primary stated purpose the provision of services to Native Hawaiians; and has expertise in Native Hawaiian affairs. ''Native Hawaiian organization'' includes the Office of Hawaiian Affairs and Hui Malama I Na Kupuna O Hawai'i Nei. ''Traditional religious leader'' is not defined in statute, but is defined in regulation at 43 CFR 10.2(d)(3).

Dated: April 1, 2014.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2014–07660 Filed 4–7–14; 8:45 am]

BILLING CODE 4312–50–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–394–A and 399–A (Third Review)]

Ball Bearings and Parts Thereof From Japan and the United Kingdom; Termination of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The subject five-year reviews were initiated in January 2014 to determine whether revocation of the antidumping duty orders on ball bearings and parts thereof from Japan and the United Kingdom would be likely to lead to continuation or recurrence of material injury. On March 26, 2014, the Department of Commerce published notice that it was revoking the orders effective September 15, 2011 (the fifth anniversary of the most recent notice of continuation of the antidumping duty orders), because ''no domestic interested party filed a notice of intent to participate'' (79 FR 16771). Accordingly, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), the subject reviews are terminated.

DATES: Effective Date: March 27, 2014.

FOR FURTHER INFORMATION CONTACT: Elizabeth Haines (202–205–3200), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*).

Authority: These reviews are being terminated under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.69 of the Commission's rules (19 CFR 207.69).

By order of the Commission.

Issued: April 2, 2014.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2014–07770 Filed 4–7–14; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–2]

Howard N. Robinson, M.D.; Decision and Order

On March 1, 2012, Chief Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached Recommended Decision.[1] The Government filed Exceptions to the ALJ's Decision. Thereafter, Respondent moved to file a Response to the Exceptions, and upon the ALJ's granting of his motion, filed a Response.

Having considered the entire record, including the Government's Exceptions and Respondent's Response to them, I have decided to adopt the ALJ's findings of fact and conclusions of law with the exception of his conclusion that Respondent violated 21 CFR 1307.21(a)(1). *See Jeffery J. Becker, D.D.S.,* 77 FR 72387, 72387–88 (2012); *see also* R.D. at 36, 41. Moreover, while I agree with the ALJ's conclusion that Respondent ''has successfully shown cause why his [registration] should not be revoked,'' R.D. at 44, and reject the Government's contention that Respondent has not put forward sufficient evidence to establish that he can be entrusted with a registration, I conclude that additional requirements should be imposed on his registration to protect the public interest. A discussion of the Government's Exceptions follows.

Exception One—Respondent Has Not Provided ''Sufficient Mitigating Evidence'' To Demonstrate That He Can Be Entrusted With a Registration

The Government contends that Respondent has not provided sufficient evidence of the remedial measures he has undertaken to prevent the recurrence of some of the violations he committed and ''to prevent future diversion.'' Exceptions at 3. With respect to the former, the Government points to Respondent's failure to complete the order forms for schedule II controlled substances (DEA Form 222s) by noting the number of commercial or bulk containers received and the date of receipt. Exceptions at 2–3; *see also* 21 CFR 1305.13(d). In the Government's view, while Respondent produced evidence that he is now keeping the forms in a separate folder and apart from other records, ''[t]he record evidence does not support that [he] is properly completing'' them. *Id.* at 3. The Government also contends that ''Respondent has not demonstrated that he has a system in place to prevent future diversion of controlled substances'' because he acknowledged that he is not in the office every day and controlled substances deliveries may occur on day when he is not present. *Id.* at 4. Finally, the Government contends that the ALJ misapplied Agency precedent when he concluded that the record as a whole does not support revocation. *Id.* at 6–8.

With regard to the completion of the Form 222s, the Government completely ignores the testimony and report of Respondent's Expert, who reviewed his recordkeeping and procedures. As the Expert testified, while Respondent ''was not aware of his obligations and requirements . . . once he was informed, he took every action possible to correct them [the violations] and [did so] as quickly as possible.'' Tr. 397. Respondent's Expert further testified that with the exception of one suggestion, on which Respondent immediately took action, he ''found total compliance at the clinic'' and that ''everything else was in complete compliance.'' *Id.*

Moreover, in his second report, Respondent's Expert found that Respondent ''now properly completes the check in procedures by listing the amount received and the date received on both the filled 222 forms and the perpetual narcotic inventory log book.'' RX 18, at 2. *See also* RX 17 (expert's report) (noting that while Respondent ''may not have fully complied with certain record keep[ing] obligations prior to the DEA investigation, . . . [w]hen the oversights were identified, he took immediate action to correct all problematic issues pointed out to him, in a timely fashion''); *id.* (''My review of the current procedures and operations of the clinic confirm that all corrective action has taken place and *all regulations are being followed*.'') (emphasis added). While the ALJ was not impressed by the Expert's various attempts to excuse Respondent's

[1] For purposes of citation, the ALJ's Recommended Decision is abbreviated as R.D. All citations to the ALJ's Recommended Decision are to the slip opinion as issued by him.

failings,[2] he nonetheless found that his testimony ''was sufficiently detailed, authoritative and candid to be credited.'' R.D. at 20. Accordingly, the Expert's testimony and report provide substantial evidence, that in the absence of refutation by the Government, establishes that Respondent is in compliance with the requirements of 21 CFR 1305.13(d).

As noted above, the Government also contends that Respondent lacks effective controls against diversion based on his testimony that he is not at the clinic every day of the week and may not be present when controlled substances are delivered. Exceptions at 3–5. The Government takes issue with the adequacy of Respondent's controls, because he is now the only person at the clinic who has access to the controlled-substances cabinet and has directed the clinic staff not to open any shipments if he is not present.

Neither the CSA nor DEA regulations require, however, that a registrant be present at his registered location whenever controlled substances are delivered to it. And while the controlled substances must be ''stored in a securely locked, substantially constructed cabinet,'' 21 CFR 1301.75(b), nothing in the CSA or DEA regulations prohibits a registrant from designating a properly-screened and trustworthy employee (or appointing an agent from the clinic's properly-screened employees if he is not the owner) to accept the delivery and place the controlled substances in the controlled-substances cabinet.

Indeed, it is undoubtedly the case that numerous clinics throughout the country receive deliveries of controlled substances when their registrants are not present and place them in the controlled-substances cabinet, and yet the Government points to no evidence that such practices create a substantial risk of diversion. While diversion clearly occurred here, the evidence establishes that this was the result of the actions of a rogue employee, who happened to be a convicted drug smuggler and who was subsequently terminated. *See* RX 21. To be sure, adherence to DEA regulations, in particular 21 CFR 1301.76(a),[3] would likely have entirely prevented this (as would have a periodic review of the narcotic log book). That being said, there is no basis to conclude that a registrant's practice of authorizing a non-registrant to accept deliveries and place the drugs in the controlled-substances cabinet, establishes that the registrant lacks an adequate system for monitoring the receipt of controlled substances, 21 CFR 1301.71(b)(14), or lacks effective controls against diversion. *Id.* § 1301.71(a).

Finally, the Government contends that the ALJ misapplied two recent Agency cases, when he explained that they stand for the proposition that '' 'when considering recordkeeping violations, the Agency has coupled consideration of the degree of severity with an analysis of whether the registrant has both acknowledged culpability and demonstrated credible efforts aimed at correction.' '' Exceptions at 7 (quoting R.D. at 34) (discussing *Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy Care, Inc.,* 76 FR 51415, 51416 (2011), and *Terese, Inc., d/b/a Peach Orchard Drugs,* 76 FR 46843, 46848 (2011)). The Government contends that the ALJ's conclusion that revocation is not supported by the record is misplaced, because the evidence shows that ''the recordkeeping violations include more than non-egregious recordkeeping violations, such as the failure to account for significant deviations of controlled substances and the failure of Respondent to correct all violations.'' *Id.* Later, relying on *Ideal Pharmacy,* a case in which I revoked a pharmacy's registration based on large shortages of controlled substances, the Government argues that its audit of Respondent's handling of controlled substance activities showed percentage deviations comparable to those found in *Ideal,* and ''represent significant amounts of controlled substances for which Respondent could not account and thus, on this basis alone, warrant revocation.'' Exceptions at 8.

While the shortages and overages found in the Government's audit are sufficiently significant to support a revocation order, *see Paul Weir Battershell,* 76 FR 44359, 44368 (2011), the audit results here must be considered along with the evidence as to their underlying cause,[4] and in any event, to adopt the Government's position would require overruling thirty years of agency precedent. *See, e.g., Leo R. Miller,* 53 FR 21931, 21932 (1988); *David E. Trawick,* 53 FR 5326, 5327 (1988). Whether there may be a case in which a registrant's misconduct is so egregious, that the protection of the public interest would require revocation even if the registrant accepted responsibility and undertook remedial measures, I need not decide.[5] Here, Respondent's misconduct cannot be characterized as anything more than negligence, and as the ALJ found, Respondent has fully accepted responsibility and demonstrated that he is not likely to commit similar omissions in the future. R.D. at 43–44.

Accordingly, I reject the Government's contention that revocation is warranted. However, because I find that Respondent's misconduct is serious, and led to the diversion of controlled substances, I conclude that additional sanctions are necessary to protect the public interest. Consistent with the sanctions I have ordered in other cases, *see Battershell,* 76 FR at 44369, I conclude that a suspension of Respondent's registration is warranted.

Accordingly, I will order that Respondent's registration be suspended for a period of six months. However, in light of Respondent's acceptance of responsibility and the unrefuted evidence that upon being informed of

[2] For example, the Expert noted that Respondent ''was not a full time practitioner'' at the clinic, RX 18, at 2, and that ''much of the problem stems from his good faith reliance on the professionalism of other co-workers and employees at the clinic, the licensed Consultant Pharmacist, and other regulatory agencies to do their jobs correctly.'' *Id.* at 3.

The Government also notes the Expert's ''testimony that it is legal to destroy all narcotics by flushing [them] down the toilet, that he had followed this practice for 30 years, and that in the past, he had not contacted the Special Agent in Charge regarding the destruction of controlled substances.'' Exceptions at 6. The Government contends that the Expert's ''testimony exhibits a disregard of federal law and therefore, should not constitute sufficient mitigating evidence to assure the Administrator that he can be entrusted with [the] responsibility of carrying such a registration.'' *Id.* (citations omitted).

As an initial matter, whether the Expert can be entrusted with a registration is not at issue in this proceeding. Moreover, even assuming that the Government meant that the Expert's testimony should not be credited because of his putative disregard for federal law, as recently explained, the Agency's disposal regulation is not a model of clarity and the Expert is hardly alone in his views. *See Jeffery J. Becker,* 77 FR at 72388 n.3 (noting testimony of dentist-anesthesiologist and professor emeritus at Ohio State University regarding standard practice of Ohio dentists, who perform sedation, as to the disposal of excess drug). Finally, I am satisfied that in finding the Expert's testimony credible, the ALJ properly considered both that which supported, and that which detracted from, crediting his testimony.

[3] This regulation provides, in relevant part, that a ''registrant shall not employ as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances.'' 21 CFR 1301.76(a). While Respondent did not hire the employee, he is still responsible for ensuring compliance with agency regulations at his registered location.

[4] In *Ideal Pharmacy,* the audit results found shortages of nearly 150,000 dosage units of hydrocodone drugs, more than 83,000 dosage units of alprazolam, and more than 1.6 million milliliters of promethazine with codeine. 76 FR at 51416. While the registrant waived its right to a hearing, it is doubtful that it could have put on any evidence to rebut the conclusion that its principals were engaged in a scheme to intentionally divert drugs.

[5] *See Robert Raymond Reppy,* 76 FR 61154 (2011); *Paul H. Volkman,* 73 FR 30630 (2008).

the violations, he immediately undertook remedial measures, I will stay the suspension and place Respondent on probation for a period of three years to begin on the date of this Order. Said suspension shall be vacated upon Respondent's successful completion of the probationary period.

In addition, I will adopt, but modify, the second and third conditions proposed by the ALJ.[6] With respect to the ALJ's recommendation that Respondent submit reports, at sixty-day intervals, regarding monthly regulatory compliance inspections, I conclude that such inspections need only be conducted on a quarterly basis ending on March 31st, June 30th, September 30th, and December 31st. Said inspections must be conducted by an independent and state-licensed consultant pharmacist and must include an audit of Respondent's controlled-substance handling, which must be verified for accuracy and signed by Respondent. The consultant pharmacist's report, which must identify any violations of controlled-substance regulations, along with a copy of the quarterly audit, must be submitted to the local DEA field office no later than fifteen (15) days after the close of each quarter. In the event Respondent materially fails to comply with this provision, his registration shall be subject to an order of Immediate Suspension.

In addition, within fifteen days of the date of issuance of this Order, Respondent shall execute a document manifesting his consent to inspections by DEA personnel and waiving his right to require that DEA personnel obtain an administrative inspection warrant prior to conducting any inspection. In the event Respondent fails to execute said document, his registration will be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I hereby order that the DEA Certificate of Registration issued to Howard N. Robinson, M.D., be, and it hereby is, continued, subject to the conditions set forth above. This order is effective immediately.

Dated: March 27, 2014.

Michele M. Leonhart,

Administrator.

Robert C. Gleason, Esq., and *Dedra Curteman, Esq.,* for the Government *Jason M. Wandner, Esq.,* for the Respondent

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Chief Administrative Law Judge John J. Mulrooney, II. On September 7, 2011, the Deputy Assistant Administrator of the Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause (OSC) proposing to revoke the DEA Certificate of Registration (COR), Number AR8666109[7] of Howard Robinson, M.D., (Respondent), pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification. On October 6, 2011, the Respondent, through counsel, timely filed a request for hearing with the DEA Office of Administrative Law Judges (OALJ). The requested hearing was conducted in Miami, Florida on November 29–30, 2011.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes, by substantial evidence, that the Respondent's COR should be revoked as inconsistent with the public interest, as that term is used in 21 U.S.C. §§ 823(f) and 824(a).

