provisions of section 207.23 of the Commission's rules; the deadline for filing is Tuesday, September 30, 2014. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is Thursday, October 16, 2014. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before Thursday, October 16, 2014. On Wednesday, October 29, 2014, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before Friday, October 31, 2014, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on E-Filing,* available on the Commission's Web site at *http://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: July 8, 2014.

By order of the Commission.

Jennifer D. Rohrbach,

Supervisory Attorney.

[FR Doc. 2014–16253 Filed 7–10–14; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On July 7, 2014, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Colorado, in the lawsuit entitled *United States* v. *Thoro Products Company,* Civil Action No. 1:14–cv–01867.

The Consent Decree resolves the claims of the United States set forth in the complaint against Thoro Products Company for costs incurred and to be incurred in connection with the Twins Inn Superfund Site, located in Arvada, Colorado (the ''Site''), pursuant to Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. § 9607. Under the Consent Decree, the settling defendant agrees to reimburse $400,000 in past costs to the United States Environmental Protection Agency, based upon its limited ability to pay.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Thoro Products Company,* D.J. Ref. No. 90–11–2–08744. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $13.25 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the appendices and signature pages, the cost is $6.75.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2014–16182 Filed 7–10–14; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–72]

Moore Clinical Trials, L.L.C.; Decision and Order

On August 8, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Moore Clinical Trials, L.L.C. (Respondent), of North Little Rock, Arkansas. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a researcher, on the ground that ''its registration would be inconsistent with the public interest.'' ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f)).

The Show Cause Order alleged that on March 15, 2011, Ms. Greta B. Moore submitted on Respondent's behalf, an ''application for a DEA research registration for [s]chedule II controlled substances.'' *Id.* The Show Cause Order alleged that while Ms. Moore would be the primary person responsible for ordering and storing controlled substances, she ''has no prior experience with handling controlled substances.'' *Id.* (citing 21 U.S.C. 823(f)(2)). The Show Cause Order then alleged that ''Ms. Moore initially informed DEA investigators that she had experience researching with controlled substances but then admitted this assertion was not true.'' *Id.* (citing 21 U.S.C. 823(f)(5)).

Next, the Show Cause Order alleged that ''[t]he only DEA registered physician that plans to work at [Respondent] will have very limited hours and contact with'' it. *Id.* at 2. The Show Cause Order further alleged that ''[i]n 2006, the Arkansas State Medical Board suspended this physician's medical license because . . . he . . . pre-signed controlled substance

prescriptions, which were issued by his staff,'' and that ''[i]n 2008, [he] was convicted of one count of Medicare fraud'' in federal district court and subsequently ''excluded . . . from participating in the Medicare programs as required by 42 U.S.C. 1320a–7(a).'' *Id.* (citing 21 U.S.C. 823(f)(5)).

Finally, the Show Cause Order alleged that the State of Arkansas ''has not granted [Respondent's] application for a research license,'' and that Respondent ''is currently without authority to handle controlled substances in the State . . . in which [it] has applied for a DEA . . . registration.'' *Id.* The Order thus alleged that ''DEA must deny [its] application based upon its lack of authority to handle controlled substances in the State of Arkansas.'' *Id.* (citing 21 U.S.C. 823(f)(1)).

On August 26, 2011, Respondent, through its owner Ms. Moore, requested a hearing on the allegations, ALJ Ex. 2, and the matter was placed on the docket of the Office of Administrative Law Judges (ALJ). Thereafter, the Government moved for summary disposition on the ground that Respondent did not possess the requisite Arkansas researcher's license and therefore could not be registered pursuant to 21 U.S.C. 823(f); the Government's motion was supported by a letter from the Deputy General Counsel of the Arkansas Department of Health stating that Respondent's application for a state license had not been granted. ALJ Ex. 3.

Respondent opposed the Government's motion, contending that it possesses a temporary Arkansas license authorizing it to handle controlled substances.[1] ALJ Ex. 4, at 4. The Government then filed a reply to the Respondent's opposition and included a further letter from the aforementioned official, which again stated that Respondent did not possess a valid state license but had been issued a temporary state registration number in order to allow it to complete its DEA application. ALJ Ex. 4, at 4–5. Thereafter, the ALJ found that there was no dispute over the material fact ''that Respondent is presently without state authority to handle controlled substances in Arkansas.'' *Id.* at 8–9. The ALJ thus granted the Government's motion and forwarded the then-existing record to me for final agency action. *Id.* at 12.

On April 16, 2012, while the matter was still pending before this Office, the Government filed a motion to remand the case, noting that on March 12, 2012, Respondent obtained a state controlled-substance registration. ALJ Ex. 6, at 1. The Government observed, however, that it had raised ''additional allegations under 21 U.S.C. 823(f) to deny [Respondent's] application'' and that an evidentiary hearing was required to litigate them. Gov. Mot. to Remand, at 1. In opposition, Respondent contended that a hearing was no longer required because the Government had ''abandoned'' its other claims by seeking summary disposition and that ''[t]he re-litigation of these issues following the [ALJ's] Order on the Government's Summary Judgment Motion would be akin to *res judicata.*'' Response of Moore Clinical Trials LLC To The Government's Motion To Remand, at 1–2. On June 4, 2012, I found neither of Respondent's contentions persuasive and granted the Government's motion to remand the matter to the ALJ ''for further proceedings.'' *Id.* at 2–3.

Thereafter, on June 22, 2012, the Government filed a second motion for summary disposition. ALJ Ex. 7. Therein, the Government asserted that while Respondent ''had planned to hire a DEA registered physician, Brian T. Nichol, M.D., . . . to administer and dispense the controlled substances to the research subjects,'' it was its ''understanding that [Respondent] now would not be hiring Dr. Nichol.'' *Id.* at 2. The Government further argued that under Arkansas law, Respondent ''cannot operate until and unless there is an authorized licensed physician in the State . . . who will be hired by [it] to administer and dispense the controlled substance that [it] seeks to use in its research facility.'' *Id.* at 3. The Government thus contended that because Respondent ''does not have such a person who will serve in this capacity . . . [its] DEA application should be summarily denied.'' *Id.* The Government did not, however, offer any evidence to support the factual premise of its motion.

Respondent opposed the motion (although here again, the ALJ failed to forward its filing), contending that it had entered into a contract with Dr. Nichol (more precisely, his entity, Brinch Clinical Research), to provide a licensed physician to administer or dispense the controlled substances to the research subjects. ALJ Ex. 8 (citing Respondent's Response, at 1–2). In contrast to the Government, Respondent provide evidence to support is contention, specifically, a copy of its contract with Dr. Nichol's entity. *Id.* at 2.

On July 6, 2012, the ALJ denied the Government's motion, finding that ''there is a genuine dispute of material fact regarding Dr. Nichol's employment with [Respondent] as the physician assigned to this research project.'' ALJ Ex. 8, at 2. However, ''because the Government asserts additional material factual allegations regarding Respondent's application for a DEA registration, allegations which the Respondent vigorously disputes,'' the ALJ set the matter for hearing. *Id.*

Following additional pre-hearing procedures, on September 19–21, 2012, the ALJ conducted a hearing in Little Rock, Arkansas. Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or R.D.), at 5. At the hearing, both parties called witnesses to testify and submitted various documents for the record. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and arguments.[2]

On November 30, 2012, the ALJ issued her Recommended Decision. Therein, the ALJ reviewed the evidence with respect to the five public interest factors. *See* R.D. at 25–35. With respect to factor one—the recommendation of the appropriate state licensing board—the ALJ found that the State of Arkansas ''has granted the Respondent a temporary controlled substance registration.'' R.D. at 26. The ALJ thus concluded that while this factor is ''not dispositive,'' because ''[t]he ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA'' and not to state officials, the ALJ found that ''Respondent meets that requirement for gaining a DEA registration.'' *Id.* (citing *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

Likewise, with respect to factor three—Respondent's record of convictions for offenses relating to the manufacture, distribution, and dispensing of controlled substances—the ALJ found that there was no evidence that Respondent has been convicted of such an offense. *Id.* at 27. However, the ALJ further noted that ''[w]hile this factor may support the

[1] Notably, in forwarding the record to this Office, the ALJ failed to include the Respondent's opposition to the Government's motion. In addition, numerous other filings were not initially forwarded to this Office, including the parties' pre-hearing statements, motions and oppositions related to various rejected exhibits, as well as the ALJ's order excluding these exhibits. Accordingly, I ordered the ALJ to forward these documents to me. Given that proper review of the record requires that the entire record be forwarded to this office for review, these filings should have been designated as ALJ Exhibits and forwarded as part of the record.

[2] Each party's brief is cited as Gov. Br. or Resp. Br.

granting of Respondent's application . . . [i]t is not dispositive [of] the public interest determination.'' *Id.* at 27–28 (citing *Morris W. Cochran,* 77 FR 17505, 17517 (2012)).

As for factor two—the applicant's experience in dispensing or conducting research with respect to controlled substances—the ALJ noted that under Agency precedent, both an applicant's lack of relevant experience and an applicant's having ''previously poorly handled controlled substances'' provide grounds to deny an application. R.D. at 26 (citing cases). The ALJ then found that ''the parties do not dispute that Ms. Moore lacks experience in handling controlled substances in a research project'' and that ''[s]he freely admitted that she is unfamiliar with the documentary requirements for the maintenance of inventories and other accountability purposes.'' R.D. at 27. The ALJ thus found that ''this lack of experience weighs against granting her a DEA registration to handle controlled substances.'' *Id.*

However, the ALJ then noted that ''Ms. Moore has extensive clinical research experience,'' including ''experience maintaining documents necessary for such research accountability.'' *Id.* While finding that ''the record contains no evidence of her success,'' the ALJ found ''the fact that AstraZeneca granted her a research project indicative of her documented experience at least to their satisfaction for purposes of this study.'' *Id.* And while finding that ''Ms. Moore has struggled to create a form document that will capture the facts necessary for an accountability audit,'' the ALJ then found that ''the record amply demonstrates her willingness to become compliant.'' *Id.* The ALJ then offered the conclusion, which she herself deemed ''speculative,'' that ''[w]ith training, [Ms. Moore] should be able to convert her research-required recordkeeping system into one compliant with DEA requirements.'' *Id.* While the ALJ ''recommend[ed] that Ms. Moore take a course in the handling of controlled substances by researchers,'' she did not make an explicit finding as to whether this factor supported either the granting or denial of Respondent's application. *Id.*

Turning to factor four—the applicant's compliance with applicable laws related to controlled substances—the ALJ noted that registrants who dispense controlled substances must comply with a number of statutes and regulations, including various registration, recordkeeping and security requirements. *Id.* at 28 (citations omitted). Moreover, the ALJ found that ''Ms. Moore signed for a shipment of [a] controlled substance when she was not registered to do so,'' and that ''[s]uch handling of controlled substances without a registration is a violation of DEA statutory and regulatory provisions.'' *Id.* at 29 (citing 21 CFR 1301.13(a)).

