug codes.'' [101] Tr. 1172. Dr. Shi also raised these two lists in her cross-examination of DI 3. Tr. 888–89. After DI 3 repeated her recollection that Dr. Shi stated she had not handled any other controlled substances, Dr. Shi asked whether DI 3 recalled whether she gave her a second list of drugs with which they were having difficulties.[102] Tr. 889. DI 3 stated she did not recall this. Tr. 889.

As to the Briviact that is the subject of Invoice OKS–00753, when this was the subject of the Government's questioning of DI 3 on direct, DI 3 testified that Dr. Shi stated OakmontScript was not handling any other controlled substances and that this demonstrated a lack of candor. Tr. 600. As to the Belviq that is the subject of Invoice OKS–00902, DI 3 again testified that Dr. Shi did not advise her of the Respondent's recent export of this drug, which DI 3 believes demonstrates a lack of candor. Tr. 612–13. I find that there was more to this conversation than a simple denial by Dr. Shi. As described above, on at least three separate occasions during the hearing, Dr. Shi referenced a ''second list'' of drugs, with which she was having problems, that she gave to DI 3 as part of their conversation regarding drug codes and controlled substances that the Respondent was exporting. At a minimum, it seems that Dr. Shi wanted to continue the conversation regarding drug codes and drugs that the Respondent wanted to export, but had encountered difficulties. Based on this attempt by Dr. Shi at further communication on this issue, I cannot make a finding that Dr. Shi exhibited a ''lack of candor'' regarding the Briviact and Belviq.

As to the clobazam that is the subject of invoice DIW–0019 and NEEC–0019, for the reasons I have just outlined I make the same finding that there was not a lack of candor. However, my finding that there was not a lack of candor is supported by additional facts. On direct examination, DI 3 was asked why Dr. Shi's failure to identify the clobazam as a drug that was being handled was not a true and accurate statement. Tr. 724. In responding, DI 3 admitted that the February 19, 2019, inspection was prior to the Respondent's clobazam export, but maintained ''they're clearly handling other controlled substances that they were not allotted to or authorized to handle.'' Tr. 724. I find this statement to be troubling. First, in response to the specific question regarding clobazam, DI 3 did not specifically state that the Respondent was handling that drug, but instead made a generalized statement

[99] The allegation regarding the Respondent's failure to complete a DEA Form 236 that is specific to this invoice was made on page 37 of the GPHS. ALJ Ex. 9 at 37.

[100] Dr. Shi did not identify what drugs were on this list.

[101] Dr. Shi also did not identify what drugs were on this second list.

[102] Dr. Shi also references this second list in her ''objection'' to DI 3's statement on direct examination that Dr. Shi stated OakmontScript had not handled any other controlled substances besides those that DI 3 had listed. Tr. 598–99.

about ''other controlled substances.'' Tr. 724. Second, the Government offered no evidence to show that any clobazam was associated with the Respondent's exporter registration on or before February 19, 2019. As previously discussed, the export of the clobazam did not occur until March 5, 2019. Furthermore, the invoice from McKesson indicated that the billing date for the clobazam was February 28, 2019. Gov't Ex. 26 at 1. Based on this evidence, the clobazam would not have been transferred to the Respondent's exporter registration until after the time of the investigators' February 19, 2019 inspection. Thus, for these additional reasons, and based on the evidence before me, I find that the Government has not demonstrated a lack of candor by the Respondent regarding its allegation that Respondent failed to disclose it was handling clobazam at the time of the February 19, 2019 inspection.

Accordingly, in review of the evidence of record, OSC Allegations 11.a, 11.b, and 11.c are *not sustained*.

Exporting To Fill Individual Chinese Prescriptions

DEA regulations provide that ''[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner. 21 CFR 1306.06. *See, e.g., Margy Temponeras, M.D.,* 77 FR 45,675, 45,677 (2012).

DEA regulations also provide that ''[a]ll prescriptions for controlled substances shall be dated as of, and signed on the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.'' 21 CFR 1306.05(a).

The Government alleges that the Respondent exported controlled substances on two occasions to fill individual prescriptions for ''underage patients'' in China and that the Respondent could not legally fill these prescriptions because it is not a registered pharmacy. The Government further alleges that these ''prescriptions'' did not contain valid DEA numbers for the prescribers and did not include other required information to be valid prescriptions.