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

The Allegations

The OSC issued by the Government contends that revocation of the Respondent's COR is appropriate because: (1) An audit of the Respondent's records revealed a number of unexplained recordkeeping abnormalities with regard to stocks of controlled substances, in violation of 21 U.S.C. §§ 827(a)(3), 842(a)(5) and 21 CFR §§ 1304.03–04, 1304.21; (2) the Respondent ''failed to maintain inventories and records of Schedule I and II controlled substances separately from all other records,'' in violation of 21 CFR 1304.04(f)(1); (3) the Respondent ''failed to properly record on a DEA Form 222, the number of Schedule II commercial or bulk containers and the dates on which the containers were received in violation of 21 CFR 1305.13(e);'' (4) the Respondent ''failed to properly dispose of controlled substances in violation of 21 CFR § 1307.21(a)(1);'' (5) the Respondent ''failed to record nine shipments of Schedule II controlled substances that were transferred from [his] registered address in violation of 21 CFR § 1305.03;'' (6) the Respondent ''failed to maintain a biennial inventory of the controlled substances on the premises of [his] registered location and failed to properly maintain records for the controlled substances in violation of 21 CFR §§ 1304.11(c) and 1304.21a(a);'' (7) the Respondent allowed a nurse anesthetist on his staff to place orders for controlled substances under the authority of his COR without having first executed a power of attorney as required by the regulations; and (8) the Respondent did not have access to the controlled substances in his office, and thus ''failed to provide an adequate system for monitoring the receipt, distribution and disposition of controlled substances,'' in violation of 21 CFR § 1301.71.

The Stipulations of Fact

The Government and the Respondent, through counsel, have entered into stipulations regarding the following matters:

(1) The Respondent is an employee of Premiere Center for Cosmetic Surgery (PCCS), which is owned by VM.[8]

(2) The Respondent has not been charged or convicted with any criminal offense in relation to the underlying cause.

(3) The Respondent has not been disciplined by the State of Florida

[6] In its Exceptions, the Government takes issue with the ALJ's criticism of its invocation of the law enforcement privilege when its lead DI was questioned as to whether she knew the identity of a person who had called her and alleged that the clinic's owner (and not Respondent) was a drug abuser and diverter. Notably, while the Government initially argued that the issue is moot, *see* ALJ Ex. 25, at 2; in its Exceptions, the Government now argues that it is not. *See* Exceptions at 8 (citing *Norman* v. *Reed,* 502 U.S. 279, 287–88 (1992) (issue not moot if capable of repetition yet evading review)).

Upon review, I conclude that the Government's initial view is correct because the DI ultimately answered the question, and testified that she did not know the caller's identity. As for whether the issue is capable of repetition yet evading review, many of the points made in the ALJ's Addendum are well taken and it is expected that they will be carefully studied by Government counsel. Thus, I conclude that it is speculative to conclude that Government counsel will, in the future, attempt to invoke the privilege in a factually similar circumstance, *i.e.,* where it has elicited testimony regarding allegations of misconduct from a putatively anonymous source without first determining whether its witness knows the identity of the person and obtaining the requisite approval to invoke the privilege if necessary.

Finally, as the ALJ acknowledged, ''the Respondent's case was not prejudiced in any cognizable manner.'' R.D. at 49. Accordingly, I decline to publish the Addendum.

[7] A copy of Respondent's COR and a certification of Respondent's registration history have been admitted into the record as Government Exhibits 1 and 2, respectively. Respondent previously possessed COR Number BR9176238. Gov't Ex. 13. However, on January 4, 2011, Respondent voluntarily surrendered the BR9176238 registration as surplusage. Gov't Ex. 13, at 2; Tr. at 67–69.

[8] *See* Addendum.

Department of Health for the allegations in the underlying cause.

(4) The Respondent has not materially falsified any application.

(5) The Respondent has not been excluded from participation in any program.

The Evidence

The Government's case-in-chief rested on the testimony of a single witness, Diversion Investigator (DI) Victoria McRae. DI McRae testified that she has been a Diversion Investigator with the DEA since 1988 and that she has been stationed in the DEA's Miami Field Division since November of 1989. Tr. 35–37. DI McRae testified that she has a college degree and has completed numerous DEA training evolutions. Tr. 37–38.

Regarding the merits of the case, DI McRae testified that, on September 20, 2010, she received a telephone call from a ''person who wished to remain anonymous,'' who informed DI McRae that ''there was a nurse anesthetist at a medical office that appeared to be abusing controlled substances and was self-administering.'' Tr. 38–39. The caller identified the alleged drug abuser as VM, the owner of PCCS in Coconut Grove, Florida. Tr. 39. In this regard, the caller informed DI McRae that: (1) There were ''bloody gauze strips left in a bathroom;'' (2) ''there was drug paraphernalia in the trash cans;'' (3) ''everyone at the office was aware of behavior by [VM] that looked like drug activity;'' and (4) the Chief Operating Officer of the PCCS clinics, an ex-boyfriend of VM, ''had the employees at both of the locations sign a form stating that they were not going to spread any rumors about any activities by [VM].'' [9] Tr. 40. The caller told DI McRae that ''patients were not given enough medication while they were on the operating table [a]nd that some of the patients were squirming because they hadn't had enough.'' Tr. 61–62. Finally, the caller stated that controlled substances were purportedly transferred from the PCCS facility in Coconut Grove to a PCCS facility in Tampa, but ''that the drugs were probably being used by [VM] and not actually arriving at the Tampa office.'' Tr. 64.

After the phone call ended, DI McRae accessed the RICS [10] database and looked up the names of the physicians mentioned during the call. Tr. 41. DI McRae also accessed the Florida Division of Corporations database [11] and confirmed that PCCS had locations in Coconut Grove and Tampa, Florida. Tr. 42–44. DI McRae found that VM was listed as the registered agent, president, vice president, secretary and treasurer of PCCS.[12] Tr. 42–44.

On January 4, 2011, based on her anonymous lead, DI McRae issued a notice of inspection to the Respondent for the Coconut Grove PCCS location. Tr. 45–46. At the time of her inspection visit, DI McRae was accompanied by three employees of the Florida Department of Health.[13] Tr. 60–61. Upon her arrival at the office, McRae presented the Respondent with the notice of inspection, which he signed.[14] Tr. 47; Gov't Ex. 3. DI McRae then ''advised [the Respondent] that [she] would be looking at his controlled substance records, and that [she] would also be counting the controlled substances that he had on hand in order to do a closing inventory.'' Tr. 47. DI McRae ''asked for copies of all controlled substance records for the past two years [and] was provided with copies of order forms [and] invoices from the wholesaler, Prime Medical.'' Tr. 83. DI McRae also asked for, and was provided with, a copy of the Respondent's narcotics log. Tr. 83. It was McRae's recollection that the requested documents were handed over by an employee at the practice named ''Priscilla.'' Tr. 169.

After the execution of the notice of inspection, VM offered to take DI McRae to the office's controlled substances safe, but stated that ''at that time the office only had Versed [15] in stock because the other medications were on backorder.'' Tr. 47–48. VM also stated that, because the controlled substances were kept in a sterile area, DI McRae would have to change into a gown and a wear a facemask and hair net. Tr. 48.

VM led DI McRae to a room where the former asked the latter to change into a set of green scrubs. Tr. 48. As McRae was donning the top of the scrubs, a capped hypodermic needle fell out of the left breast pocket of the scrubs she had been given. Tr. 48. DI McRae testified that when she picked up the needle she observed that it had some ''redness in it,'' which she believed to be blood. Tr. 48, 52–53. DI McRae inquired why a capped hypodermic needle would come tumbling out of the scrubs she was offered, and VM responded that the needle was not hers, that ''[i]t couldn't have been one of the staff members, because all of the staff wear black scrubs [but] it could have been a patient's because the patients wear green scrubs.'' [16] Tr. 50. After this exchange, DI McRae picked up the hypodermic needle and gave it to VM, who put it in a sharps container and led DI McRae into an operating room.[17] Tr. 50.

In the operating room, VM ''unlocked [a] box on the wall where the drugs were contained.'' Tr. 50. VM and DI McRae counted five sealed vials of midazolam, plus ''one vial which [VM and DI McRae estimated] to contain three milliliters of liquid in it.'' Tr. 53–54, 75; Gov't Ex. 4. Based on this count, DI McRae wrote out a closing inventory form reflecting the 53 milliliters of midazolam on hand, which VM signed at DI McRae's direction. *Id.*

In addition to the closing inventory, DI McRae conducted an inspection of the Respondent's records. Tr. 76. Of relevance to this case, DI McRae looked at a binder that was styled ''peer review pharmacy book,'' which contained ''order forms . . . among other documents.'' [18] Tr. 76. Mixed with these documents was a November 23, 2010, prescription for fifty vials of Demerol [19] written by the Respondent for VM. Tr. 76; Gov't Ex. 11. When asked about this prescription (which was written to the owner of the clinic and tucked into a book that was clearly not a patient file) the Respondent explained that he wrote this prescription for VM during a time when ''all of our drugs were on back order, [and the practice] needed some medication for office supply. So I wrote

[9] The non-disclosure document was not found during the investigation. Tr. 237. However, DI McRae testified that the document would not have been within the scope of the administrative inspection warrant. *Id.*

[10] DI McRae explained that ''RICS is a database that we have at DEA that contains all of the DEA registrants.'' Tr. 42.

[11] DI McCrae testified that the database, found at Sunbiz.org, is an open source database available to the general public on the Internet. Tr. 43.

[12] DI McRae testified that the Florida Department of Health is ''still working in [its] part of the investigation.'' Tr. 163.

[13] DI McRae contacted the Florida Department of Health because of the allegations concerning patient care. Tr. 62.

[14] Tr. 47.

[15] Versed is the brand name of a drug containing midazolam. 6–V Attorneys' Dictionary of Medicine V–123111. Midazolam is a Schedule IV controlled substance. 21 CFR § 1308.14(c)(35).

[16] DI McRae later testified that the patients she observed that day ''had on a gown, not scrubs.'' Tr. 55.

[17] Later, DI McRae asked the Respondent about the loose needle. Tr. 55–56. The Respondent speculated that an employee could have ''simply capped the needle, placed it in the pocket . . . continued on with their paperwork, and . . . forgotten to place the needle in a sharps container.'' Tr. 56.

[18] DI McRae testified that ''there were order forms [and] other forms that had to do with the office. There was a contract in there between the medical office and the consultant pharmacist that was there at the time.'' Tr. 80.

[19] Demerol is the brand name for tablets containing meperdine hydrochloride. 2–D Attorneys' Dictionary of Medicine D–32709. Meperdine is a Schedule II controlled substance pursuant to 21 CFR § 1308.12(c)(18).

the prescription for [VM], and she had it filled at a pharmacy.'' Tr. 81. DI McRae then informed the Respondent that the writing of prescriptions for office use is a violation of DEA regulations. Tr. 81. On cross-examination, DI McRae agreed that Respondent's records reflected the addition of fifty vials of Demerol on November 23, 2010. Tr. 177. Thus, DI McRae testified that, although the medication was procured by prescription through a method not authorized under the regulations, the available paperwork (such as it was) did reflect the addition of the medication to the practice's stock of controlled substances. Tr. 177–78.

DI McRae also found an order form dated December 28, 2010, but was told by VM that the order had not been received because ''everything was on backorder.'' Tr. 116. Later, DI McRae received a shipping invoice for the December 28, 2010, order directly from the supplier. Tr. 116–18. The invoice corroborates VM's account to the extent that it shows that, while both fentanyl [20] and Demerol were ordered, only fentanyl was shipped because the Demerol was on backorder. Tr. 116. DI McRae's investigation revealed that the fentanyl was shipped on December 28, 2010. Tr. 118. However, the Respondent's practice had no records of receipt of this shipment. Tr. 118.

When the closing inventory and inspection of the records were completed, DI McRae had a conversation with the Respondent wherein she inquired about office procedures related to the ordering of controlled substances. Tr. 57–58. The Respondent told DI McRae that drugs were ordered by VM, one of the nurse anesthetists, or by the anesthesiologist at the practice. Tr. 58. The Respondent told DI McRae that he believed drugs were ordered from a supplier called McKesson,[21] and that once shipped, the drugs were received at PCCS either by VM or by DM, a female employee. Tr. 59–60. McRae's assessment of what she learned was that VM ''would complete the order form as to what particular drugs the office needed and then [the Respondent] would look at it and he would sign it.'' [22] Tr. 184. DI McRae spoke to the supplier and was told ''that usually someone named Priscilla [is] responsible for receiving medication.'' [23] Tr. 189.

During the same meeting, DI McRae asked the Respondent who had access to controlled substances. Tr. 63. The Respondent answered that only VM and DM had access to the controlled substances. Tr. 63. At this point, DI McRae told the Respondent that ''because these drugs are ordered under your DEA number, you're ultimately responsible for them, so you should know what's been coming in. You should know what's on hand at all times.'' Tr. 63–64.

When asked about the alleged transfers between the PCCS facilities at Coconut Grove and Tampa, the Respondent initially indicated that he did not believe that controlled substances were transferred to Tampa, but on further reflection, told McRae that such transfers may have taken place under the direction of either VM, or Dr. Gloria Thomas—a doctor at the Tampa location. Tr. 64–65. The Respondent told DI McRae that there was no paperwork documenting such transfers.[24] Tr. 64–65. Upon learning that the transfers of controlled substances had been made without paperwork, DI McRae informed the Respondent of the regulatory documentation requirements relative to transfers between practices. Tr. 65–66. A subsequent inspection of the narcotics logbook at the Tampa location found that, while ''[t]here were notations in the log . . . there were no DEA order forms on site to . . . document that transfer.'' Tr. 147; *see also id.* at 239–40.

McRae also learned from the Respondent that biennial inventories [25] were not kept, and that needles containing controlled substances were emptied into a waste container, practices which DI McRae informed the Respondent were against DEA regulations. Tr. 60, 87. DI McRae asked the Respondent whether there had been any thefts or losses at the clinic, and Respondent stated that he was not aware of any. Tr. 63.[26] Finally, DI McRae informed the Respondent that she would be conducting an audit based upon the copies of the records that she had obtained, and that she would let him know the results of the audit at a later date. Tr. 57. DI McRae estimated that her discussion with the Respondent that day spanned approximately one half hour and that, in her view, the Respondent was cooperative throughout. Tr. 58, 66.

After the inspection,[27] DI McRae reviewed the material and information obtained during her inspection and conducted two audits incorporating data from January 5, 2010, through January 4, 2011. Tr. 85. One audit was based on the purchase records of the Respondent, and another was based on shipment records obtained from the Respondent's supplier reflecting shipments to the Respondent's practice. Tr. 120–21. McRae testified that she put the results of each of the comparative audits into separate computation charts. Gov't Ex. 10. Both audits reflected significant discrepancies between what was on hand at the time of the closing inventory and what should have been on hand based on the purchase records and the shipment records.[28] McRae testified that, based on her experience in the preparation of over a hundred audit charts throughout her career, the records that she reviewed were in violation of multiple recordkeeping requirements outlined in 21 CFR § 1304.21. Tr. 124, 144.[29] Also after the January inspection, DI McRae informed the Respondent that, ''for some unknown reason,'' he

[20] Fentanyl is a Schedule II controlled substance pursuant to 21 CFR § 1308.12(c)(9) (2011).