The ALJ also found that ''the documents kept by Dr. Nichol,'' who was supervising the two clinical trials on behalf of Respondent, ''were deficient'' and that the order forms for Schedule II controlled substances (DEA–222) ''were lacking.'' *Id.* The ALJ also found that ''Dr. Nichol transported controlled substances to the Respondent's location,'' where he was not registered to dispense them. *Id.* (citing 21 U.S.C. 822(e)). However, the ALJ declined ''to impute Dr. Nichol's errors to the Respondent,'' reasoning that while Nichol was an independent contractor, he did not act as Respondent's agent because ''Respondent's business is not meant to exercise control over the doctor's medical judgment nor is the Respondent meant to be primarily responsible for the research and recordkeeping.'' *Id.* at 31. In support of her conclusion, the ALJ further explained that ''Respondent does not even pay Dr. Nichol for his service in conducting research at Respondent's place of business, but[ ] rather[,] Dr. Nichol's payment is a 'pass-through' system of payment in which the Respondent pays [him] once [it] receives funds from the Sponsoring Organization.'' *Id.*

The ALJ thus reasoned that Dr. Nichol is not Respondent's agent ''because the Respondent does not exercise any control over Dr. Nichol's work; rather, the Respondent only offers Dr. Nichol a facility in which to conduct research.'' *Id.* at 32. Based on this conclusion, the ALJ declined to impute to Respondent what she characterized as ''the alleged wrongdoing of Dr. Nichol regarding the transporting and dispensing of the controlled substances at Respondent's location.'' *Id.*

''Although [she did] not attribute the past wrongdoings of Dr. Nichol to the Respondent, [the ALJ] recognize[d] the Respondent's responsibility in needing to maintain proper records.'' *Id.* (citing *United States* v. *Clinical Leasing Service, Inc.,* 759 F. Supp. 310, 312 (E.D. La. 1990)). However, the ALJ then explained that ''there has been no evidence placed in the record of Respondent's recordkeeping'' and that the ''[t]he records that were produced were Dr. Nichol's records.'' *Id.* at 33. Thus, while the ALJ found that the evidence is clear that Nichol's records did not comply with the Controlled Substances Act or DEA regulations, ''the shortcomings of these records are attributable to him'' and not Respondent. *Id.* The ALJ thus reasoned that while ''Respondent has failed to maintain its own recordkeeping system, it cannot be held responsible for all of the noncompliant actions of Dr. Nichol'' and that ''Nichol's failure to meet his responsibilities as a registrant is not a basis for refusing to grant the Respondent a researcher registration.'' *Id.*

As for factor five—such other conduct which may threaten public health and safety—the ALJ noted that DEA has consistently held that an applicant's candor during an investigation and failure to accept responsibility for its misconduct are '''important factor[s] when assessing whether a . . . registration is consistent with the public interest.''' *Id.* at 34 (quoting *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010), *pet. for rev. denied, Hassman* v. *DEA,* No. 10–70684, slip. op. at 4 (9th Cir., Apr. 9, 2013)). In this regard, the ALJ ''acknowledge[d] that, from the Diversion Investigators' points of view, Ms. Moore appeared to change her position on her research experience and her experience [in] handling controlled substances.'' *Id.* Also, the ALJ found that Ms. Moore ''also vacillated in her testimony concerning where the controlled substance was actually dispensed.'' *Id.* The ALJ then explained that ''[t]his lack of candor may weigh against her being granted a DEA registration.'' *Id.*

As for whether Ms. Moore had accepted responsibility, the ALJ reasoned that while the ''[t]he record is filled with wrongdoing done by Dr. Nichol, . . . his wrongdoing is not imputed to the Respondent,'' and that ''[e]xcept for Ms. Moore's signing for the receipt of one shipment of the controlled substance, . . . the Government has not cited to any regulatory or statutory provision resulting in a finding of wrongdoing done by the Respondent.'' *Id.* at 34–35. While the ALJ agreed with the Government's contention ''that Ms. Moore did not express any remorse for this wrongdoing,'' she ''disagree[d] that this one incident is enough to deny the Respondent a DEA registration.'' *Id.* at 35.

The ALJ thus ''conclude[d] that the Government has proven that the Respondent lacks experience in handling controlled substances as a researcher,'' and that while ''in the past, this has served as a basis for denying a DEA registration. . . . Respondent clearly has experience in conducting drug research.'' *Id.* The ALJ then

observed that there was no evidence that ''Respondent's proposed business plan is a sham or an excuse to gain access to controlled substances for unlawful purposes.'' *Id.* The ALJ thus ''recommend[ed] that the Respondent's application be granted'' subject to the condition that ''Ms. Moore should be required to take a course in the handling of controlled substances for researchers.'' *Id.* at 36. The ALJ further explained that ''[i]n this way she will have the knowledge necessary to both maintain the records required, and to interview future researcher registrants to ensure they have the requisite knowledge and experience to handle controlled substances in a research environment.'' *Id.*

The Government filed exceptions to the ALJ's Recommended Decision. Thereafter, the ALJ initially forwarded the transcript and exhibits, along with various filings, orders, and rulings (ALJ Exs. 1–10) to me. Thereafter, I issued an order for the ALJ to submit the rest of the record; on July 24, 2013, the ALJ complied.

Having considered the record evidence, I have decided to reject the ALJ's Recommended Decision. While I adopt the ALJ's findings of fact and conclusions of law with respect to factors one and three, I reject her legal conclusion that Respondent is not liable for Dr. Nichol's misconduct in dispensing controlled substances at its Office, where Dr. Nichol was not registered (and when Respondent was not registered). Moreover, I also conclude that Respondent is liable for failing to maintain records which comply with the CSA. Because Ms. Moore (on behalf of Respondent) has not acknowledged its misconduct in allowing Nichol to dispense from an unregistered location and failing to keep compliant records, I reject the ALJ's implicit conclusion that Respondent's registration is consistent with the public interest. While I agree with the ALJ that upon taking an appropriate course, Ms. Moore may be able to demonstrate her ability to properly comply with controlled substance laws and regulations, I will not grant Respondent's application absent Ms. Moore's acknowledgement of her wrongdoing. I make the following findings of fact.

Findings

Respondent is a limited liability company; its owner and Chief Executive Officer is Ms. Greta B. Moore. GXs 1; 9; 10, at 2; Tr. 48. On March 12, 2012, the Arkansas Department of Health, Pharmacy Services, issued Respondent a temporary certificate for an Arkansas Controlled Substances Registration. RX 19. According to the certificate, this license was good for a period of six months and was due to expire on September 12, 2012. *Id.* While Ms. Moore testified that her license had been extended for ninety days, Tr. 505, the record (as forwarded by the ALJ) contained no evidence as to whether this license remains current.

Accordingly, I issued an order directing Respondent to submit evidence that it retains authority under Arkansas law to conduct research with respect to controlled substances. Order (July 16, 2013). On July 26, 2013, Respondent submitted an email from an official with the Arkansas Department of Health stating that its state registration was extended until December 31, 2013. Email from Marci Middleton-Yates to Greta Moore (July 26, 2013).

On March 15, 2011, Ms. Moore submitted an application on behalf of Respondent for a DEA Certificate of Registration as a researcher in schedules II through V, with the proposed registered location of 3508 JFK Blvd., Suite 1, North Little Rock, Arkansas. GX 1. However, in July 2012, Respondent moved its office to 7510 Highway 107, Sherwood, Arkansas. RX 26.

Between September 1989 and March 1997, Ms. Moore worked as a respiratory therapist. RX 1, at 2; Tr. 374–75. However, as the ALJ found, Ms. Moore's duties ''did not include keeping controlled substance records, and she had very limited experience handling controlled substances.'' R.D. at 6. More recently, from October 2007 through December 2007, Ms. Moore worked as a Clinical Research Coordinator for Research Solutions, L.L.C., which was managing clinic trials for a Dr. Derek Lewis. RX 1, at 1–2. Ms. Moore's duties included the recruitment, retention, and randomization of patients. Tr. 371.

Thereafter, Dr. Lewis decided to no longer use Research Solutions and hired Ms. Moore as his site manager. *Id.* at 372. Ms. Moore was involved in managing some thirty clinical trials before she was fired.[3] *Id.* at 377, 517–18. However, none of these trials involved controlled substances. *See* RX 1, at 3–5.

Subsequently, Ms. Moore decided to open her own business to provide clinical research services and formed Respondent. Tr. 373. According to Ms. Moore, her business is to ''talk with the doctor to determine what the doctor needs'' and ''put together a program that will help the doctor's clinical research programs,'' or to ''be a full-service company, whereby a doctor can come into our site and perform studies in our site, using our resources comparatively.'' *Id.* at 381. Ms. Moore further explained that ''[s]ome doctors like to keep their clinic practice and their clinical research practice separate,'' and that ''[e]ven when a doctor is doing clinical research in his office or his practice, what you would generally find is that the clinical research practice is a total [sic] separate entity'' and that ''[t]he staff is totally different.'' *Id.* at 383. Ms. Moore also explained that while the doctors ''do the medical things that patients need,'' unless the ''doctor is solely doing research . . . most of the recordkeeping is going to be done by the coordinator.'' *Id.* at 384–85. Ms. Moore then asserted that ''[u]ltimately the doctor is totally responsible for the clinical research study.'' *Id.*

Ms. Moore also denied that she allowed anyone who was not licensed to dispense at Respondent, stating ''[w]e don't dispense. We do accountability. For instance, if a patient brings back the drug, then we are responsible to document return[ed] tablets and things like that.'' *Id.* at 386.

Ms. Moore proceeded to market Respondent to contract research organizations (CROs), which are firms that drug manufacturers contract with to provide support services for clinical trials. *Id.* at 386, 389. In the meantime, Respondent entered into a contract with Dr. Brian Nichol, an interventional pain management specialist, to perform clinical research for it pursuant to contracts it might obtain from CROs. *Id.* at 387; GX 10.

At some point in late 2010 or early 2011, Respondent received information that Quintiles, a CRO, was managing clinical trials of the drug Naloxol 6a-methoxyhepta(ethylene glycol) ether (hereinafter, NKTR–118), for AstraZeneca, a large pharmaceutical manufacturer.[4] Tr. 387–90; GX 9. NKTR–118 is, however, a schedule II controlled substance. Tr. 266; RX 9.

Respondent applied to Quintiles to participate in the study and was selected by the latter for a site visit which occurred on February 15, 2011. RX 3, at 1. During the visit, the Quintiles representative discussed with Dr. Nichol, Ms. Moore, and Kianna Marshall (Respondent's research project

[3] Ms. Moore testified that she was not fired directly by Dr. Lewis but by Dr. Lewis' subordinates. Tr. 517–18. She further testified that she never learned the reason for her dismissal and the record contains no evidence on the issue. Tr. 518.

[4] The name of the study was: ''An Open-Label 52-week Study to Assess the Long-Term Safety of NKTR–118 in Opioid-Induced Constipation (OIC) in patients with Non-Cancer-Related Pain.'' RX 14, at 1.

coordinator, *see* GX 9, at 1) ''the protocol, . . . investigational product storage, [the] document storage areas, lab area, patient exams rooms, and monitoring areas.'' RX 4, at 1. The Quintiles representative further advised Dr. Nichol and Ms. Moore of other requirements for participating in the study, including that ''[t]he site must obtain a DEA license for research with a controlled substance'' and provided ''[i]nformation for obtaining this license'' to Ms. Moore. *Id.* Moreover, Ms. Moore testified that during the meeting with the Quintiles representative,

> we were told that the drug had been scheduled by the DEA as a controlled II substance, and we were also told that the pharma does not believe that their drug has the properties of a controlled II substance, but based on the scheduling, then the sites would need a DEA license.

Tr. 400.

On March 30, 2011, Respondent (who was designated as the ''Institution'') and Dr. Nichol (who was designated as the ''Investigator'') entered into a Clinical Trial Agreement (CTA) with Quintiles, to participate in the NKTR–118 long-term safety study, with Quintiles acknowledging its agreement on April 5. RX 14, at 1–2, 16. The CTA's terms required, *inter alia,* that ''Institution, Investigator and their personnel shall perform the Study *at Institution's facility* according to the Protocol and this Agreement, and shall comply with all: (i) Applicable local, state and federal laws and regulations relating to the conduct of the Study.'' *Id.* at 2 (emphasis added). In addition, Respondent and Dr. Nichol:

> each represent[ed], warrant[ed] and promise[d] that . . . Institution and the Investigator have, at all times during the course of the Study, the appropriate licenses, approvals and certifications necessary to safely, adequately and lawfully perform the Study in accordance with good clinical practice, FDA requirements and all Applicable Laws and have no notice of any investigations that would jeopardize such licenses, approvals or certifications[.]

Id. at 2.[5]

As stated above, on March 14, 2011, Ms. Moore applied on Respondent's behalf for a DEA researcher's registration. GX 1. On March 31, 2011, a DEA Diversion Investigator (DI) with the Little Rock District Office sent Ms. Moore a list of various items of information that she should have available during the on-site inspection, RX 7, at 2; and on April 14, 2011, two DIs went to Respondent's then-location to conduct a pre-registration investigation. Tr. 31. The DIs determined that Respondent's facility was located on the ground floor of an office building, and that while the entire building had an alarm system, if another tenant turned off the alarm or left the building without turning the alarm on, the building would not be secure. Tr. 158–59. However, in response to the DIs' concerns, Ms. Moore installed an alarm in her office. *Id.* at 159–60.

During the visit, the DIs interviewed Ms. Moore, who told them that the proposed research involved studying the safety of NKTR–118 for use on patients with opiate-induced constipation. Tr. 266. Ms. Moore told the DIs that the drug would be supplied by Fisher Clinical Services and stated that Respondent had a contract with Fisher to provide the drug; however, when asked to provide the contract, Ms. Moore could not do so. *Id.* at 267. Ms. Moore also told the DIs that Dr. Brian Nichol ''would be the principal investigator.'' *Id.* at 297. A DI who conducted the inspection testified that it was her understanding that Ms. Moore and Ms. Marshall ''would dispense the drugs'' and that Dr. Nichol ''would come into the clinic approximately two to three times a week and basically review the charts and do the patient evaluations.'' *Id.* at 298.