Invoice OKS–00243 (Diazepam)

The Government's first allegation of improper exporting to fill a prescription for an individual in China involves the diazepam that the Respondent exported in May 2017. I have already found that this controlled substance was exported prior to DEA's issuance of an exporter COR to the Respondent, a violation of 21 U.S.C. 957(a) and 21 CFR 1312.21. The testimony and documentation further demonstrate that this controlled substance was exported by the Respondent for the purpose of filling a prescription issued in China for a person in China. DI 3 testified that that during her inspection of May 8, 2019, Dr. Shi stated this diazepam had been shipped for direct patient use in China. Tr. 363–64. However, the Respondent's documentation stated the ''Indicated Use'' as ''Research.'' [103] Gov't Ex. 26 at 22. Dr. Shi further stated to DI 3 that OakmontScript had to label the reason for export as ''research'' in order to get the shipment past Chinese Custom Officials and that the actual intended use of the diazepam was for direct patient use. Tr. 366.[104] The Respondent has also admitted, through counsel who was representing her at the time of DEA's investigation, that this export was for a Chinese patient. Tr. 407–08; Gov't Ex. 44 at 1. As DI 3 testified, the dispensing of controlled substances to fill prescriptions is not an allowed coincident activity for distributors and exporters. 21 CFR 1301.13(e)(1); Tr. 420.

In defense of its filling of foreign controlled substance prescriptions, the Respondent cited 21 U.S.C. 956 and 21 CFR 1301.26. These provisions exempt individuals who are traversing the United States border and possess no more than 50 dosage units of non-Schedule I controlled substances for personal medical use from the usual import/export requirements. However, the Government argued that this exemption is limited to a personal use exemption for international travelers. *See* ALJ Ex. 9 at 8–9. *See* 21 U.S.C. 956; 21 CFR 1301.26. I agree that these exemption provisions by their plain language apply only to individuals who are travelling with controlled substances for their own personal use. I therefore reject the Respondent's reliance on these provisions as a justification for its export to an individual in China.

The Respondent's other argument in its defense of exporting controlled substances to fill foreign prescriptions, is what it terms ''buy and bill distribution'' or ''provider's solution distribution.'' Tr. 1209–10. However, the Respondent provides no authority for these models, much less authority that they are a legitimate way to fill foreign prescriptions. *See* ALJ Ex. 26 at 13. The Respondent also objects to what it calls DEA's ''hypothesis'' that only pharmacies can fill prescriptions, but the Respondent provides no discussion as to why the Government's position is wrong, other than to contend it ''has the right to serve clients, which include foreign entities, with legitimate clinical and scientific needs.'' ALJ Ex. 26 at 14.

I find that the Respondent, which does not hold a pharmacy COR, unlawfully filled this prescription, in violation of 21 U.S.C. 822(a)(2) and (b) and 21 CFR 1306.06.

The tribunal admitted Government Exhibit 45, which included the prescription for the diazepam, as well as a declaration by a DEA linguist that included a translation of the prescription. Gov't Ex. 45. The translation shows that the prescription is for diazepam for a two-year and six-month old male.[105] Gov't Ex. 45 at 4. The prescription was issued by H.H. a practitioner in China. Tr. 365, 413, 435; Gov't Ex. 45 at 4. DI 3 could find no DEA registration associated with this person. Tr. 413–14. The prescription does not include a DEA number,[106] I therefore find that the prescription was invalid for failing to comply with the requirements of 21 CFR 1306.05(a). Due to portions of the prescription that the linguist found to be illegible, resulting in an incomplete translation of the information on the prescription, I find that the Government has not shown that the prescription is missing any other information required by 21 CFR 1306.05(a). Gov't Ex. 45 at 4.

Invoice DIW–0019 and NEEC–0019 (Clobazam)

The Government's second allegation of improper exporting to fill a prescription for an individual in China involves the clobazam that the Respondent exported on March 5, 2019. I have already found that the

[103] Dr. Shi testified at the hearing that her main purpose in starting her company was ''to support global research need.'' Tr. 1078, 1086. Nevertheless, there was also testimony that the Respondent fills individual prescriptions. Tr. 363–64.