[21] Subsequent investigation revealed that McKesson was not a supplier for the Respondent's practice. Tr. 62.

[22] DI McRae testified that in her opinion this practice was compliant with the relevant regulations. Tr. 184. Thus, according to McRae (and contrary to the allegation in the Government's OSC), no power of attorney would be required under this protocol.

[23] Though DI McRae did not know whether the Priscilla described by the supplier was the Priscilla at the front desk, she did not know of any other Priscilla's employed by the Respondent. Tr. 189.

[24] DI McRae does not attribute any malfeasance to the Respondent's initial denial of transfers. Tr. 185. Indeed, DI McRae testified that Respondent was cooperative during the investigation. Tr. 66.

[25] *See* 21 CFR § 1304.11(c).

[26] At the hearing, the Government introduced a March 24, 2005, theft report from the Coconut Grove location. Tr. 109; Gov't Ex. 8. The form was filled out by Jon F. Harrell, D.O., of the same address as PCCS (3370 Mary Street, Coconut Grove, Florida). *Id.* When questioned on the relevance of the document, Government counsel proffered that ''this document is relevant to the extent that the Registrant . . . was unaware or untruthful.'' Tr. 110. Although the document was received into evidence without objection, *id.,* it referred to a different registrant during a period that was outside the parameters of the audit. The regulations provide for the admission of evidence that is ''competent, relevant, material, and not unduly repetitious.'' 21 CFR § 1316.59(a). ''Relevant evidence means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.'' Fed. R. Evid. 401 (internal quotation marks omitted). This document made no fact of consequence more or less probable. Thus, this document has played no part in this recommended decision.

[27] Tr. 83–84.

[28] The audit based on the Respondent's records showed: (1) shortages of 50 mg/ml Demerol and 50 mcg/ml fentanyl; and (2) overages of 100 mcg/ml fentanyl, 10 mg/10 ml Midazolam and 2 mg/ml Versed. Gov't Ex. 10, at 1. The audit based on the supplier's records showed: (1) shortages of 50 mg/ml Demerol, 50 mcg/ml fentanyl and 1 mg/ml Midazolam (10 ml vials); and (2) overages of 100 mcg/ml fentanyl, 2 mg/ml Versed and 1 mg/ml Midazolam (2 ml vials). Gov't Ex. 10, at 2.

[29] The Respondent acknowledges that there were deficiencies regarding the controlled substance recordkeeping during the period of DI McRae's audit. Tr. 622–23; Resp't Posthearing Brief, at ¶¶ 27–28.

had two active DEA CORs at the Coconut Grove location and that he only needed to have one.[30] Tr. 67–68, 70. At DI McRae's suggestion, the Respondent filed a DEA Form 104, voluntarily relinquishing one of the CORs as unnecessary. Tr. 67–68.

In addition to the results of the audit,[31] DI McRae also testified that she found fifteen ''discrepancies'' in the narcotics log. Tr. 94. Specifically, DI McRae testified that the narcotics log kept a type of ''perpetual inventory'' whereby a remaining balance for a controlled substance was written after each entry. Tr. 95. DI McRae observed a number of instances where the perpetual inventory for a given day was updated inaccurately. Tr. 96. That is, the remaining balance was either greater or less than the difference (or sum) of the previous balance and the amount used or added (as reflected in the entry). During her testimony, McRae highlighted several examples of this phenomenon and provided the following hypothetical: ''The office may have ended the day with . . . 10 milliliters of a particular drug. The next time that drug is used, there should be 10 milliliters . . . available [but] the next day that drug was used the[y] would start with an inventory of maybe, seven [milliliters].'' Tr. 95–96.[32] Under these circumstances, three milliliters would be ''unaccounted for.'' Tr. 96. Counting up the fifteen of these ''discrepancies,'' DI McRae found the following total amount of ''unaccounted for'' drugs: (1) 213 milliliters of fentanyl; (2) 120 milliliters of Demerol; and (3) 49 milliliters of midazolam. Tr. 97–98. DI McRae testified that fourteen of the fifteen ''discrepancies'' were ''signed off'' by VM. Tr. 196.[33]

DI McRae also testified to a number of violations she found in the DEA Form 222s she collected from the Respondent's pharmacy book.[34] Tr. 101–03. Specifically, DI McRae testified that the Respondent had not completed the Form 222s by filling in the number of packages received from each order, and the dates such packages were received. Tr. 103. DI McRae also explained that the way the Form 222s were kept in the peer review pharmacy book was itself a violation of DEA regulations insofar as the regulations require that records of Schedule II controlled substances be maintained separately from other records. Tr. 105–06.

On May 16, 2011, DI McRae had a follow-up meeting with the Respondent to discuss the results of the audit. Tr. 143. During the meeting, the Respondent acknowledged to the investigator that he had been ''fairly casual about the procedures that had gone on at the office,'' but that he had taken a number of steps to remedy the problems. Tr. 143–44. In particular, the Respondent claimed that, as of that date, he was the only one with access to the controlled substances at the office. Tr. 143. The Respondent also stated that ''inventories were taken . . . before and right after procedures [and] that the records were being kept separate from the other records.'' Tr. 143. However, the Respondent also admitted that, since the January inspection, he had disposed of approximately ten vials of Demerol without documenting the destruction, a practice that McRae explained to him as being improper. Tr. 142, 206.

In summary, DI McRae persuasively testified to the following violations uncovered at the Respondent's practice: (1) ''the Schedule II controlled substances were maintained with other records [in] violation of Section 1304 in the [CFR];'' (2) ''there was no biennial inventory on hand at the facility . . . in violation of Section 1304;'' (3) ''records were not complete and accurate because there was a discrepancy between what the doctor said he received and what the distributor said he distributed to the doctor,'' and because the narcotics logbook contained discrepancies; (4) ''there were no [DEA] order forms that were completed for the transfer of medications between the Miami and the Tampa offices;'' (5) ''the [DEA] order forms . . . were not properly completed by [the Respondent];'' and (6) the Respondent destroyed controlled substances without filling out a DEA Form 41, as required by DEA regulations.[35] Tr. 140–42, 144–45. DI McRae presented testimony that was consistent, detailed, and plausible, and her testimony is fully credited in this recommended decision.

The Respondent testified on his own behalf, and presented the expert testimony and reports of Robert S. Litman, a consultant pharmacist.[36] Litman holds degrees in Zoology and Pharmacy from the University of Florida, is a licensed pharmacist and is Board certified in Pharmaceutical Geriatrics.[37] He also serves as Clinical Assistant Professor of Pharmacy Practice (Geriatrics and Advanced Geriatrics) at the Ohio State University College of Pharmacy and the Nova Southeastern University, College of Pharmacy.[38] Tr. 262; Resp't Exs. 1, 20. Over the Government's objection,[39] he was accepted as an expert in the standards applicable to the documentation, record keeping and disposal requirements of controlled substances, as those requirements pertain to medical professionals. Tr. 266, 279.

Mr. Litman explained that consultant pharmacists are employed in different venues, such as long-term care facilities, diagnostic centers and surgical centers,

[30] DEA COR Number BR9176238 and DEA COR Number AR8666109.

[31] On cross-examination the Respondent's counsel raised the possibility of an internal diverter. Tr. 195. While DI McRae allowed that internal diversion was possible, she noted that ''[t]he audit numbers would still be the same because [in her audit she was] looking at the numbers that are reflected in the records. [T]hat's what I use for the audit.'' Tr. 195; *see also* Tr. 246–47.

[32] As an example of the foregoing, DI McRae pointed to the narcotics log entry for February 5, 2010, which showed a final balance of twelve milliliters of fentanyl. The next entry showed an addition of 160 milliliters of fentanyl, yielding a final balance of 160 milliliters. Under this scenario, twelve milliliters would be unaccounted for. Tr. 99.

[33] DI McRae agreed that there were ''alterations''—physical changes—in the log not counted in her list of fifteen dates where controlled substances were unaccounted for. Tr. 198; *see also* Tr. 94. There did not appear to be a correlation between the dates of alterations and which staff member verified the entries.

[34] The relevant Form 222s were admitted into evidence as Government Exhibit 6.

[35] DI McRae testified that a practitioner seeking to dispose of controlled substances should contact a reverse distributor. Tr. 204. However, if the practitioner intends to dispose of controlled substances himself, he must send the ''DEA a letter advising of [how] he proposes to destroy the controlled substances.'' Tr. 204. It is unclear whether Respondent has followed this procedure since May of 2011. Tr. 205.

[36] Mr. Litman testified that the designation as a consultant pharmacist requires course work, continuing education and a special license. Tr. 262.

[37] The Government interposed an objection to a compilation of Mr. Litman's qualifications from a consultant Web site on the unique basis that the document was not a CV. Tr. 256, 259–61. Although this objection was overruled, and the document was received into evidence (Resp't Ex. 1), Litman's CV was subsequently provided and also admitted into the record. Resp't Ex. 25; Tr. 543–44.

[38] Mr. Litman testified that, while ''there's always further certifications you may get . . . in long term care, Board certification in geriatrics is the ultimate goal for most clinicians.'' Tr. 262–63.

[39] Tr. 275–76. Although the Government interposed an objection to receiving Mr. Litman as an expert, the nature of the objection was framed entirely as an argument as to weight and raised no appreciable issue regarding the qualifications of the witness to present expert testimony. *See* Fed. R. Evid. 702. The Government's objections, namely that the witness focused primarily on the stricter of state versus federal requirements, and that much of his consulting work is focused on long-term care facilities (Tr. 276), did not shed any insight upon the salient concerns of whether: (1) ''the expert's scientific, technical, or other specialized knowledge [would] help the trier of fact to understand the evidence or to determine a fact in issue;'' (2) the testimony is based on sufficient facts or data; (3) the testimony is the product of reliable principles and methods; and (4) the expert reliably applied the principles and methods to the facts of the case. *See* Fed.R.Evid. 702. This objection was without merit and was overruled.

and that they monitor ''for proper record keeping, acquiring of pharmaceuticals and . . . disposition of pharmaceuticals.'' Tr. 254. If a pharmaceutical consultant uncovers a violation in the course of his duties, it is his job ''to document it, to point it out and to further the correction.'' Tr. 256. Mr. Litman estimated that, since becoming a pharmacy consultant in 1984, about eighty-percent of his time has been devoted to consulting, while twenty-percent of his time has been devoted to actual pharmacy work.[40] Tr. 268. Mr. Litman also conceded that much of his consulting business relates to compliance with state law, Tr. 274–75, and that, at present, his consulting business is confined to long term care facilities. Tr. 411.

Mr. Litman testified that he was retained in this case ''to do an audit, to review records, to see if there was any diversion or any poor record keeping [or] if there were any compliance issues as far as storage of medications.'' Tr. 280–81. In this vein, Mr. Litman ''went through the [Respondent's] clinic . . . . looked at storage areas . . . . looked at narcotics aids . . . . evaluated the narcotic log book register, went through 222 forms [and] any other documentation . . . .that was available to look at.'' Tr. 281. The contracted rate for his involvement is $300 per hour. Tr. 404–05.[41]

Based on his inquiries, Mr. Litman concluded that ''[t]here was sloppy record keeping. It was very problematic. It was inconsistent. There was no consistency in the log[ins] meaning that some people would log things in by vials, others by cc[]s.''[42] Tr. 281. Mr. Litman found instances where controlled substances were added to the narcotics log without a corresponding 222 order form,[43] and where errors were made in the perpetual balance tally.[44] Tr. 321. Mr. Litman testified that Respondent failed to maintain the proper documentation for transfers and that the narcotics log contained ''write overs and changes in numbers [and] also white out.''[45] Tr. 337, 426–27. Litman characterized the recordkeeping as ''lax.'' Tr. 419.

Despite the observed discrepancies, Mr. Litman testified that he compared patient records to the dispensing records in the narcotics log and that ''they all jibed . . . . Everything that Dr. Robinson had listed [in the log] for the patients was listed on the surgery reports.''[46] Tr. 335. Stated differently, the entries reflecting medications dispensed from the narcotics log matched the amounts indicated in the surgical records from the patient charts. Further, Litman's review of the charts told him that, although the practice was ordering more controlled substances, the Respondent's dosage levels during surgical procedures remained constant. Tr. 430.

Additionally, Mr. Litman found eleven ''major discrepancies'' in the narcotics log where the amount of controlled substances ordered on a particular date varied drastically from the amount of controlled substances checked into the log.[47] Tr. 282. These ''major discrepancies'' accounted for ''a little under 95 percent of the drugs that were missing.'' Tr. 355. Mr. Litman testified that these discrepancies could not be explained by sloppy record keeping and were, in his opinion, caused by diversion ''at the point of entry of reception of the drugs.'' Tr. 281–82; *see also, id.* at 55. In addition to these major discrepancies, Mr. Litman identified forty instances of what he characterized as ''smaller theft.'' Tr. 355.

Upon investigation, Mr. Litman learned that an employee named Priscilla Arciniega received the Respondent's drug shipments. Tr. 355–56. In short, Ms. Arciniega was the functionary manning ''the point of entry'' for PCCS. Based on this information, Mr. Litman conducted a review of Ms. Arciniega's employment records. Tr. 358. The employment records showed that Ms. Arciniega was hired in November of 2009,[48] one month before Mr. Litman began to see inconsistencies in the narcotics log. Tr. 496. Mr. Litman also found that during a single week in early March 2011, a week where Ms. Arciniega was absent from PCCS, ''there was no missing narcotics,'' and that when she returned to work ''there was diversion again.''[49] Tr. 362–63. Further, Litman noted that the controlled substance losses/thefts stopped after Ms. Arciniega was terminated from PCCS in March of 2011. Tr. 358.

With regard to the November 23, 2010, prescription, Mr. Litman concluded that, while the prescription was obtained improperly, it was ''intended to be used for a medically necessary purpose.'' Tr. 338; *see also* Tr. 413. Mr. Litman based this conclusion on the fact that the prescription was kept in the peer review pharmacy book, explaining that ''[i]f they were really trying to divert that, they wouldn't have kept a copy of it.'' Tr. 339. Thus, although obtained through the improper vehicle of a prescription to a non-patient, the Demerol was entered and tracked for use on patients at the clinic. Mr. Litman further explained that drug shortages are ''becoming a big problem in our community'' and that facilities and practitioners have been forced to obtain necessary controlled substances by writing prescriptions for, in essence, office use.[50] Tr. 340–42. Litman stated

[40] Mr. Litman works about 5–10 hours per week as a pharmacist. Tr. 268–269.