At the conclusion of the interview, the Senior DI provided Ms. Moore with a copy of the Code of Federal Regulations. *Id.* at 274. She also reviewed the recordkeeping requirements of Part 1304, as well as the requirements pertaining to the ordering of schedule II controlled substances under Part 1305. *Id.*

On April 21, 2011, Ms. Moore sent a letter by fax to the Senior DI, stating that Respondent had installed ''an in suite alarm.'' RX 12. On April 27 (following a phone conversation two days earlier), Ms. Moore sent an email to the DI explaining that Respondent had met all requirements; Ms. Moore also wrote that it was ''not required to have any site license(s) to conduct human subject research.'' RX 13, at 1. Ms. Moore further noted that the DI had told her that the DI's ''superior had a couple of questions regarding our application'' and advised that ''if there are more questions please email me.'' *Id.* Following additional emails sent by Ms. Moore on April 29 and May 4, 2011 asking the DI if there were ''[a]ny further requirements,'' on May 6, the DI wrote Ms. Moore that she ''need[ed] a copy of your signed contract with Fisher for further review of your application.'' RX 13, at 1–2. Ms. Moore then emailed the Quintiles representative who had performed the February on-site visit, asking if she had a copy of the Fisher contract; the Quintiles Representative agreed to ''get right on this.'' RX 13, at 3.

Less than a week later, Ms. Moore emailed the DI regarding the issue and discussed a phone conversation the DI had with another representative of Quintiles, who explained that Respondent did not have a contract with Fisher but rather with Quintiles. RX 15, at 1. Ms. Moore then stated that the Quintiles representative had advised her to send a copy of Respondent's contract with Quintiles, as well as a letter from the FDA's Controlled Substance Staff to Astra Zeneca. *Id.* Ms. Moore testified that she sent these documents as an attachment to the email. Tr. 450. Ms. Moore further wrote that ''[i]f I have not proceeded properly, or additional information is needed please let me know as soon as possible, as time is of the essence.'' RX 15, at 1. *Id.* In response, the DI asked Ms. Moore to come to the DEA office ''to discuss further details regarding [the] application. *Id.* at 2.

On May 16, Ms. Moore went to the DEA Office and met with the two DIs who had made the onsite inspection and the Diversion Group Supervisor (GS). Tr. 32–33. According to the GS, she was concerned as to whether Ms. Moore was qualified to be a researcher ''because she did not have MD, DO or Ph.D. behind her name'' and ''didn't know what kind of qualifications, training, or experience she had.'' *Id.* at 34. The GS testified that she checked the registration database to see ''if DEA had granted any other registrations to persons who were not licensed in that fashion,'' *id.* at 34–35, ''printed out all of Fisher's customers,'' *id.* at 39, and determined that they were generally medical doctors, doctors of osteopathy, or Ph.D.s ''affiliated with a hospital or a university.'' *Id.* at 42.

During the interview, Ms. Moore was asked about her experience in handling controlled substances. *Id.* at 49. According to the GS, Ms. Moore ''at first . . . said she had quite a bit of experience, but upon further questioning, it turned out [that] controlled substances were in the facility, but she did not actually handle the drugs herself.'' *Id.* Ms. Moore further stated that she did have research experience, which primarily involved ''handling the paperwork.'' *Id.* at 50.

During the interview, Ms. Moore stated that Dr. Nichol would be responsible for ordering and receiving the controlled substances at

[5] The CTA also provided ''that if [the] Site has not enrolled at least one (1) subject by the Key Enrollment Date,'' RX 14, at 3, which was ''100 Calendar Days after [the] Site Initiation Visit,'' *id.* at 1, then Quintiles could terminate the agreement. *Id.* at 3.

Respondent, as well as keeping the controlled substance records for it. *Id.* at 50–51. Ms. Moore also stated that Dr. Nichol ''would be present at [Respondent] three to four days a week.'' *Id.* Dr. Nichol was registered at 5106 McClanahan Drive, Suite B, North Little Rock, Arkansas. Tr. 487 (testimony of Ms. Moore); RX 22.

According to Ms. Moore, during the meeting, the DIs told her that her application was being denied because she did not met the ''criteria'' found in the U.S. Code. *Id.* at 457, 460. Ms. Moore testified that when she asked what criteria she did not meet, a DI said that Fisher (the drug supplier) ''only contracted with doctors.'' *Id.* at 458. Ms. Moore testified that she had previously sent a copy of the contract she had with Quintiles [6] to the DI and clarified that ''I did not have a contract with Fisher.'' *Id.* Upon reviewing the provisions of the U.S. Code, the GS told Respondent that she did not have a state license and lacked experience in dispensing controlled substances. *Id.* at 462. The DIs eventually asked Ms. Moore to withdraw her application; when Ms. Moore declined to do so, the DIs told her that they would file an order to show cause. *Id.* at 464.

In a subsequent phone conversation, Dr. Nichol confirmed to a DI that he would be ordering the drugs and acting as Respondent's medical director. *Id.* at 56. Dr. Nichol also stated that ''[a]fter the initial work-up of a new patient coming to the clinic for the trial . . . he would be at the clinic once a month for about 30 minutes or so to dispense the medications.'' *Id.* at 56–57. However, according to the GS, Dr. Nichol also stated that he was not ''going to do research at his own facility, because he didn't have the staff.'' *Id.* at 57.

On some date which is not clear on the record, Ms. Moore started recruiting patients by advertising the study on television. *Id.* at 473–74. Following screening, which included a physical exam by Dr. Nichol, various patients who met the criteria for participation were placed in the study.[7] *Id.* at 475–77. In total, eleven patients were selected for the studies, with five being placed in the Kodiac 8 study (two of whom dropped out) and six being placed in the Kodiac 5 study. *Id.* at 477, 481.

Ms. Moore testified that she was aware that Dr. Nichol had a DEA registration and it was her understanding that he could ''participate in our study'' and ''dispense'' the drugs. *Id.* at 484–85. Ms. Moore testified, however, that Dr. Nichol was registered at 5106 McClanahan, Tr. 487, and not at Respondent's office. Ms. Moore further maintained that the drugs were to go to Dr. Nichol's site and that ''he would be required to dispense the drug to the patients'' and the drugs were not to be stored at Respondent. *Id.* at 485. Ms. Moore denied that she dispensed any of the drugs. *Id.* at 486. However, when asked where Dr. Nichol dispensed the drugs, Ms. Moore testified that he ''dispensed the drug in his site or MCT.'' *Id.*[8] Ms. Moore admitted that she never asked the DEA Investigators whether Dr. Nichol could lawfully transport the controlled substances to Respondent and dispense them there. *Id.* at 538.

Ms. Moore testified that in ''early 2012 [9],'' she learned that Dr. Nichol's relationship with DEA had changed and he ''was no longer allowed to dispense from'' Respondent. *Id.* at 497–98. Ms. Moore subsequently explained that this occurred around the time that Nichol entered into a Memorandum of Agreement (MOA) with DEA. *Id.* at 615–16. Ms. Moore maintained that following this, ''[a]ll the patients were . . . dispensed from Dr. Nichol's office.'' *Id.* at 498. However, patients would still come to Respondent for lab draws and EKGs, as there were ''different procedures that would need to be done where the equipment was.'' *Id.* at 499.

In November or December 2011, one or more of the DIs ''saw a television commercial'' which sought patients to participate in the NKTR–118 study. *Id.* at 58. In either February or March 2012, a DI contacted the Arkansas Department of Health and asked an official if Respondent had received a state license. *Id.* The official stated that ''Dr. Nichol had given them a letter, and . . . stated that he would be transporting this NKTR drug to [Respondent] for the research project.'' *Id.* at 58–59.

Months later, in July 2012, the GS contacted John Wegner, a Quintiles official and asked if Quintiles had approved Respondent for participation in the NKTR–118 study. *Id.* at 61. The GS testified that the reason why she had contacted Mr. Wegner was ''because we saw the commercials on TV that [Respondent] was doing research.'' *Id.* It is unclear, however, whether the impetus for this contact were the commercials that the DIs had seen in late 2011 or more recent ones.

In any event, Mr. Wegner told the GS that Dr. Nichol was ordering the controlled substances, which were being shipped to Nichol's registered location, and that Dr. Nichol was transporting them to Respondent, where they were being dispensed. *Id.* at 61–62; *see also* GX 16, at 2. The GS told Mr. Wegner that this ''was illegal because [Respondent] was not a DEA-registered location.'' Tr. 62. The DI then contacted Mr. Jim Phillips, Dr. Nichol's attorney, and asked him if Nichol was involved in the research study and transporting controlled substances to Respondent. *Id.* at 63. Mr. Phillips acknowledged that Nichol was involved in the study and that he was transporting the controlled substances to Respondent and dispensing them. *Id.* Moreover, Mr. Phillips stated that this had been ongoing ''[a]t least since April of 2012.'' *Id.* at 64. However, Mr. Phillips did not know if Dr. Nichol had been doing this even earlier. *Id.*

The DI also requested of Mr. Phillips that Dr. Nichol provide his records, including the dispensing records and the schedule II order forms (DEA Form 222). *Id.* Two weeks later, Mr. Phillips contacted the DI and explained that because the NKTR–118 study was double blinded, neither the patient nor Dr. Nichol knew which patient received the schedule II drug or the placebo. *See* GX 16, at 1–2. In the letter, Mr. Phillips further wrote that ''Dr. Nichol will administer the drugs only at his DEA approved address'' and that ''[w]e will notify the DEA in advance of any upcoming trials involving controlled substances.'' *Id.* at 2. Mr. Phillips then acknowledged that ''[a]ll of this has been previously agreed upon and is clearly stated in the'' MOA.[10] *Id.*

[6] As found above, Ms. Moore had previously sent a copy of her contract to the DI. RX 15.

[7] The criteria included that the patients could not be using any prohibited medications, must be taking a specified amount of opiates (which were prescribed by their regular doctor), and could not ''have any GI conditions.'' Tr. 476–77.

[8] When asked why, at the beginning of the study, Dr. Nichol would dispense at his office rather than at Respondent's location, Ms. Moore offered the incoherent response that: ''He's a busy doctor, and where it was an inconvenience to the patients to go there, we would send the patients there, because he may not be able to . . . meet them, so we would send them there, and he would dispense there.'' Tr. 488.

[9] Subsequently, Ms. Moore testified that she learned about the MOA in ''[m]id-2012. I say in the middle range of the year.'' Tr. 631.

[10] The MOA between DEA and Dr. Nichol was submitted into evidence by Respondent. *See* RX 22. The Agreement recounts that ''[o]n September 27, 2011, DEA issued an Order to Show Cause'' to Dr. Nichol, which proposed the revocation of his registration based on three allegations. *Id.* at 1. First, that the Arkansas State Medical Board had found that Dr. Nichol ''pre-signed controlled substance prescriptions, which were then issued to patients by [his] staff '' when he was ''not present and [was] not consulted by [his] staff when [the] prescriptions were issued.'' *Id.* Second, that in May 2008, he was convicted of health care fraud, in violation of 18 U.S.C. 1347, and was subsequently excluded from participating in Medicare and Medicaid by the Department of Health and Human Services pursuant to 42 U.S.C. 1320a–7(a). *Id.*

In late July 2012, the GS was notified that Respondent was moving its office. Tr. 69. On August 24, 2012, the GS and another DI went to Respondent's new office to conduct an inspection, and met with Ms. Moore and her attorney, Ashley Hudson. *Id.* at 70–71. According to the GS, Ms. Moore ''explained her recordkeeping system to us, how she got the drugs, how she made the records. She showed us how they logged dispensations to the patients. She also had copies of the DEA 222 order form in her notebook.'' *Id.* at 71–72. Ms. Moore explained, however, that the records onsite were copies and that ''all the originals were kept at Dr. Nichol's registered location.'' *Id.* at 72–73.

The GS testified that upon seeing the records, she asked Ms. Moore where the NKTR–118 was being dispensed, and that Ms. Moore stated that ''the drugs were dispensed at Moore Clinical Trials.'' *Id.* at 72; *see also id.* at 711 (testimony of second DI that during August 24 inspection, Ms. Moore ''stated that NKTR was dispensed from the new location . . . in Sherwood, Arkansas,'' and that Ms. Moore never stated that Nichol had dispensed the NKTR at his office). The GS further testified that Ms. Moore also ''stated that Dr. Nichol had transported [the] drugs to that location [Respondent's previous office] as well.'' *Id.* at 72.

After Ms. Moore told the GS that Nichol had been transporting the drugs to Respondent and dispensing them, the GS told Ms. Moore that this was illegal because Respondent's location was not registered. *Id.* at 74. According to the DI, Respondent ''made no comment'' in response. *Id.* Nor, according to the GS, did Ms. Moore ever assert that any of the dispensings had occurred at Dr. Nichol's office.[11] *Id.*

On cross-examination, the Government asked Ms. Moore if she had informed the DIs that she understood ''that Dr. Nichol was no longer allowed to dispense NKTR from MCT.'' Tr. 534. Respondent answered:

> I didn't understand that the investigators were coming to my site to talk about Dr. Nichol. I thought they were coming to my site to look at my site to get further information about my 225 application. I didn't inform them anything about Dr. Nichol until the very end, when I was asked that very question.