[104] Dr. Shi's false statement on the export documentation is relevant in assessing Dr. Shi's credibility. If Dr. Shi was willing to falsify official documentation to advance the Respondent's business interests, it is indicative of the Respondent's propensity to make other false statements in support of its business endeavors.

[105] The translation states the name is ''ILLEGIBLE,'' but other evidence in the record identifies the patient as having the initials ''S.Z.'' Gov't Ex. 45 at 4; Tr. 408.

[106] The prescription in the original Chinese includes Arabic numerals which the linguist included on the English translation. Gov't Ex. 45 at 3, 4. Because none of these numbers correspond to a format for a DEA number, and based on the testimony, I find that no DEA number is present on the prescription. Gov't Ex. 45 at 4; Tr. 430–31.

Respondent exported this controlled substance without having the required drug code for its exporter registration, in violation of 21 U.S.C. 958(b). The testimony and documentation further demonstrate that this controlled substance was exported by the Respondent to the patient's home address in China for the purpose of filling a prescription issued by a Chinese doctor. Tr. 613–41, 673–723, 727–33, 907, 912; Gov't Exs. 12 at 21, 26 at 15–16, 27 at 4, 28 at 65.

For the reasons stated above with respect to the prescription that the Respondent filled for diazepam, I find that the Respondent, which does not hold a pharmacy COR, unlawfully filled this prescription, in violation of 21 U.S.C. 822(a)(2) and (b) and 21 CFR 1306.06.

The tribunal admitted Government Exhibit 46, which included a purported prescription for the clobazam, as well as a declaration by a DEA linguist with a translation of the prescription.[107] Gov't Ex. 46. The translation shows that the prescription is for clobazam for a nine-year old male with the initials ''J.L.'' Gov't Ex. 46 at 4. The prescription was issued by G.T., a practitioner in China. Tr. 710–11; Gov't Ex. 44 at 1. DI 3 could find no DEA registration associated with this person. Tr. 715–17, 722. The prescription does not include a DEA number.[108] The prescription also does not include the address of the patient. For these reasons, I find that the prescription was invalid for failing to comply with the requirements of 21 CFR 1306.05(a).

The Government also makes three additional allegations regarding the clobazam prescription.

In paragraph 19.c.ii of the OSC, the Government alleges that the Respondent provided a Material Transfer document that showed the clobazam was transferred to Dr. W. at NEEC in Burlington, MA. This document is present in the record as Government Exhibit 26 at 16–18 and shows the invoice number of NEEC–0019 and a date of March 5, 2019.[109] The Government alleges that this documentation is inconsistent with other documents and statements made by the Respondent that show the clobazam was exported to an address in Shandong, China. Tr. 622–23. For instance, a document provided by the Respondent that contains customer and shipping information shows clobazam under invoice NEEC–019 shipped to Shandong, China, on March 5, 2019. Gov't Ex. 27 at 4. A Customs Declaration dated March 5, 2019, also shows shipment of this clobazam to Shandong, China. Gov't Ex. 26 at 15.[110] I find that the inconsistencies in the Respondent's records show that it failed to keep complete and accurate records in violation of 21 U.S.C § 827(a) and (b) and 21 CFR 1304.21(a) with respect to clobazam invoice number NEEC–0019.

In paragraph 19.c.i of the OSC, the Government alleges a lack of candor by Dr. Shi based on her representations on April 24, 2019, that the clobazam was transferred to NEEC which conflicts with her statements on May 8, 2019, that the clobazam was exported to the patient at a personal address in Shandong, China. As I have just found, there are inconsistencies in the Respondent's records as to whether this clobazam was transferred to Dr. W. or exported to China. Similarly, Dr. Shi provided DEA investigators with differing accounts as to whether the clobazam was transferred to Dr. W. or exported to China. In an April 24, 2019 email, Dr. Shi wrote that the clobazam ''was NOT exported but transferred to Dr Office from New England Executive Care in MA of USA for a patient who used to be treated at Boston Children Hospital.'' Gov't Ex. 20 at 11; Tr. 616–17. However, on May 8, 2019, Dr. Shi told DI 3 that this clobazam was exported. Tr. 623–24. I find that Dr. Shi made conflicting statements regarding whether this clobazam was transferred domestically to a doctor or whether it was exported and that these conflicting statements demonstrate a lack of candor.