[41] Mr. Litman estimated that he expected to earn approximately $5,500 for his involvement in this case. Tr. 404–05.

[42] Notwithstanding how critical Mr. Litman's testimony was of the Respondent's recordkeeping, and that it was generally consistent with the Government's position that the Respondent had committed numerous recordkeeping violations, the Government interposed an objection to Mr. Litman's testimony and expert reports based upon the Respondent's failure to provide underlying data related to Mr. Litman's audit results and opinions. Tr. 285. Agency precedent directs that expert opinions may be excluded where a timely request for underlying data has been registered. *See C.B.S. Wholesale Distributors,* 74 FR 36746, 36749 (2009) (failure on the part of the Government to disclose underlying documentation utilized by its expert that was ''necessary to support [a] critical component of [that expert's] testimony'' held to ''deny the Respondent a meaningful opportunity to challenge the expert's conclusion'' and, thus held to preclude[] a finding that the expert's conclusions are supported by substantial and reliable evidence''). However, here there was no timely request for the underlying data made by the Government in advance of the hearing. Without reaching the issue here, suffice it to say that had the Government sought this data in advance of the hearing and its request was refused, the result of its objection could well have been different and the expert opinions derived from the withheld underlying data could have been properly excluded from playing any role in a finding supported by substantial evidence.

[43] As an example of this type of discrepancy, Mr. Litman pointed to the date of February 9, 2010, where 100 ccs of fentanyl were added without a 222 form. Tr. 321. However, he allowed that this type of ''discrepancy'' may not have been the type of issue a pharmacy consultant would have looked for. Tr. 332–33. Entries reflecting additions of controlled substances from Tampa were not included in this category. Tr. 346.

[44] Mr. Litman pointed to the date of November 14, 2010, where there was an opening balance of sixty ccs, six ampuls were administered, and 48 ccs remained. Tr. 333.

[45] He explained that ''you should never use white out on anything.'' Tr. 337.

[46] On cross-examination Mr. Litman testified that he looked at approximately 20% of patient records. Tr. 409. These were a ''random sampling of charts from 2010 in various months.'' Tr. 431.

[47] As an example of such a discrepancy, Mr. Litman pointed to the date of October 21, 2010, on which an order for Demerol was sent to the supplier, but was never logged in by PCCS. Tr. 298.

[48] Resp't Ex. 15.

[49] The Respondent, through the testimony of counsel retained by PCCS, introduced a printout from the Public Access to Court Electronic Records (PACER) system reflecting the docket from a criminal matter in the Eastern District of New York, *U.S.* v. A*rciniega, et al,* 1:03–cr–00759–CBA, which shows that, in 2003, Ms. Arcieniega pled guilty to one count of conspiring to import heroin into the United States. Resp't Ex. 21, at 1.

[50] Mr. Litman testified that if a client of his was having difficulty locating necessary controlled substances, he ''would advise them to call different pharmacies. Call several hospital pharmacies to see

that drug shortages are currently so profound that hospitals and nursing homes will sometimes borrow medications from retail or hospital pharmacies. Tr. 340. According to Mr. Litman, ''it's not legal to do that[,] it's not proper to do it, but it's done quite frequently.'' *Id.* Mr. Litman also shared his experience that it is not uncommon for practitioners to (improperly) write prescriptions for office use once they have exhausted authorized channels. Tr. 342.

Also related to the November 23, 2010, prescription, Mr. Litman testified that the fifty vials of Demerol obtained by filling the prescription were added to the logbook, but that ''all the entries [that day] were altered and changed.'' Tr. 346–47. Mr. Litman testified that he became suspicious as to the accuracy of the November 23, 2010, records when he saw that all fifty vials of Demerol were used on three procedures,[51] despite that the fact that he thought that ''they may have used four to five vials'' throughout the day for such procedures.[52] Tr. 346–47. Accordingly, Mr. Litman asked to see the records for the patients who were seen on November 23, 2010, and was told by an unnamed PCCS staff member that two of the three relevant charts were missing. Tr. 347, 351. Furthermore, the lone chart that was produced to Litman by PCCS contained a significant internal inconsistency. Tr. 352–53; Resp't Ex. 19. Specifically, that portion of the chart, which reflects the quantity of Demerol administered during the patient's procedure, shows eight contemporaneous administrations of Demerol totaling three-hundred milligrams. However, the ''total'' column of Demerol administered reflects that only fifty milligrams of Demerol had been administered to the patient during the procedure. Tr. 352–53. In short, the contemporaneous entries had been obviously altered to show an increased amount of medication administered per dose, but the individual who altered the document lacked the presence of mind to alter the ultimate total figure entered, which remained fifty milligrams.

On the issue of disposal of controlled substances, Mr. Litman testified that disposal of controlled substances is ''a tricky issue'' and that it has been his experience that ''[t]he problem is when you do call the agency and many times for small amounts, they don't want to be bothered by it.'' Tr. 371. Litman testified that he has called DEA in the past to report minor thefts and destruction of controlled substances and the employee on the other end of the phone would say ''don't bother with it, call the police.'' Tr. 372. Mr. Litman further explained that if a client asked what to do with controlled substances leftover from a procedure, he would ''say you flush it with a witness.'' [53] Tr. 377. Somewhat troublingly, Mr. Litman initially insisted that he is licensed by the state to destroy controlled substances without notifying the DEA, but later retreated from this position when shown 21 CFR § 1307.21. Tr. 372–73, 377–79. Despite his testimonial epiphany on the subject of disposal authority, Litman testified that he has been disposing of controlled substances without notifying the DEA [54] for approximately thirty years.[55] Tr. 379.

Mr. Litman testified regarding an October 12, 2011, letter to the Respondent from the Florida Department of Health stating that it had received a letter from PCCS correcting deficiencies found during a September 12, 2011, inspection. Tr. 301. Mr. Litman explained that the letter would have followed an inspection and that, ''if [PCCS] were not in compliance, they would never receive this letter.'' Tr. 302. Similarly, Mr. Litman testified regarding a certificate of accreditation for PCCS from AAAA—the American Association for Accreditation of Ambulatory Surgical Facilities (''Quad A'')—for the time period from March 3, 2010, through March 31, 2011. Tr. 307; Resp't Ex. 14. Mr. Litman explained that a Quad A certification inspection would have included ''an investigation of record keeping and medication and narcotics usage and documentation and disposal'' and that a certification would be given at the conclusion of a successful inspection. Tr. 307. Mr. Litman testified that successful inspections by accrediting agencies would give a practitioner a ''false sense of security.'' Tr. 311.

Mr. Litman also testified that, in his inspection of the Respondent's records, he discovered that PCCS had retained a pharmacy consultant named Joe Koptowsky. Tr. 312–13; Resp't Ex. 7. Of relevance here, the agreement between PCCS and Mr. Koptowsky called for Mr. Koptowsky ''[t]o review the pharmacy section of patient records . . . . for conformance with State and Federal laws regarding dispensing, labeling, storage and administration of drugs; To review the drug distribution system, including ordering and administration or disposal (wastage) of medications[;] To review the labeling and storage of drugs[; and] To review the controlled substances documentation and audit records.'' Resp't Ex. 7. By reviewing inspection records prepared by Mr. Koptowsky, Mr. Litman discovered that Mr. Koptowsky performed inspections of PCCS Coconut Grove approximately once every six months from May of 2006 until May of 2009, and once every year from May of 2009, through November of 2010. Tr. 315–16, 321; Resp't Ex. 8. Remarkably, a November 9, 2010, Koptowsky inspection found no irregularities at the Coconut Grove facility, although that date fell two months prior to the DEA audit that revealed the deficient recordkeeping, and squarely within a period of time when controlled substance losses at PCCS were at an apex. Tr. 321–24; Resp't Ex. 8, at 10.

Mr. Litman testified that, if Mr. Koptowsky had found irregularities, it would have been incumbent upon him, as a pharmacy consultant, to bring the irregularities to the attention of PCCS.[56] Tr. 324. Though Mr. Litman acknowledged that the duty to maintain accurate records was the Respondent's ultimate responsibility, he testified, in essence, that it was not unreasonable for a practitioner to rely on a consultant pharmacist, and that the act of hiring a pharmacy consultant showed a desire on the part of the Respondent to comply with the applicable regulations. Tr. 407, 533–34. According to Litman, a pharmacy consultant who was acting responsibly would have identified the issues raised by DEA regarding the recordkeeping and shortage issues at PCCS and taken steps to bring the client into compliance. Tr. 525. However, Litman also freely conceded that as a registrant, the Respondent is ultimately responsible for actions taken under his registration regarding controlled substances, and that he is aware of no legal authority that would allow a practitioner to escape responsibility for

if they had it.'' Tr. 342. He said that he would ''never'' suggest that a practitioner obtain controlled substances by writing a prescription for an employee. Tr. 343.

[51] Litman testified that ''at the end of the day, all 50 vials were gone.'' Tr. 346.

[52] Mr. Litman based this assumption on a number of apparent alterations on the narcotics log. Tr. 349.

[53] Mr. Litman presented his (legally unfounded) opinion that DEA regulations related to disposal may not apply to small quantities of controlled substances. Tr. 382.

[54] Litman stated that in his opinion, storing residual controlled substance in a practice presents a greater risk of diversion than destroying it outright because it could be taken and diverted while waiting to be transported to a reverse distributor. Tr. 376–77.

[55] Mr. Litman pointed to section 64B16–28.303 of the Florida Administrative Code as authority for his disposal methods. Tr. 541.

[56] Mr. Litman has worked with Mr. Koptowsky in the past, and regards him as a ''poor quality pharmacist.'' Tr. 327.

his actions by virtue of his reliance upon a pharmacy consultant. Tr. 408.

Mr. Litman testified regarding the Government's audit. Tr. 385. He explained that, while the Government's audit, which relied on the narcotic logbook, reflected that the Respondent's practice had distributed fentanyl in 100 mcg/ml concentrations, no 100 mcg/ml concentration existed.[57] Tr. 385–87. Rather, the practice received and distributed the medication in only the 50 mcg/ml strength, not one hundred.[58] Tr. 387–88. When viewed in this light, Mr. Litman asserted that the fentanyl discrepancies found by DI McRae—the large overage of 100 mcg/ml fentanyl and the large shortage of 50 mcg/ml fentanyl—are ''almost a wash.'' Tr. 388.

Mr. Litman also set forth the results of an audit he conducted based upon the Respondent's records of fentanyl and Demerol from January 5, 2010, through March 2, 2011.[59] Tr. 391, 418; Gov't Ex. 14. When conducting the audit, Mr. Litman derived the starting and closing inventories from the logbook. Tr. 496, 500. Mr. Litman explained that he conducted an ''ongoing perpetual inventory'' based on the narcotics log, the 222 forms and the invoices.[60] Tr. 508. Under this process, he noted when controlled substances were used, transferred [61] or received, and would tally the drugs as they went missing. Tr. 508.

In his audit, Mr. Litman found shortages of Demerol and fentanyl in the approximate [62] amounts of 681 vials and 401 vials, respectively. Tr. 391–92. Converting these amounts to milliliters, the unit of measurement used by DI McRae in her audits, Mr. Litman found a shortage of fentanyl of approximately 802 milliliters, and a shortage of Demerol of approximately 681 milliliters.[63]

Mr. Litman further testified that when he was retained by the Respondent in October of 2011, ''I found everything corrected.'' Tr. 364. In particular, Mr. Litman testified that the Respondent: (1) ''instated new narcotic lock boxes [and] lock keys;'' [64] (2) had assumed sole access to the combination of the lock box; (3) separated Schedule II controlled substance records from other records; (4) instituted a procedure of conducting a twice a day inventory whenever surgical procedures are performed; (5) conducted perpetual and biennial inventories; and (6) separated DEA Form 222s from other records. Tr. 365–68. Additionally since Mr. Litman was retained, the Respondent has replaced Mr. Koptowsky.[65] Tr. 365. Mr. Litman explained that ''I've seen this kind of scenario before where employees will often steal . . . drugs and blame other employees. Basically I feel [the Respondent] was kind of a patsy in this case [and that] his greatest . . . deficit, failure would be that he didn't monitor it properly and he trusted the other people to inform him of problems that they never told him about.'' Tr. 527. Mr. Litman testified that once the Respondent gained an appreciation of the situation, he ''made every effort to put the facility in compliance with all regulations.'' Tr. 371; *see also, id.* at 523–24.

Two reports authored by Mr. Litman were received into the record. Litman's initial report (Litman Report I), dated October 28, 2011, contained a brief summary of his qualifications and a somewhat less brief summary of the Respondent's contentions and factual assertions for which Mr. Litman had no first-hand knowledge.[66] Resp't Ex. 17. Additionally (and more helpfully), the Litman Report I sets forth selective analyses of various aspects of the Respondent's records and recordkeeping practices. Included in his review was his written evaluation of Respondent's illegal controlled-substance-stock replenishment evolution. *Id.* at 2. Consistent with his testimony, Litman characterized this evolution as ''evidence of some lax attention to a record keeping regulation . . . .'' *Id.* Overall, Litman opined that his examination of the Respondent's practice demonstrated to him that:

> [T]here was a substandard job performed in the maintenance of the narcotic records as well as insufficient logging in of newly received orders as the narcotic counts were not accurate. [The Respondent] did review all narcotic orders prior to them being ordered, but did not sign in the amounts and dates arrived properly [sic], nor did he properly fill out forms for the transfer of medications from one clinic to another. There was inconsistency in the amounts of drugs received as there was no uniform system in place for this accounting. One nurse may have logged medications as ''cc'' or ''ml'' leading to difficult and improper accounting.

Id., at 2. In his report, as in his testimony, Litman provides his view that ''much of the problems stems [sic] from [the Respondent's] good faith reliance on the professionalism of other employees at the clinic, and [a] Consultant Pharmacist.'' *Id.,* at 3.

Curiously, the Litman Report I contains the observation that ''[w]hen discussing these issues with [the Respondent] he was sullen and remorseful about his poor oversight into the accounting.'' *Id.* There was also some account of Litman's recollection of some self-serving representations made by the Respondent to him concerning what he would have done had he known about his (own) lax oversight, as well as purported corrections he had and intended to make in the future, as well as Litman's peculiar estimation that (despite unreliable and inaccurate recordkeeping) the Respondent never created a risk of diversion or to public safety. *Id.*

Although Mr. Litman's second report (Litman Report II),[67] dated November 8, 2011, unquestionably suffers from many

[57] Mr. Litman believed this error was caused by the fact that the fentanyl came in different vial sizes. Tr. 387.