Id. at 534–35.

The Government then asked Ms. Moore: ''[s]o you're asked, where is Dr. Nichol dispensing the NKTR, and your answer to them was at MCT. Is that correct?'' *Id.* at 535. Ms. Moore replied:

> That is not correct. I was not asked that. Actually, there was a statement made to me by [the] GS . . . that said, you know Dr. Nichol is not supposed to dispense from MCT. And I said, Uh-huh-yes.

Id. However, Ms. Moore did admit that ''for part of the time,'' Respondent's arrangement was that Dr. Nichol ''was to receive the controlled substances in his office'' and subsequently take them to Respondent to dispense the drug to the research subjects. *Id.* at 538.

The GS also testified that the records did not indicate the name or initials of the person who had dispensed the drugs. *Id.* at 73. The GS then asked Ms. Moore who had dispensed the drugs; Ms. Moore said that Dr. Nichol had. *Id.* at 73–74. Moreover, the GS testified that upon reviewing the DEA Form 222s, the forms did not indicate the date the drugs were received and the quantity received. *Id.* at 78.

On September 4, 2012, the GS received the dispensing records she had previously requested from Mr. Phillips, Dr. Nichol's attorney. *Id.* at 75–76; *see also* GX 14. While the GS testified that the records show that the controlled substances were dispensed at Dr. Nichol's registered address, *id.* at 76, only the first page of the forms, which is not a dispensing record at all but rather a list of persons designated by Dr. Nichol ''to access controlled substances at the above location address,'' listed Dr. Nichol's address. *See* GX 14, at 1. With the exception of a single shipping document entitled ''Blinded Shipment Request,'' which appears to have been created by Astra Zeneca, *see* GX 14, at 13, all of the forms are designated as an ''MCTLLC Form'' with a number,[12] and stated that they were ''[c]reated by: Moore Clinical Trials LLC'' on August 27, 2012. *See generally* GX 14.

As for the shipping document, while it lists eighteen kits of ''[r]andomised (blinded) drug'' and Dr. Nichol's registered location as the Shipping Address, it also listed Respondent's phone number as the ''shipping phone.'' *Id.* at 13; Tr. 84–85. The GS testified that Ms. Moore had signed for the drugs. Tr. 85.

Regarding the records created by Respondent, the GS further testified that they did not differentiate between the two strengths of the drug. Tr. 88. And regarding Respondent's Form 1, an inventory record for the Kodiac 5 arm, *see* GX 14, at 22; the GS testified that the figure for the quantity on hand in the final entry of August 28, 2012 was erroneous. *Id.* at 90. The GS testified that the correct figure should have been 3500 dosage units and not either the number 1120, which was lined out, or the number 1373. *Id.* According to the GS, when the numbers were added up—more specifically the 32 bottles (each containing 35 dosage units) that were listed on the form as ''number of kits/bottles received'') to the previous quantity on hand figure of 2380—the total was 3500. *Id.; see also* Tr. 134.

On cross-examination, the GS was asked to explain how she came up with this figure. The GS maintained that she did so by ''following the methodology that Ms. Moore used, that 32 bottles at 35 tablets apiece is 1,120 tablets,'' and that she added these tablets to the previous quantity on hand ''[b]ecause all the other entries were added in.'' *Id.* at 131–32. When then asked what was listed in the August 28, 2012 entry for the Shipment ID Number, the GS acknowledged that the entry stated: ''Kits Remaining Unused'' and that no shipment was listed. *Id.* at 132. When

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Third, that he ''contracted with a researcher to administer a controlled substance [NKRT–118] to research subjects,'' but that ''[t]he owner/operator of this research clinic has no experience handling controlled substances, and that [he] and the owner/operator gave conflicting information about the operation of this research clinic.'' *Id.* at 1–2.

Notwithstanding these allegations, the Agency allowed Dr. Nichol to retain his registration subject to various terms and conditions. Of relevance here, Dr. Nichol agreed that he ''will not administer or dispense . . . controlled substances except in the course of his own medical practice as an individual practitioner and will administer or dispense . . . controlled substances only from his DEA registered location. As the physician who is contracted to administer the FDA approved study drug NKTR–118, Dr. Nichol will administer that drug at either his DEA registered location or at an approved site for the current drug study.'' *Id.* at 3. The Special Agent in Charge approved the MOA on April 17, 2012, and Dr. Nichol signed the agreement on April 20, 2012. *Id.* at 4.

[11] At the hearing, Ms. Moore denied that it was her understanding that Respondent could not dispense controlled substance until it got its DEA registration; she also testified that she did not think that it was illegal for Dr. Nichol to bring the controlled substances to Respondent and dispense them there. Tr. 537–39. Still later, Ms. Moore testified that she ''didn't understand that [Respondent] was dispensing or ordering'' and asserted that ''[w]e weren't dispensing or ordering any controlled substances.'' *Id.* at 597.

[12] More specifically, MCTLLC Form 5 lists the persons who Dr. Nichol authorized to access the controlled substances, *see* GX 14, at 1; MCTLLC Form 4 lists the DEA Order Forms (222s) which were submitted to Fisher Clinical Services, along with the amounts ordered and received, as well as the dates of the orders and receipts, *see id.* at 2; MCTLLC Form 2 lists the drug, the quantity, the date received, the distributor, and the invoice number, *id.* at 4; MCTLLC Form 3 is a perpetual inventory which lists quantities on hand, the amounts received in incoming shipments, the amounts dispensed along with the study subjects' initials and subject number, and the amounts returned by them, *id.* at 5; and MCTLLC Form 1 lists the inventory, including incoming shipments but not the drugs dispensed. *Id.* at 8. The latter also includes a final entry, dated August 27, 2012, the same date the document was created, that lists the number of bottles unused and the number of tablets that were returned by the study subjects. *See id.* at 9.

asked if she counted the 32 bottles as a new shipment, the GS testified that: ''I counted it because it was the same methodology. Now, if it had been just the number of tablets remaining, it would have been the 1,120, which is crossed out.'' *Id.* at 133. The GS then denied that the math would have worked out if she had just calculated the 32 bottles as ''kits remaining unused'' and asserted that ''[t]he math works with the 1,373 number.'' *Id.*

Throughout her testimony, the GS insisted that in coming up with the 3500 figure, she was following Ms. Moore's methodology.[13] *See id.* at 134–35. However, the GS acknowledged that she did not contact either Ms. Moore or Dr. Nichol and ask them what ''kits remaining unused meant.'' *Id.* Ms. Moore later explained that this term meant ''kits that were never dispensed'' and that this entry did not reflect a new shipment. *Id.* at 622.

The GS testified that using the records provided by Dr. Nichol's attorney, she created a computation chart in which she added the quantities of drugs received in each arm of the study to the initial inventory (which was zero), to determine the total amount that Dr. Nichol was accountable for; she then took what she called the closing inventory and added to it the quantities which were distributed to calculate the total amount Nichol could account for, and compared the two. Tr. 95–100; GX 15. However, the closing inventory was not based on an actual physical count performed by the DIs but on the records provided by Dr. Nichol. Tr. 99, 623.

The GS further testified that she made two sets of calculations, one based on the closing inventory figures Ms. Moore listed on the documents, and the other based on what the GS called ''the correct math.'' *Id.* at 105. Subsequently, the GS testified that this was not ''a normal DEA audit'' and that these ''are Dr. Nichol's records'' and ''not Ms. Moore's records.'' *Id.* at 142. Moreover, the GS testified that she did not contact Dr. Nichol about the records. *Id.* at 143.

Regarding the records which were provided by Dr. Nichol's counsel, Ms. Moore acknowledged that she had created them, and that they had been created between August 24 and 27, 2012. Tr. 544–45. The Government also asked about a computation chart (GX 18), which Ms. Moore had created, with Ms. Moore testifying that the chart was based on Dr. Nichol's records for the Kodiac 5 and 8 studies. *Id.* at 546–48. Ms. Moore denied, however, that the chart should differentiate between the 12.5mg and 25mg strength dosage units, contending that because the studies were blinded, she would not know which kits contained what strength tablet; she also testified that the information could not be discerned from the sponsor's records. *Id.* at 549.

Ms. Moore then testified:

> I'm sorry . . . but I don't know anything about the true nature of creating these records. My intent in creating these records was simply to have [the GS] affirm to me that I was on the right track, so this record is not a response to any of these other beings. I'm simply trying to create records, because my understanding after the visit with [the GS] was the DEA's main concern is compliance.
>
> So my main concern after what I thought was my . . . on-site visit at the second point was to attempt to be compliant with the DEA, so I'm simply creating forms, not for the DEA. I didn't realize that the DEA was going to get these forms. The reason that the forms are not correct is because it was eleven o'clock at night when I did the forms. My intention was to have an opportunity to think on, [w]hy are my forms not balancing. But before I could do that, which would have been the next day, when I went to Dr. Nichol's office, the forms had been submitted to the DEA.

Id. at 550–51; *see also id.* at 563 (further testimony from Ms. Moore to same effect).[14] And on further questioning, Ms. Moore again re-iterated that the bottles did not indicate whether they were 12.5 or 25 mg tablets. *Id.* at 553.

Regarding the computation chart Ms. Moore created (GX 18), the Government attempted to show that the ''total accountable for'' figures did not add up to the ''total accounted for.'' More specifically, the Government noted that on the ''total accounted for'' side of the chart, Ms. Moore had four columns: (1) the closing inventory, which included the sum of the drugs returned and not dispensed (192); (2) the number distributed/transferred (438); (3) the number of tablets returned unused (87); and (4) the number of tablets not dispensed (105). Tr. 557; GX 18. According to Ms. Moore's chart, for the Kodiac 8 study, Dr. Nichol was ''accountable for'' 630 tablets and ''accounted for'' 630 tablets. GX 18.

The Government then asked Ms. Moore how she arrived at the 630 figure, given the figures in the four columns totaled 822 and not 630. Tr. 557–60. Ms. Moore testified that ''what I attempted to do was to show the number of tablets that were received per these shipping documents. That's 630, the number of tablets that were dispensed, the number of tablets that were returned, the number of tablets that never left the site, and the closing inventory.'' *Id.* at 560. Ms. Moore then explained that ''[w]here the DEA's example of this sheet may balance the way you're saying, that's not the balance, because the balance can only be the number of tablets that were actually received per the shipping documents.'' *Id.*

When the Government then asked if the ''total accountable for'' and the ''total accounted for'' should be the same, Ms. Moore replied:

> If I'm looking at this record, if I add 438, 87—perhaps I should have done some lines more similar to this form, where you could see double lines, but because I really didn't have any real direction on how to do it, I'm simply making an example. This is not for the DEA. This was simply just to try to be compliant, which is what I was told.

Id. at 560–61; *see also id.* at 570 (''This is not a record for the DEA. This is simply just to try to be compliant, to try to do what [the GS] told me in my meeting that I did not realize was an audit.''). Ms. Moore added that she was ''simply learning how to do the form, trying to do the form properly, but you can't use this form as a proper documentation of anything. This form balances to my sponsor form, which is what is important to me, that my sponsor's count is correct.'' *Id.* at 561.[15] However, on redirect, Ms. Moore clarified that ''the number of tablets returned unused, plus the number of tablets not dispensed'' equals the closing inventory. *Id.* at 625. She also testified that the ''number of tablets returned unused'' was documented ''[i]n

[13] Likewise, in determining the closing inventory for the drugs that were received and dispensed in the Kodiac 8 study, the GS determined that ''the correct math'' was 822 dosage units and not 192 dosage units as recorded on the form. *See* GX 14, at 9; Tr. 105–07. However, the form was not a perpetual inventory, but rather, a record of inventories taken periodically as well as when shipments were received. *See* GX 14, at 8–9. Here again, the last entry (which is dated August 27, 2012) does not list a ''Shipment ID Number.'' *Id.* at 9. Rather, it states ''unused/returned'' in this column and indicates that 105 (3 kits) were unused and 87 tablets were returned, for a total quantity on hand of 192. *See id.* The GS, however, simply added up the figures for each shipment, as well as the figures that were listed for August 27, and concluded that Dr. Nichol should have had on hand 822 dosage units. *See id;* GX 15; Tr. 106–07.

[14] *See also* Tr. 564 (''So these records are simply trying to be compliant with what I was told in my on-site visit, that we needed to create records for being compliant. I used these numbers, because this was what I had at hand, but I didn't use these for the DEA. I used these to say, [i]f I were a DEA registrant and I was going to do forms, then I have information I'm trying to put in here to show, hey, I know how to do it; I'm trying to do it right. But it may or may not balance, because it can be used like that. I'm trying to figure out how to do the forms.'').