In paragraph 19.c.iii of the OSC, the Government alleges that Dr. Shi stated to DEA investigators that she pressured Dr. W. to write a clobazam prescription for Patient J.L. in order to legitimize the export of clobazam and that Dr. W. eventually did write a prescription. DI 3 testified in detail to her conversation with Dr. Shi regarding Dr. Shi's efforts to get Dr. W. to write a prescription for Patient J.L. Tr. 619–20, 1459. DI 3 never obtained any prescription written by Dr. W. for clobazam for Patient J.L. Tr. 621. In addition, DI 3 interviewed Dr. W. and he denied he ever wrote such a prescription. Tr. 681–82; Gov't Ex. 36. Dr. Shi testified at the hearing that, in his role with OakmontScript, Dr. W. does not write prescriptions ''but he know[s] the medical record.'' Tr. 1197–98. Dr. Shi did not specifically testify at the hearing regarding whether she asked Dr. W. to write a clobazam prescription for Patient J.L.

Given the documentation, discussed above, that shows the Respondent transferred the clobazam to Dr. W., as well as the detailed testimony by DI 3 recalling specific conversations she had with Dr. Shi about Dr. Shi's efforts to get Dr. W. to write the prescription, and given that DI 3 felt the need to follow-up on her conversation with Dr. Shi by interviewing Dr. W. and issuing a subpoena to him regarding any prescription he wrote, I credit DI 3's testimony that Dr. Shi made statements during the investigation that Dr. W. issued a clobazam prescription for Patient J.L. Further, Dr. Shi's testimony at the hearing that Dr. W. does not write prescriptions conflicts with what she told DI 3. Finally, the fact that the Respondent produced a prescription issued in China for the clobazam, but did not produce any prescription issued by Dr. W., leads to the conclusion that the only prescription for clobazam for Patient J.L. was from China. Based on these facts, I find that Dr. Shi's statements that Dr. W. issued a prescription for clobazam for Patient J.L. demonstrate a lack of candor.

Accordingly, in review of the evidence of record, including stipulations of the parties, OSC Allegations 18.a, 18.b, 19.a, 19.b, 19.c.i, 19.c.ii, and 19.c.iii are *sustained*. [I find that Factor Six weighs against Respondent's continued exporter registration based on Respondent's exporting of controlled substances to fill individual prescriptions in China.

Summary of the Public Interest Factors for Respondent's Exporter Registration

I find that the Government has proven that Respondent violated numerous federal laws by failing to maintain complete and accurate records, by exporting controlled substances prior to having an exporter COR, by exporting controlled substances for which it did not have approved drug codes, and by exporting to fill individual prescriptions. Accordingly, I find that Factors One, Five, and Six weigh strongly against Respondent, and I conclude that Respondent has engaged in misconduct which supports the

[107] Although both parties referred to the document as a prescription, the document describes itself as an ''instruction page'' and it appears to be more akin to a hospital medication order than a prescription. Gov't Ex. 46 at 4. Nevertheless, in the absence of any other documentation purporting to be a prescription, and because both parties relied on it as a prescription, I am evaluating it as a prescription.

[108] The prescription in the original Chinese includes Arabic numerals which the linguist included on the English translation, however these numbers pertain to the ''Patient ID.'' Gov't Ex. 46 at 3, 4.

[109] These three pages appear to be identical copies of the same one-page ''Material Transfer'' document. There is also a ''Service Transfer'' document in the Government's exhibits that shows a transfer of the clobazam for invoice NEEC–0019 to Dr. W. on March 5, 2019. Gov't Ex. 28 at 76.

[110] Another copy of the identical Customs Declaration is located in Government Exhibit 28 at 75.

revocation of its distributor and exporter registrations.

I therefore hold that the Government has established a *prima facie* case that continued registration of Respondent's exporter and distributor registrations ''would be inconsistent with the public interest.'' 21 U.S.C. 823(a), (b), (d), and (e); 824(a); and 958(a), (c), and (d).]