[58] Litman testified that the corrected data demonstrates approximately 400 missing vials, not 600 or 790, as reflected in the Government's audits. Tr. 388.

[59] Mr. Litman chose to end the audit once he found that the records ''showed no discrepancies.'' Tr. 492. Litman explained that he extended the length of the audit he conducted by two months over the audit period utilized by the Government so that he could capture the employment time of Ms. Arciniega, which was also the end (in his view) of the controlled substance discrepancies issues. Tr. 491–92, 497. Litman also noted that inconsistencies in the controlled substance records at PCCS began to appear around December 2009, and that before that, the records seemed ''very consistent.'' Tr. 496.

[60] During the course of his testimony, Litman opined that the numbers expressed in the Government audit, although placed into a chart, were ''pretty arbitrary'' and that, in his view his audit ''is more accurate because [his] is done on a daily basis [and] can actually pinpoint the days the drugs were missing,'' contrary to the Government audit, which ''just tells you what was ordered and received.'' Tr. 512.

[61] Mr. Litman assumed that additions without documentation were transfers from the Tampa office. Tr. 509.

[62] According to Mr. Litman, ''when you have somebody who's stealing narcotics, generally a seasoned addict will be able to manipulate data, change records.'' Tr. 494. Accordingly, it is difficult to ascertain the exact shortage of drugs. Tr. 494.

[63] The Respondent received shipments of Demerol containing 1 ml vials, and shipments of fentanyl containing 2 ml ampuls. Gov't Ex. 9.

[64] The Government objected to the photographs of the lock boxes the Mr. Litman examined essentially because, although he recognized the boxes in the photos, he did not actually operate the camera that took the pictures. This objection was overruled.

[65] Mr. Litman explained that approximately a week before the hearing, the Respondent ''retained'' a new consultant. Tr. 413–14. On cross examination Mr. Litman said that a contract had not been signed, ''but we will do it this week.'' Tr. 515. Subsequent to the hearing, the Respondent and Mr. Litman entered into a pharmacy consultant agreement. Resp't Ex. 22.

[66] A non-exhaustive list of the areas that the Litman Report I expounds upon on, without apparent basis for doing so, includes: (1) Whether VM, the owner of PCCS, is addicted to controlled substances; (2) the details of a conversation between VM and DI McRae where Mr. Litman was not present; (3) an analysis of the regulatory requirements for a power of attorney; (4) a signature analysis on an entry in the PCCS narcotic logbook; and (5) whether a wholesaler utilized by PCCS had a delay in providing Demerol. Resp't Ex. 17. Naturally, these matters, and any others for which Mr. Litman had no apparent factual basis for the opinions included in the Litman Report I have been afforded no weight in this recommended decision.

[67] Resp't Ex. 18.

of the same variety of unsupported overreaching and extrapolation that plagued its predecessor, the second version does a better job at describing the data and elements of the Respondent's recordkeeping that Litman analyzed in reaching his opinions. Specifically, the Litman Report II indicates that its author reviewed 36 randomly-selected charts from a total of 170 procedures conducted at PCCS in 2010 (approximately 21 percent of the procedures conducted at that facility), and found no discrepancies between entries in the patient charts compared to the narcotics logs. Resp't Ex. 18.

Litman's discovery of a 2010 spike in the Respondent's per-procedure use of Demerol and fentanyl compared to the years 2009 and 2011 is presented in his report without any suggestion as to the significance that data played in the balance of his opinions.[68] *Id.* However, during his testimony, Mr. Litman clarified the importance of this data, explaining that, in his opinion, ''[t]hey were still using the same amount for each procedure,[69] but then there was an extra amount . . . that was being stolen.'' Tr. 428–29.

The Litman Report II also presents the results of what he characterizes as ''an in-depth review of all [PCCS] narcotic usage, primarily focusing [sic] on the drugs [f]entanyl and Demerol from January 2010 thru April 2011.'' Resp't Ex 18 at 1. In what he subsequently refers to as an ''audit,'' [70] Litman catalogues ''*major discrepancies in drug counts,*'' tallying about 40 in a 15-month time frame. *Id.* (emphasis supplied). The Litman Report II documents a 681-vial shortage of Demerol and a 401-vial shortage of fentanyl.[71] *Id.* Litman also notes eight instances where controlled substances were shipped to the ''Tampa area clinic'' without filling out ''the proper DEA forms as per regulation.'' *Id.* Further, the Litman Report II contains his observation that ''[t]here appeared to be shrinkage (theft) occurring randomly on a weekly-monthly basis (~ 1 box stolen every 12 days) since January 2010 and ending immediately after March 2, 2011 . . . . [a time frame that coincides] with the employment dates of [an] employee who had access to these missing narcotics'' that Litman characterizes as ''questionable.'' [72] *Id.,* at 2. The Litman Report II also volunteers that ''[t]here were no missing drugs during a specific week this employee did not come to work and shrinkage resumed the week she returned to work,'' and that ''[t]here were also white-outs noted, combined with changed entries on the Narcotic Log Book, coincidently, on the last day of her employment.'' *Id.*

Much as is true in the initial report and the witness's testimony, the Litman Report II essays to excuse any assignment of responsibility to the Respondent under the (legally-unsupportable) theory that all noted discrepancies were understandably overlooked by the Respondent because he ''was not a full time practitioner at PCCS during the year 2010[,] was not properly up to date as to proper record-keeping, transfers of medications, logging in of new orders, and ongoing inventory control [and really] stems from [Respondent's] good[-]faith reliance on the professionalism of other co-workers and employees at the clinic, the licensed Consultant Pharmacist, and other regulatory agencies to do their jobs correctly'' *Id.,* at 2, 4.

The Litman Report II also notes some security enhancements the Respondent put into effect after the DEA audit, and once again reiterates Litman's odd assurance that the Respondent's wholly substandard recordkeeping has resulted in neither a public threat nor a risk of drug diversion. *Id.* at 2.

During his testimony, Mr. Litman did not shy away from those areas where he concluded that the Respondent fell below the standard of due care in his recordkeeping obligations, and in many respects, his audit assessments painted an even bleaker picture of the Respondent's recordkeeping than the Government's version. While his view that the Respondent should somehow be absolved of his obligations as a registrant by virtue of his reliance upon a pharmacy consultant is wholly unpersuasive, it did not undermine the value of his expert opinions in this case. In short, Mr. Litman's presented testimony that was sufficiently detailed, authoritative and candid to be credited in this decision.

The Respondent testified that he was born in St. Louis, Missouri, in 1946 and that he graduated from St. Louis University and the St. Louis University School of Medicine. Tr. 549. After graduating from medical school, the Respondent completed a two-year residency in basic surgery at the University of Florida.[73] Tr. 549. The Respondent volunteered that he has published scholarly articles in his field of practice, and that as a medical student, he discovered the cause of burn anemia and presented his findings at a meeting of the Saint Louis Surgical Society, where he was awarded a prize in recognition of his achievement. Tr. 550. Once done with his residency, the Respondent performed general surgery for two years in St. Louis, and then completed a one-year fellowship in burns.[74] Tr. 549. After the burns fellowship, the Respondent finished a two-year residency in plastic surgery at the University of Illinois in Chicago. Tr. 549, 562. During this time, the Respondent taught a course in burn management to pediatricians at the University of Illinois-Chicago, lectured in pediatric burn care, and was appointed as Instructor in Surgery. Tr. 562. The Respondent moved to Broward County in 1979 to open a practice in plastic surgery. Tr. 549. The Respondent stated that he has remained in southern Florida since 1979. Tr. 549.

Though the Respondent maintained a general plastic surgery practice in Pembroke Pines, Florida, he explained that for years he also covered emergency rooms and focused his practice on ''reconstructive surgery, primarily facial skin cancers, post-mastectomy breast reconstruction, and . . . difficult wounds.'' Tr. 551. According to the Respondent, ''[u]ltimately, like most plastic surgeons, as [he] got older, [his] practice gravitated to primarily cosmetic surgery,'' but allowed that he still performs some reconstructive work. Tr. 551–52. In 1999 the Respondent ''began doing some work'' [75] at a PCCS office in Weston, Florida.[76] Tr. 550. The Respondent testified that, while he initially worked at PCCS ''one day a week or every other Saturday . . . . as the other physicians came and went, I seemed to get more . . . time there.'' Tr. 550–51. Although other physicians

[68] Mr. Litman's report states that the Demerol calculations were ''based on 222 form drug orders, not actual procedures.'' Resp't Ex 18, at 1. Litman's testimony explained that he garnered surgical procedure information from the Respondent's surgical records.

[69] Mr. Litman concluded that they were using the same amount per procedure after going through the records, and after being told by the Respondent that he was ''using consistent the same as . . . always.'' Tr. 429–30.

[70] *Id.*

[71] In contrast to the audit conducted by DEA, Litman found only shortages, and no overages. Resp't Ex. 18, at 1; Gov't Ex. 10.

[72] It is clear from Mr. Litman's testimony that he was referring to Ms. Arciniega.

[73] The Respondent's CV was received into evidence without objection. Resp't Ex. 2.

[74] The Respondent has published several articles in the fields of burns. However, he tested that he was ''unfortunate [in] that in south Florida, they were unwilling to need somebody who had my expertise.'' Tr. 550.

[75] At this time, the Respondent was an ''independent contractor'' at PCCS and was paid a percentage of the amount PCCS charged for a surgery he performed. Tr. 554. The Respondent also testified that PCCS maintained the state required certifications for conscious and general sedation. Tr. 555–56.

[76] Weston is in ''western Broward County west of Ft. Lauderdale.'' Tr. 553.

seemed to come for periods of time and move on, he testified that he stayed with PCCS. Tr. 558–59. The Respondent explained that over the years several physicians were appointed by PCCS as the primary doctor. Tr. 559. According to the Respondent:

> I would occasionally become the primary doctor because someone left, moved on, got fired. But I was really never the primary doctor until maybe 2008. And even then, they would occasionally bring someone in to either do some work or even to the majority of the work. It disappointed me a little bit but since I had my private office at the time, and I wasn't willing to give it up, I didn't feel there was much I could say about that because I was not devoting all my time to PCCS.

Id.

In or around 2005, the surgeon working at the Coconut Grove PCCS location moved to Weston, so PCCS asked the Respondent to ''go down to Coconut Grove and take his place.'' Tr. 552. Because Respondent's home at the time was equidistant from Weston and Coconut Grove, he accepted the proposed move. Tr. 553. It was in 2005, when he assumed the duties at PCCS Coconut Grove,[77] that his COR was utilized to handle controlled substances in the clinic.[78] Tr. 559–60. The Respondent testified that ''when the supply of drugs got low, they would tell [him] that they needed for [him] to fill out a form. Sometimes they would write in the amounts, sometimes they'd tell [him] and [he] would just write it in and sign it and they'd send it off and order the drugs.'' Tr. 560. The Respondent indicated that he became ''the primary doctor'' at PCCS sometime around 2008. Tr. 559.

According to the Respondent, just over a year ago he began ''slowing down'' his private practice, a process which he explained as ''limiting [his] procedures, not taking on any more complicated cases or cases that would require multiple procedures or a long time[, a]nd basically telling the patients that [he] was going to be leaving in some period of time.'' Tr. 571–73. On April 18, 2011, the Respondent closed his private practice to focus on his work at PCCS.[79] Tr. 571–73, 665. In this regard, the Respondent explained that ''about 99 percent'' of his practice involves controlled substances and that a limitation on his ability to use narcotics ''would be like cutting off my hands.'' Tr. 575.

Turning to the allegations underlying this case, the Respondent testified that ''when I first discovered that I had done something wrong . . . I was pretty devastated. I couldn't believe it. The center seemed to run so well for a number of years.'' [80] Tr. 566.

As a partial explanation for his surprise, the Respondent offered PCCS' employment of Mr. Koptowsky as a pharmacy consultant. Tr. 567. In this regard, the Respondent testified that he met Mr. Koptowsky once, during his November 9, 2010, inspection, and that, while he had never seen the actual inspection forms, he ''was aware that they existed and that there wasn't anything that applied, there wasn't any correction or problem that was listed that . . . I needed to do something about.'' Tr. 630, 639. 41; Resp't Ex. 9.

Relatedly, the Respondent also testified that the Board of Medicine requires that a facility be accredited by one of three organizations—Quad A, AAA, or the State—''in order to be able to perform procedures which require general anesthesia or conscious sedation.'' [81] Tr. 580. To obtain certification through either the State or the Quad A, a facility must undergo an inspection conducted by a medical doctor. Tr. 587–88. The Respondent presented his understanding that the physician conducting such an inspection examines many facets of the practice, including procedure manuals, a random sampling of charts, and the operating room. Tr. 588, 590.

On March 31, 2010, the PCCS facility in Coconut Grove passed a Quad A inspection, and was granted a certification to March 31, 2011. Resp't Ex. 14. Sometime after the Quad A inspection, PCCS opted to obtain a certification through the State. Tr. 590–91. However, due to a backlog, the State inspection did not occur until September of 2011. Tr. 590–91. When the State inspection took place, the inspector found some violations, which the Respondent explained as ''mostly small things,'' such as ''some of the more recent charts [not having] their operating notes.'' Tr. 592–93. After the inspection, PCCS sent a letter to the State stating that the uncovered deficiencies had been corrected. Tr. 592–93; Resp't Ex. 4. On October 12, 2011, the State sent a letter to PCCS acknowledging the receipt of the correction letter.[82] The Respondent explained that the October 12, 2011, letter was ''final.'' Tr. 593.

The Respondent testified that when the allegations regarding VM's drug abuse surfaced, ''she wanted to be drug tested because she totally denied the allegations.'' Tr. 577. Accordingly, the Respondent authorized a drug test for VM. Tr. 577. On April 19, 2011, a hair sample from VM was collected. Gov't Ex. 3. Three days later, on April 22, 2011, the sample tested negative for all controlled substances. Gov't Ex. 3.[83]

With regard to the November 23, 2010, prescription to VM, the Respondent explained that, on the relevant date, he had three surgeries planned, but there were no narcotics on hand at the practice. Tr. 593–94. To address this problem, the Respondent issued a prescription in VM's name ''so that at least we'd have some for future surgeries if we needed them [a]nd that was obviously a mistake.'' Tr. 595–96.[84] Later, when reviewing the patient charts for the three patients seen on November 23, 2010, the Respondent discovered that two of the three anesthesia records from the November 23, 2010, operations were missing. Tr. 599–600. Furthermore, the remaining anesthesia record that was found reflected indicia of alterations. Tr. 599–602.