[15] Ms. Moore further testified that the GS had told her she ''could email a form that I put together, and she would give me a response on whether it was the information that was needed for the DEA.'' Tr. 620. Ms. Moore asserted that she did send the GS a form to review but received no response. *Id.* at 621; *see also* RX 25.

our sponsor's records[16],'' and that ''every time the patient would return drug, you're required to do accountability, because in the study, there's a certain accountability that the patient has to maintain to stay in the study.'' *Id.* at 636–37. Finally, Ms. Moore testified that the numbers on the forms she created ''match my sponsor's records'' and that ''[t]he sponsor has signed off on the records.'' *Id.* at 638.

Regarding the forms she created (GX 14), Ms. Moore testified that she used the sponsor's records to create them. *Id.* at 562. Ms. Moore further explained that:

> [t]hose are the records that are important to the sponsor and important to the study. Nowhere in keeping records was there ever any indication, until [the GS] came to my site, that we were to keep two sets of books. I never heard that, but I'm not a registrant, so maybe if I were, I would have heard it and known that. But this was simply in response to the on-site visit in my office on 24th of August 2012.

Id. at 564–65. Still later, Ms. Moore reiterated that she was not aware that Dr. Nichol was required to keep controlled substance records for the NKTR studies (for DEA) until the August 24, 2012 visit. Tr. 822–23.

Addressing the GS's computation chart (GX 15), Ms. Moore maintained that the Kodiac 8 study had received only 630 dosage units and not 717 as asserted by the GS. Tr. 574. She also disputed the GS's conclusion that using the ''correct math'' for the Kodiac 8 study resulted in an overage of 630 dosage units. *Id.* at 575. And when asked about the closing inventory figure for the Kodiac 5 study (GX 14, at 22), Ms. Moore maintained that neither the GS's 3500 figure, nor the 1120 figure (which was crossed out), were correct. Tr. 576. Instead, she explained that 1373 (as is written on the form) was correct, because it included both the bottles that were not dispensed (32, each with 35 tablets) and the tablets that the patients returned.[17] *Id.*

The Government also asked Ms. Moore if she knew ''that it is a required dispensing record to put down the location where the controlled substances were dispensed from?'' Tr. 583. Ms. Moore testified that she does not

> know what is required, but as a compliant person, I'm more than happy to learn what is required as a DEA registrant, because I am prepared to do whatever needs to be done, as I do my clinical research, because there are requirements that are required there as well. So after I learn what is required . . . I'm fully prepared to be compliant.

Id. at 584. Ms. Moore also testified that in her discussion with the GS regarding the records, the GS ''did not'' tell her that she needed to have a column to indicate where the drugs were dispensed.[18] *Id.* at 620.

On cross-examination, the Government also asked Ms. Moore whether, prior to entering into the contract with Dr. Nichol in 2010, she was aware of his history with the Arkansas Medical Board, which had suspended him for pre-signing controlled substances prescriptions. *Id.* at 590. Ms. Moore answered that she was not aware of his history, but was aware that he had a current medical license. *Id.* Ms. Moore then added that she found out ''some things'' later, but could not say when she did. *Id.*

The Government then asked Ms. Moore whether, prior to entering into the contract with Dr. Nichol in 2010, she was aware that he had been convicted of felony health care fraud in federal district court. *Id.* Apparently referring to an un-admitted exhibit, Ms. Moore testified that she had ''never seen this before'' but that she ''would like to have . . . documentation to just confirm . . . what you're saying is true.'' *Id.* at 590–91. Ms. Moore then testified that she did not know this information, and that she ''can't just confirm it, based on what you're showing me here.'' *Id.* at 591. When the Government followed-up by asking whether, regardless of the documentation (that was not admitted), she knew, prior to entering into the contract, that Dr. Nichol had been suspended by the state board and been convicted of health care fraud, Ms. Moore testified that she did not ''know the answer to that'' but did ''know that in our relationship, I knew it.'' *Id.* at 592. Ms. Moore then explained that when she ''met Dr. Nichol, he had a valid license, and he was not under any restrictions on the license that I obtained, and so in my estimation of our business relationship, he was okay to do research.'' *Id.*

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that ''[t]he Attorney General shall register practitioners . . . to dispense, or conduct research with, controlled substances in schedules II, III, IV, or V . . . if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under

[16] On rebuttal, Respondent also introduced copies of a Sponsor Record entitled: ''NKTR–118 Accountability Form.'' RX 23. This form includes a column for the date drugs were either received or dispensed, a column for a shipment ID number, a column for a Subject Number, Kit Number, number of tablets dispensed or returned, the recorder's initials, the balance, and comments (the latter indicating whether drugs were dispensed or returned, or a new shipment was received). *See* RXs 23 & 24. While these records were introduced into the record to refute the testimony of the DIs that Dr. Nichol had continued to dispense controlled substances from Respondent's new office, the documents show that a dispensing occurred on August 3, 2012, two days after Ms. Moore said the new office had opened. *See* RX 23, at 12; RX 26, at 2.

[17] Having reviewed Respondent's Form 3 for the Kodiac 5 study, *see* GX 14, at 14–20; I find that 253 tablets were returned by the study subjects. When added to the number of dosages units that were not dispensed (1120), the total is 1373.

[18] Respondent also called as a witness a former DEA Diversion Investigator from the Little Rock office, who asserted that Ms. Moore's application was not handled in the same manner as other researchers' applications, which apparently he routinely approved in a perfunctory fashion such as by not even writing the required reports. Tr. 657–58, 716. In addition to expressing his typically erroneous views on various issues (such as whether NKTR–118 was subject to being removed from the schedule of controlled substances or moved to a less-restrictive schedule, *see id.* at 685–86, 714), the former DI also alleged that one of the subordinate DIs involved in the investigation of Respondent had been the subject of an investigation by the Office of Professional Responsibility into her use of racial slurs made to a roommate at the DEA Academy, and that someone intervened to prevent her termination. Tr. 665. The former DI also provided an affidavit, in which he stated: ''I speculate that when the Investigators learned of Ms. Moore's race, that this may have contributed to an Investigator requesting Ms. Moore's application be denied. The Investigator has a history of racial problems.'' RX 21, at 2. However, when asked what information he had that there was a specific complaint that the DI had engaged in racist conduct, the former DI replied: ''What information do I have? You want details on the allegation?'' Tr. 695. The former DI then further acknowledged that he did not have the names of those involved in the purported incident. *Id.*

The former DI did not identify any incidents on the part of the Investigator beyond the purported incident described above, and on rebuttal, the GS testified that she had checked with the Agency's Office of Professional Responsibility and determined that no complaint had ever been filed against the DI. Tr. 715.

Moreover, the former DI admitted that he had been denied a permanent promotion to Group Supervisor and had resigned after the Agency proposed his removal for failing to meet medical standards. *Id.* at 697, 700. Thereafter, the former DI filed an EEO complaint, a petition before the Merit Systems Protection Board, and two lawsuits against the Agency challenging his removal on various grounds. *Id.* at 696–701. However, the former DI lost every challenge. *See id.* Of further note, the DI, who he had accused of racism, had testified against him in a federal court proceeding in which he unsuccessfully sought to enjoin his removal. *Id.* at 697–98.

As did the ALJ, I reject the former's DI contention that Ms. Moore was treated differently on account of her race. *See* R.D. at 8 n.3. While there is evidence that other researchers' application were approved during the former DI's time in Little Rock without an on-site inspection, as the GS testified, Ms. Moore was neither a medical doctor nor a Ph.D., as is typically the case with researcher applicants, and she also had no experience in conducting research with respect to controlled substances. Beyond the fact that Agency personnel have discretion to conduct an on-site inspection whenever they deem it necessary, the unique circumstances posed by this applicant clearly warranted an on-site inspection.

the laws of the State in which [s]he practices.'' 21 U.S.C. 823(f). However, ''[t]he Attorney General may deny an application for such registration . . . if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA directs that the following factors be considered:

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

(2) The applicant's experience in dispensing or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether'' an application for registration should be denied. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[19]

The Government has ''the burden of proving that the requirements for . . . registration . . . are not satisfied.'' 21 CFR 1301.44(d). However, where the Government has met its *prima facie* burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest, an applicant must then ''present sufficient mitigating evidence'' to show why she can be entrusted with a new registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))).

In this matter, I have considered all of the factors. I agree with the ALJ's finding that Ms. Moore violated federal law when she signed for and took possession of a shipment of controlled substances and Respondent was not registered. Moreover, I further agree with the ALJ's finding that Dr. Nichol violated federal law when he dispensed controlled substances at Respondent's office without being registered at that location.

However, for reasons explained below, I reject the ALJ's conclusion that Dr. Nichol's misconduct cannot be imputed to Respondent because the Government has not proved that he acted as Respondent's agent. Contrary to the ALJ's understanding, the Government was not required to prove an agency relationship existed in order to impute Dr. Nichol's violations to Respondent and Ms. Moore. Rather, Dr. Nichol's violations can be imputed to Ms. Moore and Respondent because at a minimum, the evidence shows that they aided and abetted his violations of federal law in dispensing controlled substances at Respondent, which was not registered. Moreover, I find that Ms. Moore and Respondent failed to maintain complete and accurate records as required by the CSA. Because Ms. Moore has failed to accept responsibility for both the dispensing and recordkeeping violations, and, as found by the ALJ, lacked candor in her testimony regarding the dispensing violations, I conclude that she has not rebutted the Government's *prima facie* case.

Factor One—The Recommendation of the State Licensing Authority

Pursuant to 21 U.S.C. 823(f), ''[t]he Attorney General shall register practitioners . . . to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V . . . if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices.'' *See also* 21 U.S.C. 802(21) (''The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.''); *id.* § 824(a)(3) (authorizing the suspension or revocation of a registration ''upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances'').

As explained above, the Government initially sought to deny Respondent's application on the ground that it did not hold authority under state law to engage in research with respect to controlled substances. However, on March 12, 2012, Respondent obtained a temporary Arkansas Controlled Substance Registration, which was due to expire on September 12, 2012. RX 19. Moreover, Respondent's state registration has since been extended until December 31, 2013.

However, while the possession of state authority is an essential condition for obtaining a practitioner's (and researcher's) registration, it '''is not dispositive of the public interest inquiry.''' *George Mathew, M.D.,* 75 FR 66138, 66145 (2010), *pet. for rev. denied, Mathew* v. *DEA,* No. 10–73480, slip op. at 5 (9th Cir., Mar. 16, 2012); *see also Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009). As the Agency has long held, ''the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Mortimer Levin, D.O.,* 57 FR 8680, 8681 (1992). Ultimately, because I conclude that other grounds exist to deny Respondent's application, I hold that this factor is not dispositive and give it nominal weight in the public interest analysis.[20]

Factors Two and Four—The Applicant's Experience in Dispensing, or Conducting Research with Respect to Controlled Substances and The Applicant's Compliance with Applicable Laws Related to Controlled Substances

As found above, it is undisputed that Ms. Moore was previously employed as

[19] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[20] As for factor three, there is no evidence that Respondent has been convicted of an offense ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

a Respiratory Therapist and as a Clinical Research Coordinator. As the ALJ found with respect to Ms. Moore's employment as a Respiratory Therapist, Ms. Moore had limited experience handling controlled substances and no experience in keeping controlled substance records. R.D. at 6. As for her more recent employment as a Clinical Research Coordinator, while Ms. Moore was involved in managing a number of clinical trials, none of these involved controlled substances.[21] *Id.* at 7.

Indeed, Ms. Moore's lack of experience in research with respect to controlled substances was manifested throughout her testimony. For example, Ms. Moore denied that she understood that Respondent could not dispense controlled substances until it obtained a DEA registration, Tr. 537–38, and—as if the law isn't clear enough—did so notwithstanding that the Quintiles representative had advised her in writing that her ''site must obtain a DEA license for research with a controlled substance.'' RX 4. Ms. Moore also testified that she did not think it was illegal for Dr. Nichol to bring the controlled substances to Respondent's office and dispense them there. Tr. 538–39. Subsequently, and notwithstanding that at the very first DEA visit, the DIs provided Ms. Moore with a copy of the Code of Federal Regulations and reviewed the recordkeeping requirements found in Part 1304, Ms. Moore testified that she was not aware that Dr. Nichol was required to keep controlled substance records until the August 24, 2012 visit.[22] *Id.* at 822–23.

Later, when asked if the dispensing record was required to include the location of where the controlled substances were dispensed from, Ms. Moore testified that she does not ''know what is required, but as a compliant person, I'm more than happy to learn what is required as a DEA registrant, because I am prepared to do whatever needs to be done. . . . So after I learn what is required . . . I'm fully prepared to be compliant.'' *Id.* at 584. Thus, while there is some evidence to support Ms. Moore's contention that she is prepared to be compliant (*e.g.,* her installation of the alarm, provision of information to the DIs, and attempts to create compliant records), it is shocking that even at the time of the hearing, Ms. Moore still lacked knowledge of several of the fundamental requirements imposed by the CSA and Agency regulations.