[Sanction] *[H]

Egregiousness, Deterrence, and Lack of Candor

[Where, as here, the Government has met its *prima facie* burden of showing that the respondent's continued registration is inconsistent with the public interest, the burden shifts to the respondent to show why it can be entrusted with the responsibility carried by its registration. *Garret Howard Smith, M.D.,* 83 FR 18,882, 18,910 (2018) (citing *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007)). DEA cases have repeatedly found that when a registrant has committed acts inconsistent with the public interest, ''the Respondent is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Holiday CVS,* 77 FR at 62,339 (internal quotations omitted). *See, also, Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 FR 78,745, 78,749, 78,754 (2010) (holding that respondent's attempts to minimize misconduct undermined acceptance of responsibility); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

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. *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972 (2019). A registrant's candor during the investigation and hearing is an important factor in determining acceptance of responsibility and the appropriate sanction, *Garret Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases); as is whether the registrant's acceptance of responsibility is unequivocal, *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728 (2017) (collecting cases). In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence. *Wesley Pope,* 82 FR 14,944, 14,985 (2017) (citing *Joseph Gaudio,* 74 FR 10,083, 10,095 (2009)); *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general as a component in analyzing the remedial efficacy of sanctions.'').]

Here, the egregiousness of the offense favors revocation. The Respondent exported controlled substances before even being issued its exporter COR and, after acquiring its exporter COR, repeatedly exported controlled substances when it did not have approved drug codes and found it could not complete the required DEA–236 forms. The Respondent distributed to a non-registrant and even altered its distributer COR to make it appear that it was a DEA-registered pharmacy.

Considerations of specific and general deterrence in this case militate in favor of revocation. Through the testimony of its owner, the Respondent has made it clear that in some instances it feels it did nothing wrong, such as in the case of its exports to fill prescriptions in China, where the Respondent has ''a bundle of knowledge while [DEA investigators] obviously lack it.'' Tr. 1497. In other instances, it feels that its violations were not so serious because they did not result in ''somebody killed'' or ''some pandemic we caused.'' Tr. 1417. The Respondent's owner appeared to value her personal relationships with her employees and her friends and acquaintances in China, over her responsibilities as a DEA registrant to adhere to the CSA and its regulations. The Respondent filled prescriptions for patients in China who had personal relationships with those who worked at OakmontScript. Tr. 363–64, 624, 1195; Gov't Ex. 44 at 1. The Respondent also failed to take decisive action against the employee responsible for altering its distributor registration—and with whose family the Respondent's owner had ties. Tr. 302. The Respondent's owner's comments lead to the conclusion that she is unwilling or unable to effectively submit to DEA oversight and regulation of her controlled substances operations. She believes she is and has been correct, and it can be confidently assumed that the absence of a registration sanction will result in the continuation of operations that run afoul of the safeguards required by the CSA and its regulations. Thus, the interests of specific deterrence, even standing alone, motivate powerfully in favor of the revocation of the Respondent's CORs.

The interests of general deterrence compel a like result. As the regulator in this field, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *Ruben,* 78 FR at 38,385. Where the record demonstrates that the Government has borne its burden and established that the Respondent has exported controlled substances from the United States without authority, failed to maintain the closed system of distribution with its distributor COR and levelled substantial blame for its violations against DEA investigators, rather than itself, the unmistakable message to the regulated community would be that such conduct can be overlooked with little or no consequence. Thus, on this record, the interests of general deterrence support the revocations sought by the Government.

Another factor that weighs significantly in favor of the revocation sanction sought by the Government is the lack of candor demonstrated by the Respondent's owner during certain of her interactions with DEA investigators and at the hearing. In making the public interest determination, ''this Agency places great weight on [a respondent's] candor both, during an investigation and in a subsequent proceeding. *Fred Samimi, M.D.,* 79 FR 18,698, 18,713 (2014) (quoting *Robert F. Hunt, D.O.,* 75 FR 49,995, 50,004 (2010)).