The Respondent explained that, when he performs a surgery requiring anesthesia, the nurse anesthetist or the anesthesiologist will keep the anesthesia record by ''writ[ing] in each of the drugs that are being administered and . . . what dosage is administered [a]nd then at the end, they usually put some sort of a total.'' Tr. 599. However, the anesthesia record from November 23, 2010, reflected ''way too many drugs . . . listed across the contemporaneous portion.'' Tr. 601. Specifically, the

[77] The Respondent clarified that this was not ''a compensation position.'' Tr. 561.

[78] The Respondent indicated that he could not recall whether he signed a document specifically authorizing the use of his DEA COR. Tr. 561. However, he testified that he thought the document appointing him medical director ''calls . . . for them to use my narcotic registration.'' Tr. 561.

[79] The Respondent testified that his decision to focus on PCCS was motivated by his desire to ''not have any overhead to worry about, not have to worry about payrolls and all the other things that you have to concern yourself with and then . . . [he] could pretty much walk away from there because [he] didn't have the same responsibilities [he] had in a private practice.'' Tr. 573.

[80] The Respondent testified that there were ''very minor'' problems regarding entries in the narcotics log, where ''one person was using cc[]s and the other person was using vials.'' Tr. 567–68.

[81] The Respondent never sought certification for his private practice because he was able to perform surgeries at a local ambulatory surgical facility. Tr. 557.

[82] According to the Respondent, in a State inspection, deficiencies are outlined in a letter directing correction and that when the issues are minor, no post-correction re-inspection customarily occurs. Tr. 589.

[83] Respondent Exhibit 3, which was admitted into evidence, also contains two negative drug tests from September of 2011. The Respondent testified ''I don't think I wrote the one in September.'' Tr. 663.

[84] The Respondent further testified (incorrectly) that ''I should have written a prescription to each, for each patient for the amount of narcotic I thought we were going to use. And that way, probably would be all proper. I'm not sure . . . .'' Tr. 595. *See* 21 CFR § 1305.03.

Respondent testified that the particular procedure reflected on the chart would have taken about an hour, but that he saw what ''looked like seven ampules had been administered [a]nd that's . . . just not going to be done for a procedure that takes less than an hour.'' Tr. 601–02.[85] The Respondent allowed that if the high doses reflected on the chart reflected the reality, the patient's respiratory muscles would have been paralyzed, which the Respondent testified did not occur. Tr. 609–10. It is the Respondent's opinion that the logs were altered. Tr. 611. When questioned about who would have access to the logs, the Respondent testified that ''the three people that would always be present in the operating room were the anesthetist . . . [DN], who was the scrub nurse; and myself.'' Tr. 611. However, Priscilla Arciniega, the receptionist at the office, would ''often'' help clean up. Tr. 611–13. Furthermore, it ''was part of Ms. Arciniega's responsibility to at least . . . ha[ve] access to all the medical records.'' [86] Tr. 614.

The Respondent testified that Ms. Arciniega was ''hired as kind of a jack of all trades. [I]t turned out that another plastic surgeon whose office [VM] used to provide anesthesia for was retiring or closing his office and . . . had worked with [Arciniega] . . . before. And since we needed a person [VM] gave [Arciniega] a job.'' Tr. 612. The Respondent testified that although he was not present when Arciniega left the practice, it was his understanding that she was terminated for cause when she was unable to supply a physician's note as requested by VM to excuse a work absence. Tr. 658–59. The Respondent testified that the allegedly unexcused absence occurred sometime at the end of February of 2011. Tr. 655. However, a timecard admitted into evidence shows that from February 23 through March 9, 2011, Ms. Arciniega worked 34.5 hours. Resp't Ex. 15, at 5. The Respondent also testified that, during the preparation for his testimony with his counsel, he learned that Ms. Arciniega had ''been arrested in New York for distribution of narcotics.'' [87] Tr. 660.

The Respondent testified that he took numerous steps to address the compliance issues that had been related to him by DI McRae during her January visit. Tr. 569. Specifically, the Respondent testified that he: (1) ''Assumed immediate control of the key [to the controlled substances safe];'' (2) ''took control of the record keeping and [checks] the addition and subtraction after every single case and at the end of the operating day;'' and (3) implemented a new policy wherein he personally oversees the opening of all controlled substance shipments to the office.[88] Tr. 569–71. The Respondent explained that ''if there [is] any medication that's sitting on the anesthesia cart, we put it back in the box after our inventory has been done. I lock the box and take the key, put it back in the lock box and close it.'' Tr. 620. The Respondent also fixed a broken lock on the controlled substance safe and created separate folders for DEA Form 222s and biennial inventories. Tr. 624–27. During the hearing he expressed an intention to begin performing background checks on new hires. Tr. 661. When asked about his current level of attention to his responsibilities as a registrant, the Respondent declared that his current practice is ''[a] 180 from what was going on before. I have taken complete control and I have now accepted my responsibility, which I obviously had neglected before.'' Tr. 623.

The Respondent presented testimony that was sufficiently detailed, internally consistent, and plausible to be fully credited in this recommended decision. When asked about his missteps as a registrant, the Respondent unequivocally offered: ''Obviously I made some terrible mistakes but I felt there wasn't anything there that I couldn't correct, that I didn't want to correct.'' Tr. 569. At another point in his testimony, the Respondent declared that he ''absolutely recognize[s]'' that he has not complied with his obligations as a registrant, and flatly acknowledged that, notwithstanding the fact that his practice prior to 2005 involved others handling controlled substances during his procedures, that he ''was ultimately responsible.'' Tr. 575. His demeanor presented all the indicia generally associated with candor, including unfaltering acknowledgements of weaknesses in his past performance as a registrant and mistakes he has made founded in lack of the oversight required by his position. He presented the fact that a (derelict) consultant had been retained by PCCS in a manner that made it clear that he was not shrinking from his own culpability regarding the condition of his recordkeeping and other issues.

The Government presented the testimony of DI McRae in a purported rebuttal to Mr. Litman's testimony. Tr. 607. In truth, while some nuances of Littman's audit and some elements (such as time span covered) of that audit that distinguished it from the Government's audit were elicited, there was little of consequence that was actually rebutted. The Respondent's recordkeeping, as he has conceded from the outset, was problematic.

Other facts required for a disposition of this matter are set forth in the balance of this recommended decision.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4) (2006), the Administrator [89] is permitted to revoke a COR if persuaded that the registrant ''has committed such acts as would render . . . registration under section 823 . . . inconsistent with the public interest . . . .'' The following factors have been provided by Congress in determining ''the public interest'':

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

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

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

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

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

21 U.S.C. § 823(f) (2006 & Supp. III 2010).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether a registration should be rejected. *Morall* v.

[85] The patient chart was admitted as Respondent's Exhibit 19. The chart shows eight contemporaneous administrations of Demerol totaling 300 milligrams. However, the ''total'' column reflects that only 50 mgs of Demerol had been administered to the patient. Though acknowledging that he is ''not a handwriting expert,'' the Respondent testified that the handwriting for the higher dosages appeared different than other entries on the chart. Tr. 607. However, he could not remember the name of the anesthesiologist. Tr. 672–73.

[86] The Respondent testified that it is standard for office staff to have access to patient medical records. Tr. 614–15. When asked whether he could limit staff access to medical records the Respondent replied that ''it's not efficient and it's not required.'' Tr. 616–17.

[87] The Respondent testified that, if he had known that Ms. Arciniega had been arrested for drug trafficking, ''I don't think she would have ever been hired . . . and if she were hired, she would have been terminated immediately.'' Tr. 660.

[88] The Respondent indicated his intention to seek Agency advice on the issue of how to better implement this control in light of the limited number of days he works in the PCCS office. Tr. 569–71, 621, 674–77, 688.

[89] This authority has been delegated pursuant to 28 CFR §§ 0.100(b) and 0.104 (2010).

DEA, 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs,* 53 Fed. Reg. 43945, 43947 (1988); *David E. Trawick, D.D.S.,* 53 Fed. Reg. 5326, 5327 (1988); *see also Joy's Ideas,* 70 Fed. Reg. 33195, 33197 (2005); *David H. Gillis, M.D.,* 58 Fed. Reg. 37507, 37508 (1993); *Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16422, 16424 (1989). Moreover, the Administrator is ''not required to make findings as to all of the factors . . . .'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173–74. The Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 462 (2009).

In an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR § 1301.44(e) (2011). The Government may sustain its burden by showing that the Respondent has committed acts inconsistent with the public interest. *Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8235–36 (2010). Once DEA has made its *prima facie* case for revocation of the registrant's COR, the burden of production then shifts to the Respondent to present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23848, 23853 (2007);. *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 Fed. Reg. 72311, 72312 (1980). ''[T]o rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. at 8236. Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Abbadessa,* 74 Fed. Reg. at 10078; *see also Gregory D. Owens, D.D.S.,* 74 Fed. Reg. 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (2010) (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *East Main Street Pharmacy,* 75 Fed. Reg. 66149, 66165 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Abbadessa,* 74 Fed. Reg. at 10078; *Krishna-Iyer,* 74 Fed. Reg. at 463; *Medicine Shoppe,* 73 Fed. Reg. at 387.

While the burden of proof at this administrative level is a preponderance-of-the-evidence standard, *see Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981), the Administrator's factual findings will be sustained on review so long as they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. Thus, ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case. *Shatz,* 873 F.2d at 1092; *Trawick,* 861 F.2d at 77. However, in rendering a decision, the Administrator must consider all ''important aspect[s] of the problem,'' such as a Respondent's defense or explanation that runs counter to the Government's evidence. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys,* 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported. *Morall,* 412 F.3d at 183. Mere unevenness in application standing alone does not, however, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co.,* 411 U.S. 182, 188 (1973)), *cert. denied,* U.S., 129 S. Ct. 1033, 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in a recommended decision are entitled to significant deference. *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951). Thus, a recommended decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are not binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. § 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority; and Any Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine in Florida. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant state licensing board or professional disciplinary authority. However, that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 Fed. Reg. 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 Fed. Reg. at 461. It is well-established Agency precedent that a ''state license is a necessary, but not a sufficient condition for registration.'' *Leslie,* 68 Fed. Reg. at 15230; *John H. Kennedy, M.D.,* 71 Fed. Reg. 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 Fed. Reg. 9209, 8210 (1990).

The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* U.S., 129 S. Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General, not state officials. *Stodola,* 74 Fed. Reg. at 20375. Here, there is no evidence of record that the state licensing board has even considered the issue of a formal action against the Respondent's licensure. Thus, on these facts, the absence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest. *See Roni Dreszer, M.D.,* 76 Fed. Reg. 19434, 19444 (2011) (''[T]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.'').

Regarding the third factor (convictions relating to the manufacture, distribution, or dispensing of controlled substances), the record in this case does not contain evidence that the Respondent has been convicted of (or charged with) a crime related to the manufacture, distribution, or dispensing of controlled substances. DEA administrative proceedings are non-punitive and ''a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA COR, and who have not presented sufficient mitigating evidence to assure the [Administrator] that they can be trusted with the responsibility carried by such a registration.'' *Jackson,* 72 Fed. Reg. at 23853; *Leo R. Miller, M.D.,* 53 Fed. Reg. 21931, 21932 (1988). Where evidence in a particular case reflects that the Respondent has acquired convictions relating to the manufacture, distribution, or dispensing of controlled substances, those convictions must be carefully examined and weighed in the adjudication of whether the issuance of a registration is in the public interest. 21 U.S.C. § 823(f).

Although the standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest, evidence that a registrant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA certificate. The probative value of an absence of any evidence of criminal prosecution is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities. *See Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.,* 75 Fed. Reg. 49956, 49973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry''), *aff'd, Mackay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.,* 74 Fed. Reg. 6056, 6057 n.2 (2009).

Accordingly, consideration of the evidence of record under the first and third factors neither supports the Government's argument for revocation nor militates against it.

Factors 2 and 4: Experience in Dispensing Controlled Substances and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

In this case, the gravamen of the Government's case seeking revocation relates to its allegations that the Respondent failed to adhere to the CSA's recordkeeping and security requirements and was unable to account for both shortages and overages of controlled substances. Factors Two and Four are relevant to the analysis.

Regarding Factor Two, in requiring an examination of a registrant's experience in dispensing controlled substances, Congress manifested an acknowledgement that the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he or she has been in the business of doing so, are significant factors to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA COR. In some cases, viewing a registrant's actions against a backdrop of how she has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

Evidence that a practitioner may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration, which must be accorded due weight. The registrant's knowledge and experience regarding the rules and regulations applicable to practitioners also may be considered. *See Volusia Wholesale,* 69 Fed. Reg. 69409, 69410 (2004) (List I case).[90] However, the Agency has taken the reasonable position that this factor can be outweighed by acts held to be inconsistent with the public interest. *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463; *see also Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8235 (2010) (acknowledging Agency precedential rejection of the concept that conduct which is inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities which occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 63 Fed. Reg. 51592, 51560 (1998) (''[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''). The Agency's approach in this regard has been sustained by on review. *Mackay,* 664 F.3d at 819.

Experience which occurred prior or subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even

[90] In *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. 19450, 19450 n.1 (2011), the Agency reasonably ruled that the *Volusia Wholesale* List I analysis of Factor Two experience would not be applied to practitioner cases where intentional diversion allegations were sustained. However, insofar as the CSA requires consideration of ''experience'' in both the List I and practitioner contexts, it is reasonable (and not inconsistent with existing Agency precedent) to apply this measure in practitioner cases where intentional diversion has not been established. *Compare* 21 U.S.C. 823(h) (List I section mandating consideration of ''any past *experience* of the applicant in the manufacture and distribution of chemicals,'') (emphasis added) *with* 21 U.S.C. 823(f) (practitioner section mandating consideration of ''[t]he applicant's *experience* in dispensing, or conducting research with respect to controlled substances.); *see U.S.* v. *Tinklenberg,* 131 S.Ct. 2007, 2019–20 (2011) (''Identical words used in different parts of a statute are presumed to have the same meaning absent indication to the contrary.''). In reaching this conclusion, the word ''past'' in 823(h) is treated in surplusage for the simple reason that all experience is past. *See* Merriam-Webster's Collegiate Dictionary 440 (11th ed. 2007); *c.f. TMW Enterprises, Inc.* v. *Federal Ins. Co.,* 619 F.3d 574, 580 (6th Cir. 2010) (''[A]pplying the rule against surplusage is often overrated.'').

acknowledging the gravity of a registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against his registration may not be compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are congruous with a consistent past pattern of poor behavior can enhance the Government's case.

