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DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[Docket No. 12-42]

Fred Samimi, M.D.
Decision and Order

On February 29, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Fred Samimi, M.D. (Respondent), of both Roseville and Elk Grove, California. ALJ Ex. 1, at 1. The Show Cause Order proposed the denial of Respondent's applications for DEA Certificates of Registration as a practitioner, with authority to dispense controlled substances in schedules II through V, at his proposed registered locations in Roseville and Elk Grove, California, on the ground that his registrations would be inconsistent with the public interest. Id.

More specifically, the Show Cause Order alleged that during undercover visits that were conducted by the Medical Board of California (MBC) in June 2006, June 2008, and December 2009, Respondent "allowed [his] medical assistants to dispense controlled substances to patients without supervision." Id. at 1. The Order also alleged that Respondent dispensed controlled substances "to patients without placing instruction for use on [the] labels attached to the prescription bottles." Id. at 1-2.

Next, the Show Cause Order alleged that on May 6, 2011, the MBC "issued a Stipulated Settlement and Disciplinary Order" to Respondent which made several findings. Id. at 2. First, the Show Cause Order alleged that the MBC found that during a December 10, 2009 audit of his Gold River, California clinic, the controlled substances were kept in an "unlocked and wide

open" metal cabinet, and that Respondent told the MBC Investigator "that the room where the cabinet was located was typically left opened and unlocked during the work day" and that the "room was accessed by [Respondent] and [his] staff and was only locked at the conclusion of the work day." Id.

Second, the Show Cause Order alleged that the MBC found that on January 28, 2010, "[d]uring a follow-up . . . inspection" of the Gold River clinic, Respondent was dispensing controlled substances "through the use of post office boxes" that were located in the "drug room," and "that any person having the appropriate post office box key was able to obtain medication left in the . . . box." Id. The Show Cause Order further alleged that this practice involved maintaining "controlled substances in an unsecured areas" and violated 21 CFR 1301.75(b). Id.

Third, the Show Cause Order alleged that the MBC found that Respondent "failed to properly document [the] transport of controlled substances from one medical clinic location to a second clinic location and further failed to document medication strengths in [his] drugs logs." Id. The Show Cause Order then alleged Respondent "fail[ed] to properly document the transport of controlled substances between clinic locations" and violated 21 CFR 1304.11 and 1304.21(a). Id.

Next, the Show Cause Order alleged that on May 26, 2011, Respondent surrendered his DEA registrations, and that while conducting an inventory of the controlled substances at his Elk Grove clinic, the Government "learned that [he] continued storing controlled substances in an unsecured fashion," in that the controlled substances were "stored on an open bookshelf inside a closet along with protein bars, vitamins, and non-controlled substances." Id. The Show Cause Order also alleged "that the controlled substance inventories [Respondent] provided to agency

investigators contained numerous inaccuracies" and "did not comply with the requirements of 21 CFR 1304.11." Id.

Finally, the Show Cause Order alleged that after Respondent surrendered his DEA registrations, he "phoned in prescriptions for controlled substances under the DEA registration number of another DEA registered practitioner." Id. at 2-3. The Show Cause Order alleged that this conduct violated 21 U.S.C. 822(a)(2) and 843(a)(2). Id.

Following service of the Show Cause Order, Respondent requested a hearing on the allegations and the matter was placed on the docket of the Office of Administrative Law Judges. Following pre-hearing procedures, an ALJ conducted a hearing on August 1-3, 2012, in Sacramento, California. At the hearing, both parties called witnesses to testify and introduced various exhibits into the record; after the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On October 17, 2012, the ALJ issued her Recommended Decision (hereinafter, R.D.). With respect to factor one – the recommendation of the state licensing board – the ALJ found that "the Board ha[d] not made a recommendation concerning the resolution of the Respondent's DEA applications." R.D. 20. The ALJ also noted that "Respondent currently holds a valid medical license in California, but that [his] license has also been the subject of recent disciplinary" action, including a May 6, 2011 Stipulated Settlement and Disciplinary Order, which suspended his medical license for thirty days and imposed a three-year probation. Id. While the ALJ further noted that Respondent had "one minor recordkeeping problem" in that he failed to "provid[e] the complete address of patients" in a log of his dispensings and marijuana recommendations which he was required keep, the ALJ noted that Respondent had not received a non-compliance report for this violation. Id. The ALJ, applying Agency precedent, concluded

that this factor neither "weighed in favor or against the granting of Respondent's applications." Id. (citations omitted).