In regard to the investigation, I found the Respondent's owner demonstrated a lack of candor both in her representation that Dr. W. issued a prescription for Patient J.L., where she was unable to produce a copy of the prescription, Dr. W. denied to investigators that he issued a prescription, and a prescription from a Chinese practitioner was used as a basis for the export. Similarly, I found a lack of candor where the Respondent's owner made conflicting statements about whether the clobazam for invoice DIW–0019/NEEC–0019 was transferred domestically to NEEC or exported to China. Also disturbing was the Respondent's owner's creation of records for presentation to Chinese authorities that falsely stated the diazepam invoice OKS–00243 was for ''research'' rather than direct patient use, so that the package would clear Chinese customs. Finally, there were

*[H] I am replacing portions of the Sanction section in the RD with preferred language regarding prior Agency decisions; however, the substance is primarily the same.

several instances during the hearing where the Respondent's owner was evasive when answering questions posed by Government counsel and this tribunal. *See supra* at 36 n.52, 37 n.55, 40 n.57, 44 n.63, 45 n.67. Hence, the Respondent's lack of candor undermines the confidence that the Agency can have in the Respondent's ability to be a responsible DEA registrant.

For the above reasons, I find that the proven misconduct is egregious and that deterrence considerations weigh in favor of revocation.

Acceptance of Responsibility and Rehabilitative Measures

With the Government's *prima facie* burden having been met, an unequivocal acceptance of responsibility stands as a condition precedent for the Respondent to prevail. *George Mathew, M.D.,* 75 FR 66,138, 66,148 (2010). This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay* v. *DEA,* 664 F.3d 808, 822 (10th Cir. 2011). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *Ruben, M.D.,* 78 FR at 38,364.

Accordingly, the Respondent must present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough,* 73 FR 363, 387 (2008); *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007). As past performance is the best predictor of future performance, DEA has repeatedly held that where an applicant has committed acts inconsistent with the public interest, the applicant must accept responsibility for his actions and demonstrate that it will not engage in future misconduct. *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.). *See also Hoxie,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination).

Dr. Shi failed to take unequivocal acceptance of responsibility at any point during these proceedings. Although Dr. Shi made several references that an issue was her fault, such statements were immediately proceeded with a qualifying statement putting the onus on someone—or something—else. In fact, Dr. Shi put the blame on just about everyone else she has come into contact with, even going so far as to blame her printer,[111] the United States Postal Service,[112] and even her own clients.[113]

In regards to receiving OakmontScript's exporter registration and exporting controlled substances prior to receiving its exporter registration, Dr. Shi consistently blamed DI 1 and/or the DEA for ''mistreating'' and ''neglecting'' her exporter applications. Tr. 1094, 1115. Dr. Shi later went on to state that she did not ''want to blame [DI 1] for neglect'' and that Dr. Shi should have ''check[ed] every step,'' but also stated that the she had ''put too much trust on [her] 30-year pharmacist,'' L.U., who was also her former boss. Tr. 1096. She further stated that she ''shared in the responsibility,'' and believed that OakmontScript's exporter registration ''should be coming any time'' despite not receiving information to support such a belief. Tr. 1095. Because of this belief, she assured and ''soothed [her] people'' by telling them that they could ''start preparing'' because the registration was coming ''any minute.'' Tr. 1096. She continued to believe that the registration ''should come any minute'' and that it would ''come in before May.'' Tr. 1097. Dr. Shi specifically taught her ''people it's not to set up the date what is right. I teach my people say I just record what is things happen. I keep telling them I never allow them to assume what is the right date. They have to record what, how the things happen, right.'' Tr. 1130.

Even more startling, in her post-hearing brief, Dr. Shi states that OakmontScript ''shares responsibility'' regarding the issue of exporting prior to receiving its registration, however, Dr. Shi does not claim she should have waited to export. ALJ Ex. 26 at 8. Instead, she claims that OakmontScript ''needed to do more than fulfill its bureaucratic obligations to fill an application, pay the fee, and pass a security inspection; they also should have more strongly advocated for their correct application. . . .'' *Id.* Dr. Shi goes on to explain that OakmontScript ''takes the position that [OakmontScript] has fulfilled their obligation for proper registration on April 27, 2017 and should have been granted its license in June 2017 or prior.'' *Id.*

It is evident that Dr. Shi does not comprehend the gravity of her many violations. In particular, when asked for clarification by Government counsel about the Lyrica, invoice OKS–00315–2 having a different shipping date listed in different records provided by OakmontScript, Dr. Shi initially indicated that she did not know which document was incorrect and claimed that regardless, it is ''one days apart. This is not like somebody get killed or something.'' Tr. 1340. Dr. Shi went on to say ''I know it's mistake. It's 20 or 21st.'' Tr. 1340. But just moments later, Dr. Shi stated ''I can say both [dates] are correct, or I mean, both are incorrect . . . I also can say both are right. Because that's just the date.'' Tr. 1341. Dr. Shi stated OakmontScript did the best it could when entering these dates into the spreadsheets. Tr. 1341.