In a similar vein, conduct which occurs after proven allegations can shed light on whether a registrant has taken steps to reform and/or conform his conduct to appropriate standards. Contrariwise, a registrant who has persisted in incorrect behavior, or made attempts to circumvent Agency directives, even after being put on notice, can diminish the strength of his case. *Novelty, Inc.,* 73 Fed. Reg. 52689, 52703 (2008), *aff'd,* 571 F.3d 1176 (D.C. Cir. 2009); *Southwood Pharm., Inc.,* 72 Fed. Reg. 36487, 36503 (2007); *John J. Fotinopoulous,* 72 Fed. Reg. 24602, 24606 (2007).

In *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463, DEA acknowledged the reality that even a significant and sustained history of uneventful practice under a DEA certificate can be offset by proof that a registrant has committed acts inconsistent with the public interest. *Id.* The Agency, in its administrative precedent, has further curtailed the scope of Factor Two. The Agency's current view regarding Factor Two is that, while evidence of a registrant's experience handling controlled substances may be entitled to some weight in assessing whether errant practices have been reformed, where the evidence of record raises intentional or reckless actions on the part of the registrant, such evidence is entitled to no weight where a practitioner fails to acknowledge wrongdoing in the matters before the Agency. *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. at 19450 n.3; *Roni Dreszer, M.D.,* 76 Fed. Reg. 19434 n.3 (2011); *Michael J. Aruta, M.D.,* 76 Fed. Reg. 19420 n.3 (2011); *Jacobo Dreszer, M.D.,* 76 Fed. Reg. 19386–87 n.3 (2011). Even, ''evidence that a practitioner has treated thousands of patients does not negate a prima facie showing that the practitioner has committed acts inconsistent with the public interest.'' *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. at 463.This evolution is rooted in the sensible logic that conduct that is never acknowledged as improper cannot reasonably be argued as aberrant. This is so because the actor in such a scenario has not isolated his past actions to be in any way wrong and worthy of avoidance in the future. This feature of the Agency's interpretation of its statutory mandate has also been sustained on review. *Mackay,* 664 F.3d at 822.

As discussed more fully, *infra,* the Government's evidence that the Respondent improperly prescribed Demerol to replenish office stocks, as well as the actions he took upon being apprised of his deficiencies as a registrant reflect negatively and positively, respectively under Factor Two.

Regarding Factor Four (compliance with laws related to controlled substances), to effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). ''Recordkeeping is one of the central features of the CSA's closed system of distribution. . . . . A registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.'' *Satinder Dang, M.D.,* 76 Fed. Reg. 51424, 51429 (2011) (internal punctuation and citations omitted). There is no question that the maintenance of accurate records by registrant's is key to the DEA's ability to fulfill its obligations to regulate controlled substances. As previously held by the Agency, ''[r]ecordkeeping 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.'' *Paul H. Volkman,* 73 Fed. Reg. 30630, 30633 (2008), *aff'd, Volkman,* 567 F.3d at 224 (DEA Administrator's reliance on recordkeeping violations in denying COR application specifically upheld). Thus, recordkeeping deficiencies may ''provide[] reason alone to conclude (with respect to factors two and four) that [a registrant's] continued registration is inconsistent with the public interest.'' *Id.* (internal punctuation omitted). However, the Agency has also held that where non-egregious recordkeeping errors are acknowledged and remedied promptly, revocation may not always be required. *Terese, Inc., d/b/a/Peach Orchard Drugs,* 76 Fed. Reg. 46843, 46848 (2011).

In *Terese,* substantial evidence established that the registrant had failed to conduct an initial inventory as required under 21 CFR § 1304.11(b), failed to execute a power of attorney form as required by 21 CFR § 1305.05(a), and failed to include dates on DEA Forms 222, as required by 21 CFR § 1305.13(e). In declining to revoke Terese's registration, the Agency, emphasizing that the registrant had accepted responsibility for its violations and had instituted corrective actions, determined that, under the circumstances, the three recordkeeping violations did not render its continued registration inconsistent with the public interest. *Id.* at 46848. In *Ideal Pharmacy Care, Inc. d/b/a/Esplande Pharmacy,* 76 Fed. Reg. 51415, 51416 (2011), an audit of the registrant's records showed a shortage of 150,000 dosage units of hydrocodone, 83,000 dosage units of alprazolam, and 1.6 million milliliters of promethazine with codeine. However, in contrast to *Terese,* the Agency found [91] that Ideal Pharmacy's failure to maintain accurate records constituted an act which rendered its continued registration inconsistent with the public interest. *Id.* Taken together, *Ideal* and *Terese* indicate that, when considering recordkeeping violations, the Agency has coupled consideration of the degree of severity with an analysis of whether the registrant has both acknowledged culpability and demonstrated credible efforts aimed at correction. The current state of the Agency's precedent thus provides a logical framework upon which the current evidence can be evaluated.

DEA regulations provide that ''[e]very registrant required to keep records pursuant to § 1304.03 [92] shall maintain on a current basis a complete and accurate record of each substance . . . imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.'' 21 CFR § 1304.21(a). Additionally, Florida law requires that all persons dispensing or distributing controlled substances must, ''on a current basis, [maintain] a complete and accurate record of each substance, manufactured, received, sold, delivered, or otherwise disposed of by him or her.'' Fla. Stat. § 893.07(1)(b).

In this case, factual issues related to compliance with applicable laws do not reflect well on the Respondent's suitability as a registrant. DI McRae's audit revealed shortages of Demerol and 50 mcg/ml fentanyl accounting for approximately 75% and 100% of the Respondent's inventory, respectively.

[91] The registrant in *Ideal* waived its right to hearing and presented no evidence to the Agency on its behalf. *Id.*

[92] Section 1304.03 provides that ''[e]each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section.'' Respondent does not contend that any of the § 1304.03 exemptions apply in this case.

Furthermore, the audit revealed overages of: (1) 2,371.6% of the Respondent's inventory of 100 mcg/ml fentanyl; (2) 100% of the Respondent's inventory of 10 mg/10ml Midazolam; and (3) 290.2% of Respondent's inventory of 2 mg/2 ml Versed. Gov't Ex. 10. The audit conducted by Respondent's expert likewise found significant shortages of Diazepam and fentanyl, but no overages.[93] Resp't Ex. 18. While the dates and results of the audits conflict, it is unnecessary to resolve the differences because, regardless of the audit considered, it is clear that the Respondent's records were disturbingly inaccurate, that the discrepant amounts were significant, and that substantial evidence supports the conclusion that the Respondent violated federal law by failing to maintain a complete and accurate record of each substance. *See Bill Lloyd Drug,* 64 Fed. Reg. 1823, 1824 (1999) (''The shortages and overages revealed by the accountability audit show that Respondent does not keep complete and accurate records of its controlled substance handling as required by 21 U.S.C. 827 and 21 CFR 1304.21.''); *see also Alexander Drug Company, Inc.,* 66 Fed. Reg. 18299, 18303 (2001) (Shortages or overages constitute violations of 21 CFR § 1304.21 and 21 U.S.C. § 827.); *Ellis Turk, M.D.,* 62 Fed. Reg. 19603, 19605 (1997) (same). Furthermore, insofar as it is clear that the Respondent failed to maintain accurate records of the controlled substances received at his office, substantial evidence supports a conclusion that he violated Fla. Stat. § 893.07(1)(b). These are conclusions that the Respondent does not resist.

DEA regulations also require that ''[i]nventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant.'' 21 CFR § 1304.04(f)(1). Florida law has also adopted the separate record requirement for inventories and records of Schedule I or Schedule II controlled substances. Fla. Stat. § 893.07(4)(A). In the present matter, substantial evidence supports the conclusion that the Respondent violated the foregoing federal and state separate records requirements by maintaining his Schedule II records with other records in the peer review pharmacy book. Tr. 105–06.

DEA regulations require that each registrant ''take a new inventory of all stocks of controlled substances on hand at least every two years.'' 21 CFR § 1304.11(c). Florida law has also adopted this biennial record requirement. *See* Flat. Stat. § 893.07(1)(a). The Government's evidence establishes that the Respondent did not conduct the biennial inventory as required by these federal and state regulations. Tr. 87.

DEA regulations also contain a requirement that a purchaser desiring to obtain a supply of Schedule I or Schedule II controlled substances must execute three copies of a DEA Form 222. *See* 21 CFR §§ 1304.03, 1304.13. Upon completion, two copies must be sent to the supplier, while one copy must be retained by the purchaser. 21 CFR § 1301. These federal regulations require that the purchaser retain its copy of the form in its files, and that the supplier retain its copies of the form in its files. *Id.* ''The purchaser must record on [its copy] of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.'' 21 CFR § 1305.13(e). It is a violation of the regulations to file an incomplete, illegible, improperly prepared, improperly executed, or improperly endorsed Form 222. 21 CFR § 1305.15(a)(1). Similarly, 21 CFR § 1305.03, requires that (subject to specified exceptions not applicable here) ''a DEA Form 222 or its electronic equivalent . . . is required for each distribution of a Schedule I or II controlled substance.'' In the present case, the Respondent transferred Schedule II controlled substances from his registered address, in Miami, Florida, to a Tampa, Florida, PCCS office, without complying with the federal recordkeeping requirements of section 1305.03. Tr. 64–65, 426–27. Furthermore, it is undisputed that the Respondent failed to fill out at least fourteen Form 222s properly, insofar as he did not record the quantity of controlled substance shipments received, or the dates that the shipments arrived. Gov't Ex. 6.

Beyond the recordkeeping violations at issue here, the Government has also alleged that the Respondent ''failed to properly dispose of controlled substances in violation of 21 CFR § 1307.21(a)(1).'' Section 1307.21(a)(1) provides that, a person desiring to dispose of a controlled substance may contact the cognizant DEA Special Agent in Charge in order to gain authority to dispose of the substance. Necessarily, this language implies that a person who does not request assistance to dispose of a controlled substance does not have authority to dispose of such substance. This is a classic example of permissive language which ''plainly carr[ies] a restrictive meaning.'' *See Forest Grove School Dist.* v. *T.A.,* 129 S.Ct. 2484, 2499 n. 1 (2009) (citing *Carlisle* v. *U.S.,* 517 U.S. 416–431–32 (1996) (collecting cases)). Under a plain reading of the regulation, a registrant is not required to dispose of controlled substances, but once he or she elects to do so, such disposal may not be made without authorization from the specified DEA official. To obtain the necessary authorization, a registrant ''shall list the controlled substance or substances which he . . . desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his . . . area.'' 21 CFR § 1307.21(a)(1). Here, substantial evidence supports the conclusion that, on numerous occasions, the Respondent disposed of controlled substances without notifying the DEA. Tr. 60, 142.

In its charging document, the Government also alleged that the Respondent failed to execute a power of attorney to authorize VM to order controlled substances on his behalf, as required by 21 CFR § 1305.05(a). ALJ Ex. 1 at 2. Section 1305.05 provides, in relevant part, that ''[a] registrant may authorize one or more individuals . . . to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual . . . .'' As with the disposal provisions discussed above, the language of section 1305.05 clearly is intended to create a restrictive meaning whereby a registrant may not authorize another person to issue orders for Schedule I or Schedule II controlled substances absent an authorized power of attorney. *See Forest Grove School Dist.,* 129 S.Ct. at 2499 n. 1. During the hearing, DI McRae testified that the Respondent's practice of having a staff member fill out the DEA Form 222s was not a violation of the relevant regulation because the Respondent signed the DEA Form 222s. Tr. 184. Thus, this allegation stands unsupported by the evidence of record.

The Government contends that the Respondent ''failed to provide an adequate system for monitoring the receipt, distribution, and disposition of controlled substances, in violation of 21 CFR §§ 1305.05(a) and 1301.71.'' Gov't Posthearing Brief, at 20; *see also* ALJ Ex. 1, at 2. As an initial matter, as discussed immediately above, DI McRae testified that the Respondent's ordering process was not a violation of the power of attorney requirements of section 1305.05. Tr. 184. As to the allegation of a security violation, 21 CFR § 1301.71 provides, in relevant part, that ''[a]ll applicants and registrants shall provide effective controls and procedures to

[93] As explained above, the Mr. Litman's audit did not consider the Respondent's supplies of Midazolam.

guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.'' However, 21 CFR § 1301.71(b) sets forth fifteen factors which may be used to determine whether there is a ''need for strict compliance with [the] security requirements.'' Of relevance here, one of the section (b) factors is ''[t]he adequacy of the registrant's . . . system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.'' 21 CFR § 1301.71(b)(14).

While the ''security requirements'' set forth in sections 1301.72 through 1301.76 are used as standards to determine compliance with section 1301.71(a), the language of each of these sections is phrased in mandatory terms. *See e.g.,* 21 CFR § 1301.75(a) (''Controlled substances listed in Schedule I *shall* be stored in a securely, locked, substantially constructed cabinet.'') (emphasis added); 21 CFR 1301.76(a) (''The registrant *shall not* . . . .'') (emphasis added). Thus, while compliance with the security provisions is a consideration under 21 CFR § 1301.71(a)'s inquiry into the adequacy of a registrant's security system, violation of any such provision will be an independent consideration under Factor Four. In contrast, insofar as the factors set forth in subsection (b) are to be used only to determine the ''need for strict compliance with [the] security requirements,'' it follows that non-compliance with any of the factors in subsection (b) is not a *per se* violation of the security requirements. Accordingly, the Government's contention that the Respondent's alleged violation of section 1301.71(b)(14) may be used to sustain a violation of section 1301.71(a)'s security requirements is a facially defective allegation *ab initio.*

Finally, DEA regulations provide explicitly that ''[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.'' 21 CFR § 1306.04(b). Similarly, Florida law provides as grounds for a disciplinary action the act of ''[p]rescribing any medicinal drug appearing on Schedule II [94] in chapter 893 by the physician for office use.'' Fla. Stat. § 458.331(1)(bb). Here, the Government's evidence establishes that on a single occasion, the Respondent procured Demerol through a prescription written in the name of an individual who was never intended as its recipient, in violation of federal and state law.[95]

In light of the foregoing, substantial evidence of record supports a finding that: (1) The Respondent violated 21 CFR § 1304.21(a) and Fla. Stat. § 893.07(1)(b) by failing to keep accurate records of controlled substances; (2) the Respondent violated 21 CFR § 1304.04(f)(1) and Fla. Stat. § 893.07(4)(A) by failing to maintain inventories and records of Schedule I and Schedule II controlled substances separately from other inventories and records; (3) the Respondent transferred Schedule II controlled substances from his registered address without complying with the recordkeeping requirements of section 1305.03; (4) the Respondent disposed of controlled substances without completing a DEA Form 41, as required by 21 CFR § 1307.21(a)(1); and (5) the Respondent violated 21 CFR § 1306.04(b) and Fla. Stat. § 458.331(1)(bb) by prescribing Demerol for office use, which also reflected negatively on the Respondent's experience in dispensing controlled substances under Factor Two.