For example, regarding Dr. Nichol's dispensings at Respondent's office, the CSA provides that ''[a] separate registration shall be required at each principal place of business or professional practice where the applicant . . . dispenses controlled substances.'' 21 U.S.C. 822(e). Interpreting this provision, the Fifth Circuit has held that ''[i]f a physician intends to dispense controlled substances from a particular location several times a week *or month,* he must first file a separate registration for the location. This aspect of the registration provisions is beyond cavil.'' *United States* v. *Clinical Leasing Serv., Inc.,* 930 F.2d 394, 395 (5th Cir. 1991) (emphasis added). *See also id.* § 822(b) (''Persons registered by the Attorney General under this subchapter to . . . dispense controlled substances . . . are authorized to possess . . . or dispensed such substances . . . (including any such activity in the conduct of research) *to the extent authorized by their registration and in conformity with the other provisions of this subchapter.*) (emphasis added); *see also* 21 CFR 1301.12(a); *Jeffery Becker, M.D.,* 77 FR72387, 72387–88 (2012).

As for Ms. Moore's testimony that she was not aware that Dr. Nichol was required to keep controlled substance records until August 24, 2012, the CSA provides that ''every registrant . . . shall . . . as soon . . . as such registrant first engages in the . . . dispensing of controlled substances . . . make a complete and accurate record of all stocks thereof on hand.'' 21 U.S.C. 827(a)(1). So too, the CSA requires that ''every registrant . . . dispensing a controlled substance . . . shall maintain, *on a current basis,* a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.'' *Id.* at § 827(a)(3)(emphasis added).

As the Agency has previously explained, ''the CSA creates 'a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the [Act].' '' *Daniel Koller, D.V.M.,* 71 FR 66975, 66981 (2006) (quoting *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005) (citing 21 U.S.C. 841(a)(1), 844(a))). Of particular relevance here, the Supreme Court has noted that '' '[t]he CSA and its implementing regulations set forth strict requirements regarding registration . . . and recordkeeping.' '' *Koller,* 71 FR at 66981 (quoting *Raich,* 545 U.S. at 14). *See also Paul H. Volkman,* 73 FR 30630, 30644 (2008) (''Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.''). In short, the requirements that a practitioner be registered at each principal place of professional practice where he dispenses controlled substances and maintain complete and accurate records of the controlled substances he handles are not arcane rules; rather, they are two of the fundamental features of the closed regulatory system created by the CSA. Yet Ms. Ms. Moore claimed to be unaware of these rules. Ms. Moore's lack of experience in conducting research with respect to controlled substances, when coupled with her lack of knowledge of these essential requirements, provides ample reason to conclude that her registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).[23]

Moreover, the record clearly establishes that Dr. Nichol violated both the separate registration provision and DEA recordkeeping requirements. As for Dr. Nichol's violations of the separate registration provision, it is true that Ms. Moore disputed the testimony of the GS and another DI that during the August 24, 2012 on-site inspection, she was asked where Dr. Nichol was dispensing the drugs and said they had been dispensed at Respondent's offices, and that Ms. Moore never claimed that Nichol had dispensed the controlled substances at his office. Tr. 72, 710–11. Of note, Ms. Moore specifically denied that she was even asked if Dr. Nichol was dispensing the drugs at Respondent. Tr. 535; *see also id.* at 726–27.

[21] I place no weight on the fact that Ms. Moore was fired by her previous employer or that she failed to produce letters of recommendation. *See* Gov. Br. at 24. The Government produced no evidence regarding the circumstances surrounding her termination. Nor has it cited any authority that DEA requires an applicant for a research registration to produce letters of recommendation.

[22] The Government also argues that ''Dr. Nichol's past experience with controlled substances does not qualify him . . . to handle controlled substances.'' Gov. Br. 24. As support for this assertion, the Government cites Dr. Nichol's state board suspension and his exclusion from participation in federal health care programs. *Id.* The Government does not explain why it nonetheless entered into an MOA with Dr. Nichol, pursuant to which it allowed him to keep his registration and did so even after it became aware that he was transporting controlled substances to Respondent's office and dispensing them. I thus reject its contention.

[23] In assessing Respondent's experience in conducting research with respect to controlled substances, the ALJ found ''the fact that Astra Zeneca [actually, Quintiles] granted her a research project indicative of her documented experience at least to their satisfaction for purposes of this study.'' R.D. at 27. As explained above, the determination of whether granting a researcher's registration is consistent with the public interest is vested in the Agency (by delegation from the Attorney General) and not in pharmaceutical companies or CROs. Accordingly, I reject the ALJ's rumination as totally irrelevant.

While the ALJ's opinion contained inconsistent findings on the issue of whether Nichol was still dispensing the drugs at Respondent after he entered the MOA,[24] the ALJ did find that Ms. Moore ''vacillated in her testimony concerning where the controlled substance was actually dispensed,'' and most significantly, that she lacked candor. R.D. at 34. In any event, even accepting Ms. Moore's testimony that Dr. Nichol stopped dispensing at Respondent's offices following his entering into the MOA, I would still conclude that Nichol violated the separate registration provision by dispensing controlled substances at Respondent.[25] In short, the evidence shows that Dr. Nichol made the dispensings on a regular and non-random basis, even if he did so only a few times a month. *See Jeffery J. Becker, D.D.S.,* 77 FR 72387, 72388 (2012). Indeed, for purposes of Dr. Nichol's activities as a researcher, Respondent's office was in every sense an '' 'important or consequential' '' place of professional practice. *Clinical Leasing Serv.,* 930 F.2d at 395; *see also id.* (''If a physician intends to dispense controlled substances from a particular location several times a week or month, he must first file a separate registration for the location.'').

Moreover, while Ms. Moore maintained that if she is granted a registration, the physicians Respondent contracts with will be responsible for the dispensing and recordkeeping of the controlled substances, as the ALJ recognized, under federal law, if controlled substances were dispensed at Respondent's office, it was responsible for maintaining complete and accurate records. *United States* v. *Clinical Leasing Serv., Inc.,* 759 F. Supp. 310, 313 (E.D. La. 1990), *aff'd* 925 F.2d 120, 123 (5th Cir. 1991). As the court explained:

> The clinic is charged with failure to maintain proper records. The law clearly requires every ''person'' (including a corporation) to maintain proper records if that person dispenses controlled substances. By employing physicians to dispense drugs in connection with its operation, the clinic is a dispenser of controlled substances. Therefore, *the clinic, as well as the physicians it employs, must maintain the proper records required by law.*

759 F. Supp. at 312 (emphasis added).

The court expressly rejected the clinic's contention that ''it was not required to maintain records,'' because ''the record keeping requirements pertain only to 'registrants,' '' noting that 21 U.S.C. 842(a)(5) ''does not require that one who refuses or fails to make, keep, or furnish records be a 'registrant,' '' but applies to ''any person,'' including '' 'an individual, corporation . . . business trust, partnership, association, or other legal entity.' '' *Id.* at 313 (quoting 21 CFR 1301.02(j)). Multiple federal courts have likewise rejected the contention that the CSA's recordkeeping requirements do not apply to non-registrant owners of clinics which dispense controlled substances. *See United States* v. *Robinson,* 2012 WL 3984786, *6–7 (S.D. Fla., Sept. 11, 2012) (holding non-registrant owner of cosmetic surgery clinic liable for recordkeeping violations under section 842(a)(5); statute ''includes the broader term of 'any person' and does not limit application of the subsection to registrants''); *United States* v. *Stidham,* 938 F.Supp. 808, 813–15 (S.D. Ala. 1996) (holding non-registrant owner of methadone clinic liable for recordkeeping violations); *United States* v. *Poulin,* 926 F.Supp. 246, 250–51 (D. Mass. 1996) (''The recordkeeping provisions of the [CSA] apply to all persons who dispense drugs, even if they have not registered as required under the Act'' and holding both pharmacy's owner/proprietor and corporate entity liable for recordkeeping violations); *see also* 21 U.S.C. 842(a)(5).

Of note, the GS testified that during the August 24, 2012 inspection of Respondent's new office, she examined the Schedule II order forms and noted that they had not been completed by indicating the date the drugs were received and the quantity received. Tr. 78; *see also* 21 CFR 1305.13(e). The evidence also shows that in response to the GS's request (through Dr. Nichol's attorney) for Dr. Nichol's dispensing records, Nichol provided the GS with the records found in Government Exhibit 14. Tr. 75.

Notably, it is undisputed that the dispensing record for each study—which Dr. Nichol provided—was not created until August 27, 2012, well after all of the dispensings were made. *See* GX 14, at 5–7 (Kodiac 8); *id.* at 14–20 (Kodiac 5). The CSA requires, however, that a dispensing record be ''maintain[ed], on a current basis.'' 21 U.S.C. 827(a)(3). Thus, the records presented to the GS by Dr. Nichol clearly did not comply with federal law.

As for whether Ms. Moore was maintaining the records which complied with the CSA, the ALJ's decision again contains several inconsistent findings and conclusions. For example, the ALJ found that ''it is unknown whether Ms. Moore's sponsor-required records would satisfy the DEA's recordkeeping requirements, since neither party made them exhibits in this matter.'' R.D. 20; *see also id.* at 32 (''Evidence of Ms. Moore's Sponsor Records was not entered into this record.''). However, Ms. Moore testified that the NKTR–118 Accountability Forms, which were introduced into the record at RXs 23 and 24, were ''my sponsor's record[s].'' Tr. 811; *see also id.* at 813–23 (discussing notations in records made by the sponsor's representative or CRA).

The ALJ nonetheless concluded that because ''[e]vidence of Ms. Moore's Sponsor records was not entered into this record . . . the Government has failed to prove by a preponderance of the evidence that the Respondent's records are deficient.'' R.D. at 33. Yet the ALJ then explained that ''[a]lthough *Respondent has failed to maintain its own recordkeeping system,* it cannot be held responsible for all of the noncompliant actions of Dr. Nichol.'' *Id.* (emphasis added). And later, the ALJ explained that Ms. Moore ''clearly lacks experience in handling controlled substances, for *she has not prepared the paperwork required in remaining accountable for the controlled substances* in Dr. Nichol's charge.'' R.D. at 35 (emphasis added).

Moreover, regarding the obligation to keep records under the CSA, Ms. Moore testified that ''I only learned on the 24th of August 2012, when the DEA came into my site for onsite inspection, that there was a requirement to have separate books. So I wasn't keeping records for the DEA.'' Tr. 811. As for the sponsor record, Ms. Moore testified that she ''was simply recording everything

[24] More specifically, the ALJ found that the GS had spoken with the John Wegner, a Quintiles representative and ''confirmed that the controlled substance was being dispensed from MCT. The drug was being ordered by Dr. Nichol, sent to his office location, and transported to MCT for dispensing. This procedure was ongoing from *at least* April of 2012.'' R.D. at 10 (citing Tr. 61–64) (emphasis added and citations omitted). As found above, the record indicates that while the GS spoke with Mr. Wegner in July 2012 and was told that Dr. Nichol was taking the drugs to Respondent, where they were dispensed, she then contacted Dr. Nichol's attorney, who confirmed that his client had been doing this ''[a]t least since April of 2012.'' *Id.* at 64.

Yet later in the R.D., the ALJ found that ''[a]t some unspecified time in 2012, Ms. Moore became aware that Dr. Nichol's relationship with the DEA had changed. She understood that Dr. Nichol could no longer dispense controlled substances from the Respondent's location. Thereafter, patients were dispensed controlled substances from Dr. Nichol's office.'' R.D. at 16 (citing Tr. 497–98; 531–35, 631). However, the evidence shows that Nichol did not enter into the MOA until the middle of April 2012. RX 22, at 4.

[25] Given the ALJ's finding that Ms. Moore vacillated in her testimony and lacked candor on the issue of where the dispensings occurred, as ultimate factfinder I give no weight to her testimony that even before Nichol entered into the MOA, he made some of the dispensings at his office. Indeed, the Clinical Trial Agreement expressly required that the ''Institution, Investigator and their personnel shall perform the Study *at Institution's facility.''* RX 14, at 2 (emphasis added).

. . . we were just to count the drug and send it away.'' *Id.* at 811.[26] Ms. Moore then reiterated that ''I was not keeping records for the DEA.'' *Id.* at 812.