When Dr. Shi discussed controlled substances that OakmontScript had exported despite not possessing the proper drug code, she stated that she was ''not blaming'' DI 3 and it was not ''her fault'' for Dr. Shi not getting the drug code. Tr. 1149–50. Furthermore, in regards to not being able to file the proper information on the DEA Form 236 for the diazepam, invoice OKS–00243, Dr. Shi blamed a USPS system update that ''erase[d] all the information.'' Tr. 1368. According to Dr. Shi, the USPS maintained records on its website for up to ninety days, but sometime in 2017, the USPS performed an upgrade to its system and records during that time were ''not retrievable.'' Tr. 1369. Although she agreed that the departure date is information that OakmontScript would have, Dr. Shi failed to provide any reason why this information was not in OakmontScript's records that were provided to DI 3. Tr. 1368–71.

One of Dr. Shi's most shocking revelations occurred during her direct testimony when she declared that she had ''shared more than I should'' with DI 3. Tr. 1174, 1368 (Dr. Shi ''offer[ed] too much information.'') After being further prompted by the tribunal, Dr. Shi elaborated that she believed she had been ''too eager to share too much,'' or that there was a ''miscommunication'' between Dr. Shi and DI 3. Tr. 1176. At some point, Dr. Shi decided that she would ''stop[ ] our oversharing with [DI 3]'' and took the liberty of deciding what exactly this oversharing entailed. Tr. 1381. For instance, despite OakmontScript ''hav[ing] the date'' and ''hav[ing] all the records,'' Dr. Shi decided that she would only ''provide a portion'' of certain invoices to DI 3,

[111] Dr. Shi claimed that she did not provide some required documents to DI 3 because her printer did not have ink. Tr. 1260–61.

[112] Dr. Shi stated that OakmontScript was not able to provide the export date for diazepam because the USPS updated its online system sometime in 2017 and ''erased'' all the information during the upgrade. Tr. 1368–69.

[113] For instance, when discussing the export process, Dr. Shi noted that the custom ticket could ''tak[e] as fast as two to four weeks'' but if the client is a new employee, ''they might screwed up the whole process and taking years or something.'' Tr. 1130.

including invoices written in Chinese or that included ''customer information.'' Tr. 1344–45, 1347, 1373, 1381.

It is worth noting that although Dr. Shi may not have exhibited a lack of candor regarding the firing of her intern, what it is particularly disturbing in this instance is Dr. Shi's cavalier response to this incident. During cross-examination, Government counsel questioned Dr. Shi regarding the falsification of OakmontScript's distributor registration and the following exchange took place:

Q Do you agree that falsifying a DEA registration in this manner is a serious issue?

A I admit it. From, you know, when the DI 3 first time to—

Q I know you admitted it. But do you—or at some point you admitted it. But do you agree that this is a serious issue?

A Well, a serious issue to the consequences. And to the, you know, to what we're trying to do. And this is, *I know if somebody killed, or if some pandemic we caused,* or if something and it is a serious. But in our SOP we have layers, layers of the protection. So my explanation, just to try to alleviate some of your concern about our how dangerous this could be. Yes, I know that. We can be, imagine how serious it is. But we also, you know, need to be focused on how it happened and what have caused.

Tr. 1416–17 (emphasis added).

Dr. Shi's apparent notion that for something to be deemed a dangerous issue it must culminate in a client's or bystander's demise or cause a pandemic is particularly startling. Dr. Shi further stated that ''the falsification of the DEA distributor and the pharmacy . . . is not a controlled-substance related issue'' and OakmontScript had done ''more than the minimum[,] . . . did 500 times more than what's required to address this incident.'' Tr. 1496.