Insofar as the preceding statutes and regulations relate to controlled substances, this litany of violations weighs substantially in favor of revocation under Factor Four. *See Ideal Pharmacy,* 76 Fed. Reg. at 51416 (Severe recordkeeping violations sufficient to meet Government's *prima facie* burden). Regarding the Respondent's experience in dispensing controlled substances under Factor Two, the record establishes that, prior to the events underlying this case, the Respondent practiced uneventfully for more than thirty years—at least to the extent that his conduct did not arouse the attention of DEA or other regulatory authorities. Tr. 549–62. As discussed, *supra,* in view of the Respondent's election to take responsibility for his wrongdoings, and because there has been no intentional diversion proven in this case, such experience may be considered in a positive light under Factor Two. *See supra* note 98 and accompanying text. However, the positive value of such experience is tempered by the Respondent's admitted uncertainty regarding certain requirements of DEA regulations. *See* Tr. 595, 680–81 (Where the Respondent expressed uncertainty regarding DEA requirements); *see also Volusia Wholesale,* 69 Fed. Reg. at 69410 (Factor Two requires consideration of the Respondent's knowledge of DEA regulations and requirements). Furthermore, the evidence or record which unequivocally establishes that he issued a Demerol prescription to improperly replenish his office stocks reflects that the Respondent is an individual who simply did not make any serious effort to understand his important responsibilities as a registrant.[96] Under these circumstances, the experience component of Factor Two, even assuming, *arguendo,* that the Respondent's many years of prior practice were compliant with the applicable regulations, weighs in favor of revocation.

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

The fifth statutory public interest factor directs consideration of ''[s]uch *other conduct* which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5) (emphasis supplied). Existing Agency precedent has long held that this factor encompasses ''conduct which creates a probable or possible threat (and not only an actual [threat]) to public health and safety.'' *Dreszer,* 76 FR at 19434 n.3; *Aruta,* 76 FR at 19420 n.3; *Boshers,* 76 Fed. Reg. 19403 n.4; *Dreszer,* 76 FR at 19386–87 n.3. Agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the CSA. *Terese,* 76 FR 46848; *Tony T. Bui, M.D.,* 75 FR 49979, 49989 (2010) (prescribing practices related to a non-controlled substance such as human growth hormone may not provide an independent basis for concluding that a registrant has engaged in conduct which may threaten public health and safety); *cf., Paul Weir Battershell, N.P.,* 76 FR 44359, 44368 n.27 (2011) (although

[94] Meperidine, the generic form of Demerol, is listed as a Schedule II drug under Chapter 893 of the Florida code. *See* Fla. Stat. § 893.03(2).

[95] As discussed elsewhere in this recommended decision, the evidence of record presented by the Government simply did not support its espoused theory that VM was addicted to and abusing Demerol which was supplied by the Respondent. Agency precedent is clear that ''under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939)).

[96] The act of prescribing is a form of ''dispensing'' under the CSA. 21 U.S.C. § 802(10).

a registrant's non-compliance with the Food, Drug, and Cosmetic Act is not relevant under Factor Five, consideration of such conduct may properly be considered on the narrow issue of assessing a respondent's future compliance with the CSA).

Similar ''catch all'' language is employed by Congress in the CSA related to the Agency's authorization to regulate controlled substance manufacturing and List I chemical distribution, but the language is by no means identical. 21 U.S.C. 823(d)(6), (h)(5). Under the language utilized by Congress in those provisions, the Agency may consider ''such *other factors* as are relevant to and consistent with the public health and safety.'' *Id.* (emphasis supplied). In *Holloway Distributors,* 72 FR 42118, 42126 (2007), the Agency held this catch all language to be broader than the language directed at practitioners under ''other conduct which may threaten the public health and safety'' utilized in 21 U.S.C. 823(f)(5). In *Holloway,* the Administrator stated that regarding the List I catch all:

> [T]he Government is not required to prove that the [r]espondent's conduct poses a threat to public health and safety to obtain an adverse finding under factor five. *See T. Young,* 71 [Fed. Reg.] at 60572 n.13. Rather, the statutory text directs the consideration of ''such other factors as are relevant to and consistent with the public health and safety.'' 21 U.S.C. § 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. See id. § 823(f)(5) (directing consideration of ''[s]uch other conduct which may threaten the public health and safety'').

72 FR at 42126.[97] Thus, the Agency has recognized that, while the fifth factor applicable to List I chemical distributors—21 U.S.C. 823(h)(5)—encompasses all ''factors,'' the Factor Five applied to practitioners—21 U.S.C. § 823(f)(5)—considers only ''conduct.'' However, because section 823(f)(5) only implicates ''such *other* conduct,'' it necessarily follows that conduct considered in Factors One through Four may not be considered at Factor Five.

In this case, the Government has not alleged any conduct which may be properly considered under Factor Five.[98] Accordingly, Factor Five does not weigh for or against revocation.

Recommendation

Based on the foregoing, the Government has certainly established that the Respondent has committed acts that are inconsistent with the public interest. Consideration of the record evidence under the Fourth and Second Factors weighs in favor of revocation. On this record, the recordkeeping violations are alone are sufficient to establish a *prima facie* case that the Respondent has committed acts which render his continued registration inconsistent with the public interest. *See Ideal Pharmacy,* 76 Fed. Reg. at 51416 (Severe recordkeeping violations sufficient to meet Government's *prima facie* burden). However, this is not a case of only recordkeeping violations. Indeed, the record also establishes violations of the disposal and dispensing provisions of the CSA. Accordingly, a balancing of the statutory public interest factors as presented by the Government in its case-in-chief is sufficient to sustain a revocation of the Respondent's COR. *Id.*

Because the Government has sustained its burden of showing that Respondent committed acts inconsistent with the public interest, the burden shifts to the Respondent to show that he can be entrusted with a DEA registration. As discussed above, ''to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. at 8236; *Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 463 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008). This feature of the Agency's interpretation of its statutory mandate has been sustained on review. *Mackay,* 664 F.3d at 822. Evidence that the Respondent has persisted in wrongful activity after being informed of a violation will weigh against a finding that he may be entrusted with continued registration. *See Paul Weir Battershell, N.P.,* 76 Fed. Reg. 44359, 44368 (2011) (finding that continued violations ''raises a serious question as to whether Respondent can be trusted to responsibly discharge his obligations as a registrant.''). In contrast, prompt corrective action weighs in a respondent's favor. *Terese,* 76 Fed. Reg. at 46848.

In this case, the preponderant credible evidence establishes that, after learning that his Form 222s were not completed at the time of receipt and were stored improperly, the Respondent assumed control of the receipt of drugs and created a separate folder for the Form 222s. Tr. 569–71, 624–27. Upon his (albeit late) estimation that controlled substances may have been diverted at the time of receipt at PCCS, the Respondent prohibited the opening of controlled substance shipments without his supervision. Tr. 569–71. As a further safeguard against diversion, the Respondent assumed exclusive control of the controlled substances safe and has installed procedures requiring the keeping of an accurate perpetual inventory. Tr. 365–68; 569–71. Violations regarding the creation and maintenance of biennial inventories have been corrected as well. Tr. 365–68. Finally, to ensure future compliance, the Respondent has retained a new pharmacy consultant. Tr. 365. While it is unquestionably fair to observe that these steps amount to no more than a prudent registrant would be required to undertake without the Government enduring the expense of an administrative enforcement action, these proceedings are not punitive, and current Agency precedent places high value on acknowledgement of wrongdoing and establishment of measures to preclude future transgressions.

The Government argues that, despite taking these steps, the Respondent has failed to rebut the Government's case because: (1) The ''Respondent was unaware of his obligations [as a registrant]'' (2) the Respondent ''exhibited ongoing violations of Federal law;'' and (3) the Respondent ''admitted that he does not have a system in place to prevent the future of diversion [sic] of controlled substances.'' Gov't Posthearing Brief, at 22–23.

Addressing the purported lack of controls against diversion, the Government contends that the

[97] In *Bui,* the Agency clarified that ''an adverse finding under [Factor Five did not require a] showing that the relevant conduct actually constituted a threat to public safety.'' 75 Fed. Reg. 49888 n.12.

[98] In the section of its brief dealing with Factor Five, the Government alleges that the ''Respondent was unaware of his obligations [as a registrant]'' (2) the Respondent ''exhibited ongoing violations of Federal law;'' and (3) the Respondent ''admitted that he does not have a system in place to prevent the future of diversion [sic] of controlled substances.'' Gov't Posthearing Brief, at 22–23. These issues are more properly considered under the discussion of the Respondent's rebuttal case, *infra. See Hassman,* 75 Fed. Reg. at 8236 (''to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'').

''Respondent specifically testified that he is not at his registered address when controlled substances arrive and that controlled substances are left unguarded at the registered location and can be left unsecured for up to two days due to his absence from the clinic.'' Gov't Posthearing Brief, at 24. Without entering a specific finding on the issue, it would be difficult to characterize this argument as anything other than a clear misstatement of the Respondent's testimony. The Respondent testified that, because he has prohibited employees at PCCS from opening shipments of controlled substances, and because he is not in the practice every day, it is possible that a *future* shipment of controlled substances *could* be left unsecured, but that he is in the process of divining a solution to the issue and intends to contact DI McRae to seek her counsel on the matter. Tr. 569–71, 675–77. The Respondent also testified that he felt that he could place an order for controlled substances so as to avoid a shipment from being delivered on a day that he is absent. Tr. 689. Given this testimony, and the specified remedial steps outlined above, the Government's contention that the Respondent replied at this hearing that he ''does not have a system in place to prevent . . . future diversion'' [99] is simply not what the man said.[100]

Turning to the alleged post-inspection violations, the record establishes that the Respondent disposed of approximately ten vials of Demerol in May of 2011 and that, despite learning of thefts of controlled substances which occurred as late as February or March of 2011, the Respondent failed to notify the Miami Field Division Office of such thefts and to file a DEA Form 106 reporting the thefts, in violation of 21 C.F.R. § 1301.76(b).[101] Under the circumstances presented here, where the Respondent first became aware of the recordkeeping deficiencies in the course of an audit that was conducted by DI McRae, that the Respondent did not submit a report of theft to DEA during active enforcement proceedings, based on the litigation theory of his counsel that a former employee may have perpetrated diversion, is not evidence that persuasively militates in favor of revocation. While post-inspection violations can raise ''a serious question as to whether [the] Respondent can be trusted to responsibly discharge his obligations as a registrant,'' they do not compel revocation on their own, *Battershell, N.P.,* 76 Fed. Reg. at 44368–69 (declining to revoke registration despite post-inspection violations), and clearly do not do so in this case.

In whole, the Respondent has expressed contrition for his negligence and has corrected every violation represented to him, but for the unlicensed disposal, which was brought to the attention of the DEA by the Respondent himself, and the failure to report thefts, which were brought to the Government's attention during this proceeding as a potential defense investigated and tendered by Respondent through counsel. While the post-inspection violations are relevant considerations, on this record, they are not dispositive to the public interest inquiry. *Battershell, N.P.,* 76 Fed. Reg. at 44368–69. Rather, the record has a whole shows that the Respondent has transgressed profoundly in his failure to understand and execute his obligations as a registrant, acknowledged his failings without discernible reservation, made a committed and sustained effort to come into compliance with the requirements of the CSA, DEA, and state law, and has outlined a reasonable approach to maintaining that compliance. Thus, the Respondent has successfully demonstrated, that he can be entrusted with continued registration. *Jeri Hassman, M.D.,* 75 Fed. Reg. at 8236. These proceedings are non-punitive,[102] and current Agency precedent requires no more to lodge successful rebuttal to the Government's prima facie case.

Accordingly, the Respondent, consistent with the direction set forth in the OSC issued in this matter, has successfully shown cause why his Certificate of Registration should not be revoked, and thus, the Government's petition to revoke the Respondent's Registration should be DENIED. However, the record in this matter justifies the IMPOSITION OF SPECIFIED CONDITIONS ON THE RESPONDENT'S REGISTRATION, *to wit:* (1) the Respondent must comply with all regulatory obligations relative to the prescribing, dispensing, storage, and handling of controlled substances under his COR; (2) the Respondent, at his own expense, shall submit regular reports at sixty-day intervals (or such other interval as directed by DEA) to a designated DEA official, from an independent pharmacy contractor, pre-approved by a designated DEA official, reflecting monthly regulatory compliance inspections; and (3) within thirty days of the issuance a final Agency order in this case, the Respondent will execute a document memorializing an irrevocable consent for any and all agents of DEA to inspect any and all records related to the handling and prescribing of controlled substances for a period of one year. The Respondent is placed on notice that the failure on his part to timely and correctly submit all documentation required by these conditions, and to comply scrupulously with all requirements set forth in these enumerated conditions, will constitute an independent basis for administrative enforcement proceedings.

Dated: March 1, 2012.

John J. Mulrooney, II,

Chief Administrative Law Judge.

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[99] Gov't Posth'g Brf. at 23.

[100] *C.f., Berger* v. *United States,* 295 U.S. 78, 88 (1935) (a prosecutor ''may strike hard blows [but is not] at liberty to strike foul ones'').

[101] 21 C.F.R. § 1301.76(b) provides, in relevant part: ''The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft.''

[102] *See Jackson,* 72 Fed. Reg. at 23853; *Leo R. Miller, M.D.,* 53 Fed. Reg. 21931, 21932 (1988).

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

TIME AND DATE: 10:00 a.m., Thursday, April 17, 2014.

PLACE: U.S. Parole Commission, 90 K Street NE., 3rd Floor, Washington, DC

STATUS: Open.

MATTERS TO BE CONSIDERED: Approval of January 14, 2014 minutes; reports from the Chairman, the Commissioners, and senior staff; Short Intervention For Success Program; Proposed Rulemaking Revising Conditions of Release update.

CONTACT PERSON FOR MORE INFORMATION: Jacqueline Graham, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street NE., 3rd Floor, Washington, DC 20530, (202) 346–7001.

Dated: April 3, 2014.

J. Patricia W. Smoot,

Acting General Counsel, U.S. Parole Commission.

[FR Doc. 2014–07912 Filed 4–4–14; 11:15 am]

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