Accordingly, I find that substantial evidence supports the conclusion that neither Dr. Nichol nor Respondent was maintaining dispensing records for the two studies which complied with federal law.[27] And because federal law requires that both the physician and the clinic are required to maintain records, *see Clinical Leasing,* 759 F. Supp. at 312; I conclude that Respondent violated federal law when it failed to maintain on a current basis, complete and accurate records of its dispensings of controlled substances. I thus reject the ALJ's conclusion that ''the Government has not cited to any regulatory or statutory provision resulting in a finding of wrongdoing done by the Respondent'' other than the violation which Ms. Moore committed when she accepted a shipment of controlled substances.[28] R.D. at 35; *see also* GX 14, at 13 (receipt for shipment of drugs signed by Ms. Moore on July 31, 2012).

The ALJ also declined to impute Dr. Nichol's violations of the separate registration provision to Respondent, reasoning that under Arkansas law, an employer is not responsible for the acts of its independent contractor. R.D. at 30. As support for her conclusion, the ALJ noted that Dr. Nichol's contract with Respondent stated that he was an independent contractor and not an employee. *Id.* at 31 (citing RX 16, at 6). The ALJ then explained:

> Ms. Moore testified that her vision of the Respondent's business is to provide site resources for the doctor who is conducting the research. Respondent's business is not meant to exercise control over the doctor's medical judgment nor is the Respondent meant to be primarily responsible for the research and recordkeeping. Additionally, the Respondent does not even pay Dr. Nichol for his services in conducting research at Respondent's place of business, but, rather, Dr. Nichol's payment is a 'pass-through' system of payment in which the Respondent pays Dr. Nichol once the Respondent receives funds from the Sponsoring Organization. Simply put, Dr. Nichol is not an employee or an agent of the Respondent because the Respondent does not exercise any control over Dr. Nichol's work; rather, the Respondent only offers Dr. Nichol a facility in which to conduct research.

R.D. at 31–32 (citing Tr. 381, 383–85; RX 16).

Not only is the ALJ's reasoning counterfactual, it reflects a stunning misunderstanding of the CSA. As for the ALJ's reliance on Ms. Moore's vision, it is beside the point.[29] Indeed, here, the evidence shows that Respondent did far more than ''provide site resources for [a] doctor who is conducting research.'' *Id.* Rather, the evidence shows that Ms. Moore sought out, and contracted with Dr. Nichol, to perform clinical research *for* Respondent, pursuant to contracts it might obtain from contract research organizations, *id.* at 387, and that upon receiving information that Quintiles would be managing clinical trials of NKTR–118, Ms. Moore applied for Respondent to participate in the study. RX 3, at 1.

Moreover, upon Respondent's being approved by Quintiles, Ms. Moore (on behalf of Respondent) and Dr. Nichol jointly agreed with Quintiles to ''perform the Study at [Respondent's] facility according to the Protocol and th[e] [Clinical Trial] Agreement.'' RX 14, at 2. Thus, the evidence shows that Respondent did not simply provide a facility for Dr. Nichol to undertake the research. To the contrary, Ms. Moore, on behalf Respondent, undertook to perform the clinical trials. Furthermore, it is clear that there was an agreement between Ms. Moore and Dr. Nichol to dispense controlled substances at Respondent's office. *See also* Tr. 57 (Ms. Moore's statement during May 2011 interview that Dr. Nichol ''would be present at the clinic [Respondent] three to four days a week.'').

Notwithstanding that Dr. Nichol was an independent contractor and not Respondent's employee, he was still obligated to comply with the terms of his agreement with Respondent, which required that he ''act in accordance and compliance with any and all applicable Federal, State, and local laws, rules, regulations, guidelines, including but not limited to the . . . CFR . . . as amended.'' RX 16, at 4. Indeed, Respondent had the power to terminate the agreement ''upon the breach of'' the agreement by Dr. Nichol and his failure to cure the breach. *Id.* at 5. Thus, even if Respondent could not exercise control over Dr. Nichol's medical decisions, she still retained authority to supervise various other aspects of his activities and to ensure that he complied with the requirements of federal law, including the CSA.[30] Accordingly, whether Dr. Nichol was an agent under the standards set forth in the Restatement of the Law (Third) Agency (2006), *see* R.D. at 31, the evidence shows that he clearly acted on Respondent's behalf in performing the Clinical Trial Agreement and Ms. Moore clearly knew that Dr. Nichol was dispensing controlled substances at Respondent. *See* 21 U.S.C. 802(3). Thus, Dr. Nichols' misconduct in dispensing controlled substances at Respondent's unregistered location is properly imputed to Respondent.

Indeed, even if the evidence is not sufficient to establish the existence of an

[26] Notably, Respondent does not argue that Respondent's Exhibits 23 and 24 (the NKTR–118 Accountability Forms) comply with the CSA and DEA regulations, notwithstanding that they document various dispensings. *See generally* Resp. Br. Indeed, in seeking admission of these documents, Respondent's counsel represented to the ALJ that they were offered ''for a very limited purpose, only with regard to the date of [the] last dispensal'' [sic] and that ''[w]e do not offer them for anything else with regard to the dispensal [sic] records.'' Tr. 750. The ALJ thus admitted these records—over the Government's objection—only ''for the limited purpose of'' showing the dates of the last dispensings. *Id.*

In any event, the records support the conclusion that Respondent failed to comply with federal recordkeeping obligations. Indeed, a review of these records shows that multiple entries are not in chronological order, thus indicating that these logs were not maintained on a current basis as required by federal law, but were created after the fact. *See* RX 24, at 3 (listing entries dated in following order: 25 Oct. 2011, 09 Nov. 2011, 15 Sep. 2011, 26 Sep. 2011, 22 Nov. 2011, 20 Dec. 2011); *id.* at 5–6 (single entry containing crossed-out date of 18 Aug., and two dates of 18 July 2012 and 15 Aug 2012). *See also* RX 23, at 11–13 (listing more dates of dispensings which are not in chronological order).

[27] In its post-hearing brief, the Government makes extensive arguments, based largely on the GS's audit, that the dispensing records Ms. Moore created were inaccurate. Gov. Br. 28–32. However, the Government never performed a physical count of the drugs on hand for the closing inventory. Instead, as found above, it based its closing inventory figures on records which showed inventories taken on various dates. GX 14, at 22. However, the GS ignored that these records (MCT Form 1) were not perpetual inventories. Thus, the GS simply added any quantities received in a new shipment to the previous balance, ignoring that the last count was dated weeks earlier and that dispensings had been ongoing. Tr. 90, 133. The GS also treated the last entry on each form as if it was a new shipment (adding it to the previous figure) when the forms indicated that the quantities were of the drugs that were ''unused/returned'' and ''kits remaining unused.'' *Id.* at 133. Moreover, the GS acknowledged that she did not ask either Dr. Nichol or Ms. Moore to explain what these entries showed. *Id.* at 134–35. As for the GS's testimony that she was simply following Ms. Moore's methodology, the GS never asked Ms. Moore to explain her methodology. *Id.*

Accordingly, I find the Government's contention not proved.

[28] As relevant here, under the CSA, it is ''unlawful for any person knowingly or intentionally to possess a controlled substance . . . except as otherwise authorized by this subchapter.'' 21 U.S.C. 844(a); *see also id.* § 822(b) (''Persons registered by the Attorney General under this subchapter to . . . distribute, or dispense controlled substances . . . are authorized to possess . . . distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.'').

[29] So too, the fact that Respondent was not contractually required to pay Dr. Nichol until it was paid is beside the point.

[30] It is not uncommon that pharmacies utilize the services of relief pharmacists, who are not employees, but rather independent contractors. Under the ALJ's theory, a pharmacy owned by a non-pharmacist could not be held liable for violations committed by a relief pharmacist who is an independent contractor.

agency relationship between Dr. Nichol and Respondent, the ALJ was simply mistaken in concluding that proof of an agency relationship was necessary to impute Nichol's misconduct to Respondent. Contrary to the ALJ's understanding, the CSA recognizes the principle of agency for the purpose of allowing ''an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser,'' 21 U.S.C. 802(3), to handle controlled substances without having to be registered as well. *See id.* § 822(c) (''The following persons shall not be required to register and may lawfully possess any controlled substance . . . under this subchapter: (1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance . . . if such agent or employee is acting in the usual course of his business or employment.''). The CSA's agency provision does not, however, limit the liability of a person for the misconduct of another to the circumstance in which the latter acts as an agent of the former. Thus, while obviously any misconduct in handling controlled substances which is committed by an agent in the course of the agency is properly imputed to his principal, *see Mediplas Innovations,* 67 FR 41256 (2002),[31] this is not the only basis for imputing Dr. Nichol's violations of the separate registration requirement to Respondent and Ms. Moore.

Significantly, Dr. Nichol's violations can be imputed to Respondent because Ms. Moore knowingly aided and abetted Dr. Nichol's violations. *Cf.* 18 U.S.C. 2; *FDIC* v. *First Interstate Bank of Des Moines, N.A.,* 885 F.2d 423, 431 (8th Cir. 1989) (noting that ''under the common law, liability is sufficiently established by an aider-abettor's knowledge of the wrong and its awareness of its assistance in furthering the scheme'') (citing *Restatement (Second) of Torts* § 876 comment d (other citation omitted)). Here, in addition to the Clinical Trial Agreement (by which Respondent, through Ms. Moore, and Dr. Nichol agreed with Quintiles to ''perform the Study at [Respondent's] facility,'' RX 14, at 2), the evidence shows that Ms. Moore provided Respondent's facility to Dr. Nichol for the purpose of performing the clinical studies.

Moreover, the evidence shows that Respondent did not have a registration to conduct research, Tr. 62, and that during the February 15, 2011 site selection visit, Quintiles' representative informed both Ms. Moore and Dr. Nichol that ''[t]he site must obtain a DEA license for research with a controlled substance.'' RX 4, at 1; *see also* Tr. 400 (testimony of Ms. Moore that sponsor told her and Nichol that ''based on the scheduling [of NKTR–118], then the sites [sic] would need a DEA license''). So too, the evidence shows that Dr. Nichol was not registered at Respondent and Ms. Moore knew this. [32] Tr. 487; RX 22, at 1. Finally, the evidence further shows that Dr. Nichol proceeded to dispense controlled substances at Respondent's office when neither he, nor Respondent, held a registration at this location and did so on numerous occasions through at least April 2012.[33] Thus, the evidence establishes that Ms. Moore and Respondent aided and abetted Dr. Nichol's violations of section 822(e), by allowing him to dispense at Respondent's office, which was not registered.

I therefore reject the ALJ's conclusion that Dr. Nichol's violations of section 822(e) cannot be imputed to Ms. Moore and Respondent.[34] Moreover, as

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[31] Citing *Mediplas Innovations,* 67 FR 41256 (2002) and *Daniel Koller, D.V.M.,* 71 FR 66975 (2006), the ALJ explained that these decisions ''regarding imputing a worker's conduct to an employer turn on the fact that the worker was deemed an agent of the employer.'' R.D. at 31. The ALJ misread both cases.

In *Mediplas,* the Agency held that a firm, which sought to import list I chemicals, was liable for the failure of its customs broker to timely file import notification forms (DEA—486), explaining that the firm had a statutory duty to file the forms and that under the law of agency, it was liable ''for its agent's failure to timely file'' the forms. 67 FR at 41262 (citing, *inter alia, Restatement (Second) of Agency* §§ 272, 275, 277 (1958)). While the liability of a principal for the acts committed by an agent in the course of its agency is hardly disputable, *Mediplas* simply does not address whether, absent an agency or employment relationship, a person can be held liable under the CSA for the misconduct of another person, such as a co-conspirator.

Nor does *Koller* support the ALJ's reasoning. Rather, *Koller* simply addressed whether a relief veterinarian, who was an independent contractor and not an employee of a clinic owner, could act as an agent of the owner and lawfully dispense controlled substances under the exemption from registration provided under 21 U.S.C. 822(c). *See* 71 FR 66975.

[32] Obviously, Dr. Nichol knew that he was not registered at Respondent.

[33] As for Ms. Moore's testimony that she did not think it was illegal for Dr. Nichol to bring the controlled substances to Respondent and dispense them there, this is not a mistake of fact, but rather, a mistake of law. As such, even if I deemed it credible, it offers no comfort to Respondent.

Moreover, the record shows that at the April 2011 meeting, the DIs provided Ms. Moore with the Code of Federal Regulations. Among the regulations contained therein are 21 CFR 1301.11, which requires that ''[e]very person who . . . dispenses . . . any controlled substances or who proposes to engage in the . . . dispensing of any controlled substance shall obtain a registration unless exempted by law or'' regulation, and as well as 21 CFR 1301.12, which provides that ''[a] separate registration is required for each principal place of professional practice at one general physical location where controlled substances are . . . dispensed by a person.'' *See also* 21 CFR 1301.12(b)(3) (exempting from the separate registration requirement, ''[a]n office used by a practitioner . . . where controlled substances are prescribed *but neither administered nor otherwise dispensed* as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.'') (emphasis added).