When questioned by the tribunal regarding this incident, Dr. Shi indicated that the intern had ''made that mistake,'' so she changed her to a different position instead of firing her. Tr. 1397. Dr. Shi also indicated that the reasons the intern had left OakmontScript were because her visa expired and it was a ''little far stretch'' for the intern, who had an interest in being a musician, to switch to pharmaceutical trading. Tr. 1398–99. Rather than leaving OakmontScript due to an employment termination for her misdeeds, the intern left of her own volition. Despite the ''huge risk'' that the intern's action imposed on OakmontScript's registration, Dr. Shi believed it would have been ''a little bit too much'' to fire her. Tr. 1400. Furthermore, not only did Dr. Shi decide not to terminate the intern's employment, but she also allowed the intern to continue bringing her personal computer into the office. Tr. 1407. Ultimately, it appears that Dr. Shi placed more value in her relationship with the intern and the intern's family in China than protecting the integrity of her business and its DEA registration.

In light of the foregoing, it is bewildering that Dr. Shi proclaims that she has ''a better than ever understanding'' of the law. Tr. 1422. Dr. Shi even goes so far as to state in her closing argument that the DEA ''should limit their authority on the controlled substance matter.'' Tr. 1496. According to Dr. Shi, OakmontScript never tried to cut corners and made significant efforts to stay in compliance. Tr. 1493. She also stated that OakmontScript encountered many difficulties while working with the DEA, including the DIs not having an understanding of how a drug code is different from a drug schedule and lacking a ''basic understanding about pharmaceutical industries.'' Tr. 1494. Dr. Shi asserts that throughout this entire process, OakmontScript ''has . . . demonstrated and we've tried to please, we tried to cooperate, we tried to be respectful,'' but ''things have been misunderstood.'' Tr. 1495. Although Dr. Shi expresses that her ''license is privilege, it's not my right,'' Tr. 1085, as the old adage goes, actions speak louder than words and Dr. Shi failed to take the proper actions.

I therefore find that the Respondent has not unequivocally accepted responsibility.[114]

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. Furthermore, I find evidence that the Respondent poses an ongoing threat to the public health and safety. The Respondent also failed to take unequivocal responsibility for its conduct and it has not presented convincing evidence demonstrating that the Agency can entrust it to maintain its CORs.

Accordingly, I *recommend* that the Respondent's DEA CORs RO0504680 and RO0527082 be *revoked*, and any pending applications for renewal or modification of such registrations be *denied*.[115]

Dated: June 11, 2021.

Paul E. Soeffing,

U.S. Administrative Law Judge.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a); 21 U.S.C. 958(a), (c), and (d); and 21 U.S.C. 823(a), (b), (d) and (e), I hereby revoke DEA Certificate of Registration Nos. RO0504680 and RO0527082 issued to OakmontScript. Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a); 21 U.S.C. 958(a), (c), and (d); and 21 U.S.C. 823(a), (b), (d) and (e), I further hereby deny any pending applications for renewal or modification of these registrations, as well as any other pending application of OakmontScript for additional registration in Massachusetts. This Order is effective May 11, 2022.

Anne Milgram,

Administrator.

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[114] Where a registrant has not accepted responsibility, it is not necessary to consider evidence of the registrant's remedial measures. *Ajay S. Ahuja, M.D.,* 84 FR 5479, 5498 n.33 (2019) (citing *1 Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,202–03 (2016)). However, there were a few times that OakmontScript's witnesses mentioned remedial steps taken since being served with the OSC. For instance, after learning of the macro issue populating the current date in OakmontScript's templates, Dr. Yu stated that she has ''corrected this template'' and employees are now instructed to input dates manually before converting and saving the document as a PDF file. Tr. 985–86. Dr. Shi admitted during her testimony that the shipping of Lunesta to Mr. Z.Y. at his home address for further transport to China was an ''informal channel'' of exporting and ''since this incident and since DI 3 have point this out, we no longer accept informal channel of delivery for any order.'' Tr. 1182, 1183. These few measures, however, certainly do not overcome OakmontScript's past violations, or allow me to find that OakmontScript should be entrusted with a DEA COR.

[115] As discussed at the conclusion of the hearing, pursuant to 21 CFR 1316.66, the parties have twenty days from being served with this Recommended Decision to file any exceptions. Tr. 1507; 21 CFR 1316.66(a).