As the Fifth Circuit has recognized, the statute (21 U.S.C. 822(e)) and regulation provide fair notice such that:

> A physician of ordinary means and intelligence would understand that the federal registration provisions apply to *each* important or consequential place of business where the physician distributes controlled substances. It is sufficiently clear that the application of the provisions is not limited to a *single* important or consequential place of business where controlled substances are distributed.

Clinical Leasing Serv., 925 F.2d at 123 (emphasis added). Moreover, Ms. Moore admitted that she never asked DEA whether Dr. Nichol could lawfully transport the controlled substances to Respondent and dispense them there. Tr. 538. *See Clinical Leasing Serv.,* 925 F.2d at 122 (''licensing or registration requirements, are afforded considerable deference in the vagueness analysis because the regulated party may 'have the ability to clarify the meaning of the regulation[s] by its own inquiry, or by resort to an administrative process'''') (quoting *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.,* 455 U.S. 489, 498 (1991)).

[34] So too, liability can be imputed based on proof that a conspiracy existed, even where the conspiracy had a lawful objective but was carried out through unlawful means. *See* 21 U.S.C. 846 (''Any person who . . . conspires to commit any offense defined in this subchapter [*i.e.,* the CSA] shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the . . . conspiracy.'').

To establish the existence of a conspiracy, the Government ''must prove there was a conspiracy with an illegal purpose, that the defendant was aware of the conspiracy, and that [s]he knowingly became a part of it. Moreover, there must be evidence that the defendant entered into an agreement with at least one other person and that the agreement had as its objective a violation of law.'' *United States* v. *Fitz,* 317 F.3d 878, 881 (8th Cir. 2003) (citations omitted). Proof of the existence of an agreement '''does not require evidence of a formal or express agreement''' but only evidence '''that the parties have a tacit understanding to carry out the prohibited conduct.''' *United States* v. *Nusraty,* 867 F.2d 759, 763 (2d Cir. 1989) (quoting *United States* v. *Rubin,* 844 F.2d 979, 984 (2d Cir. 1988)) (other citation omitted).

However, because the act of entering into a conspiracy is itself an actionable offense, the Government was required to allege this in either the Show Cause Order or its Pre-Hearing Statements. I therefore do not rely on this theory.

By contrast, the aiding and abetting statute does not create a separate offense, but simply ''abolishes the distinction between common law notions of 'principal' and 'accessory.''' *United States* v. *Kegler,* 724 F.2d 190, 200 (D.C. Cir. 1983). Accordingly, in a criminal prosecution, ''[a]iding and abetting . . . need not be alleged in the indictment.'' *United States* v. *Alexander,* 447 F.3d 1290, 1298 (10th Cir. 2006). *See also United States* v. *Good Shield,* 544 F.2d 900, 952 (8th Cir. 1976) (''Aiders and abettors and those causing an act to be done are punishable as principals. The indictment may charge a defendant as a principal, and need not specifically allege that he aided and abetted in the commission of the crime.'').

discussed above, Ms. Moore and Respondent violated federal law by failing to maintain complete and accurate dispensing records. These findings support the conclusion that granting Respondent's application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

Sanction

Under Agency precedent, where, as here, ''the Government has proved that [an applicant] has committed acts inconsistent with the public interest, [the applicant] must ' ''present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration.'' ' '' *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))).

''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where [an applicant] has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination). So too, in making the public interest determination, ''this Agency also places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt,* 75 FR 49995, 50004 (2010) (citing *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy,* 72 FR 74334, 74338 (2007) quoting *Hoxie,* 419 F.3d at 483 (''Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.'')).

While an applicant must accept responsibility and demonstrate that it will not engage in future misconduct in order to establish that granting its application is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

Moreover, as I have noted in several cases, ' '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.' '' *Gaudio,* 74 FR at 10094 (quoting *Southwood,* 72 FR at 36503 (2007)); *see also Robert Raymond Reppy,* 76 FR 61154, 61158 (2011); *Michael S. Moore,* 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36504). *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'').

The ALJ reasoned that while ''[t]he record is filled with wrongdoing done by Dr. Nichol . . . his wrongdoing is not imputed to Respondent'' and that the only violation Respondent ''had . . . to be remorseful about,'' was Ms. Moore's act of signing for, and taking possession of, the July 31, 2012 shipment of controlled substances. R.D. at 35. While acknowledging that ''Ms. Moore did not express any remorse for this wrongdoing,'' the ALJ concluded that ''this one incident is [not] enough to deny the Respondent a DEA registration.'' *Id.*

As explained above, the ALJ's conclusion rests upon the erroneous premise that Ms. Moore is only responsible for her act of taking possession of a shipment of controlled substances. Rather, the evidence shows that Ms. Moore aided and abetted Dr. Nichol's violations of the CSA by dispensing controlled substance at an unregistered location. *See* 21 U.S.C. 822(e), 841(a)(1), 846. As explained above, this misconduct constitutes a violation of one of the CSA's core provisions.

Yet Ms. Moore utterly failed to acknowledge her misconduct, insisting that she did not understand that: (1) Respondent could not dispense controlled substances without first obtaining a DEA registration, Tr. 537, 539; and (2) it was illegal for Dr. Nichol to dispense controlled substances at Respondent. *Id.* at 539. Not only is Ms. Moore's ignorance of the law no excuse, *see Sigrid Sanchez, M.D.,* 78 FR 3933, 39336 (2013); her assertions are extraordinary when considered in light of the facts that: (1) She was explicitly told by the Quintiles representative that Respondent must obtain a DEA license, RX 4; (2) she was provided with a copy of the Code of Federal Regulations, Tr. 274; and (3) she admitted that she never asked DEA Investigators if Dr. Nichol could lawfully transport the drugs to Respondent and dispense them there. *Id.* at 538.

Ms. Moore also failed to accept responsibility for Respondent's recordkeeping violations. Ms. Moore did not address at all the failure to properly annotate the Schedule II order forms with the date of receipt and quantity of drugs received. Moreover, while both

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Of significance here, '''''[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.''''' *Citizens States Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984) (quoting *Aloha Airlines* v. *Civil Aeronautics Bd.,* 598 F.2d 250, 262 (D.C. Cir. 1979)) (quoted in *George Mathew, M.D.,* 75 FR 66138, 66146 n.20 (2010)). ''An agency is not required ''to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront.''' *Boston Carrier, Inc.,* v. *ICC,* 746 F.2d 1555, 1560 (D.C. Cir. 1984) (quoted in *Mathew,* 75 FR at 66146 n.20). ''Thus, the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.'' *Mathew,* 75 FR at 66146 n.20. *See also Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996) (''the parameters of the hearing are determined by the prehearing statements''); *accord Nicholas A. Sychak,* 65 FR 75959, 75961 (2000).

Here, the Government provided adequate notice that it intended to litigate the issue of Dr. Nichol's transporting controlled substances to Respondent's office to dispense them there and that this was illegal because he was not registered at that location. *See* Gov. Second Supplemental Prehearing Statement, at 1–2. More specifically, the Government disclosed that it intended to sponsor testimony from the GS that she was told by a Quintiles employee that ''the MCT study situation was unique in that they had to send the drugs to Dr. Nichol who then transported them to MCT to dispense.'' *Id.* at 1. The Government further disclosed that the GS would testify that she contacted Dr. Nichol's attorney and ''informed him of the problems with transporting and dispensing drug from an unregistered location and that it was not legal to do so unless the location was registered'' and that ''Dr. Nichol needed to be registered at the MCT location if he wished to dispense there.'' *Id.* The Government then disclosed that the GS would testify that on August 22, 2012, she received a letter from Dr. Nichol's attorney which ''assured her that Dr. Nichol would administer the controlled substances for research at his DEA approved address.'' *Id.* at 2.

Finally, the Government disclosed that the GS would testify that during the August 24, 2012 meeting with Ms. Moore, the latter ''admitted that Dr. Nichol was dispensing [NKTR–118] from MCT both at the new and old locations for MCT.'' *Id.* I thus conclude that Respondent had adequate notice that the issue would be litigated.

Respondent and Dr. Nichol failed to maintain dispensing records on a current basis, *see* 21 U.S.C. 827(a)(3); 21 CFR 1304.21(a), Ms. Moore asserted that she was not aware that Dr. Nichol was required to keep controlled substances records for the studies until August 24, 2012. Tr. 822–23. As for Respondent's failure to keep records, Ms. Moore asserted that ''[n]owhere in keeping records was there ever any indication, until [the GS] came to my site, that we were to keep two sets of books. I never heard that, but I'm not a registrant, so maybe if I were, I would have heard it and known that.'' *Id.* at 565.

However, as stated above, during the April 2011 on-site inspection, Ms. Moore was provided with the Code of Federal Regulations. Tr. 274. And during the visit, one of the DIs explained the recordkeeping requirements to Ms. Moore. *Id.* Regardless of whether Ms. Moore was required to keep two sets of books, Respondent was obligated to maintain current records of the controlled substances that were received and dispensed by Respondent and Dr. Nichol. Here again, Ms. Moore's testimony manifests that she does not accept responsibility for the failure of Respondent and Dr. Nichol to keep records that complied with the CSA. Indeed, Ms. Moore's testimony is all the more remarkable in light of the fact that it occurred at a hearing at which the issue was whether her entity should be granted a registration. *Cf. 4 OTC, Inc.,* 77 FR 35031, 35035 (2012) (''it is not too much to expect that an applicant seeking to show its intent to comply with applicable state laws, would produce [Standard Operating Procedures] which were not riddled with misstatements of those laws and which correctly reflected those States where its proposed method of operations would be unlawful'').

I therefore hold that Ms. Moore has failed to accept responsibility for her (and Respondent's) misconduct. *See Jeffery P. Gunderson,* 61 FR 62884, 62887 (1996). While there is no evidence that any of the drugs that were dispensed in the NKTR–118 study were diverted, both the registration and recordkeeping violations involve core provisions of the CSA. Moreover, Respondent's violations of the registration requirements were clearly intentional. Accordingly, Ms. Moore's failure to acknowledge her wrongdoing provides ample reason to reject Respondent's application. This conclusion is buttressed by the ALJ's finding that Ms. Moore lacked candor when she testified ''concerning where the controlled substance was actually dispensed.'' R.D. at 34 (citing *Jeri Hassman, M.D.,* 75 FR 8,194, 8236 (2010), *pet. for rev. denied, Hassman* v. *Office of the Deputy Administrator,* No. 10–70684 (9th Cir., Apr. 9, 2013)).

To be sure, Ms. Moore put on some evidence of her willingness to comply with the CSA and Agency regulations, including her installation of the alarm, her timely provision of information to investigators, and her efforts to create compliant records. However, where, as here, the evidence shows that an applicant has engaged in knowing or intentional misconduct, Agency precedent has long held that the acknowledgement of such misconduct is an essential element of rebutting the Government's *prima facie* case. *See Hoxie* v. *DEA,* 419 F.3d at 483; *see also Medicine Shoppe,* 73 FR at 387; *Kennedy,* 71 FR at 35709; *Daniels,* 60 FR at 62887. And in any event, the weight to be given Ms. Moore's evidence of her willingness to comply is greatly diminished by her aiding and abetting Dr. Nichol's violations of federal law when he dispensed at an unregistered location. Moreover, Ms. Moore's testimony shows that she still does not understand the scope of the recordkeeping obligations of a DEA registrant.

Accordingly, I conclude that Respondent's application should be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Moore Clinical Trials, L.L.C., for a DEA Certificate of Registration as a Researcher, be, and it hereby is, denied. This Order is effective immediately.

Dated: July 2, 2014.

Michele M. Leonhart,

Administrator.

[FR Doc. 2014–16162 Filed 7–10–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Research Triangle Institute

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before August 11, 2014. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before August 11, 2014.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, and dispensers of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to sec. 7(g) of 28 CFR part 0, subpart R, App.

In accordance with 21 CFR 1301.34(a), this is notice that on April 8, 2014, Research Triangle Institute, Kenneth S. Rehder, Ph.D., Hermann Building East Institute Drive, P.O. Box 12194, Research Triangle Park, North Carolina 27709, applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
AM-2201 (7201)	I
AM-694 (7694)	I
JWH-018 (7118)	I
JWH-073 (7173)	I
JWH-200 (7200)	I
JWH-250 (6250)	I
JWH-019 (7019)	I
JWH-081 (7081)	I
SR-19 and RCS-4 (7104)	I
JWH-122 (7122)	I
JWH-203 (7203)	I
JWH-398 (7398)	I
1-(1-Phenylcyclohexyl)pyrrolidine (7458).	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470).	I
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine (7473).	I
1-Methyl-4-phenyl-4-propionoxypiperidine (9661).	I
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine (9663).	I
2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzl) ethanamine (25C-NBOMe) (7537).	I