Similarly, with respect to factor three – Respondent's conviction record for offenses relating to the manufacture, distribution or dispensing of controlled substances – the ALJ found that there is "no evidence that Respondent has been convicted of" such an offense. Id. However, applying Agency precedent, the ALJ noted that while this factor "weighs against a finding that Respondent's registration would be inconsistent with the public interest," it was not dispositive. Id. (citation omitted).

The ALJ then addressed factors two and four – Respondent's experience in dispensing controlled substances and his compliance with applicable laws relating to controlled substances – together. The ALJ began by noting that "[u]nder the Controlled Substances Act and Agency regulations, it is fundamental that a practitioner who directly dispenses controlled substances maintain an effective recordkeeping system," including initial and biennial inventories, as well as "records of receipts, dispensings and transfers of controlled substances." Id. at 21 (citations omitted). The ALJ found that "[t]he record demonstrates that . . . Respondent failed to maintain an accurate drug inventory" and that "[t]his failure made it impossible for the DEA, the Board, or the Respondent to conduct a meaningful drug audit." Id. The ALJ then observed that "[t]he DEA's attempt to audit the Respondent's controlled substances resulted in the finding of significant shortages," and that "[t]his inability to account for this significant number of dosage units creates a grave risk of diversion." Id. (citations omitted). The ALJ also noted that "Respondent violated multiple provisions of California law in his dispensing of controlled substances." Id. at 22. The ALJ thus concluded that "Respondent's conduct in dispensing

controlled substances violated state and federal laws" and that these "violations weigh in favor of a finding that the Respondent's registration would be inconsistent with the public interest." Id.

As for factor five – such other conduct which may threaten public health and safety – the ALJ found that "the record contains no evidence of other conduct related to controlled substances . . . that would threaten the public health and safety," concluding that there was "no direct or credible evidence of diversion." Id. The ALJ then found that "Respondent has accepted responsibility for his past misconduct, and he has credibly demonstrated that he has learned from his past mistakes." Id. at 23. Yet, the ALJ observed that "the record demonstrates that [Respondent] was never able to dispense controlled substances and remain in compliance with the Board's and the DEA's regulations." Id. However, the ALJ then noted various actions Respondent took to address several of the violations found by the MBC's investigator. Id.

The ALJ thus concluded "that the Government has established a prima facie case in support of denying Respondent's applications," explaining that "[t]here is no doubt that the Respondent has failed properly to account for, store, and dispense controlled substances." Id. at 23-24. However, the ALJ then found that "Respondent has sustained his burden to accept responsibility for his past misconduct and has successfully demonstrated that he will not engage in future misconduct related to his handling of controlled substances." Id. at 24. The ALJ then concluded that "outright denial of [Respondent's] application is too severe a resolution," even though "his mistakes in his dispensing of controlled substances are egregiousness enough to warrant the placing of restrictions" limiting him to prescribing, on his registrations. Id.

Both parties filed exceptions to the Recommended Decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the entire record in this matter, including the parties' exceptions, I adopt the ALJ's findings of fact and conclusions of law except as discussed below. More specifically, I adopt the ALJ's conclusion that the Government established a prima facie case for denial of Respondent's applications. Moreover, even accepting the ALJ's finding that Respondent has credibly accepted responsibility for his misconduct, I reject the ALJ's conclusion that he has successfully demonstrated that he will not engage in future misconduct related to his handling of controlled substances, because as the ALJ herself observed, the record demonstrates that he has never been able to dispense controlled substances and remain in compliance with the MBC's and DEA's regulations. I make the following findings of fact.

FINDINGS

Respondent is a medical doctor licensed by the Medical Board of California. GX 8. While Respondent currently practices neurology, he previously owned and operated four weight loss clinics, at which he held DEA practitioner registrations. Tr. 22-23, 494, 504. The clinics were located in Elk Grove, Roseville, Stockton, and Gold River, California. GX 9; Tr. 22-23. On May 25, 2011, after the MBC suspended Respondent's medical license for a period of thirty days, GX 8, at 5; Respondent voluntarily surrendered each of these registrations. GX 9.

On June 23, 2011, Respondent applied for a new DEA registration at his clinics in Roseville and Elk Grove, California. GX 2, at 1-4. It is these applications which are at issue in the proceedings.

The MBC Investigations

In 2006, the MBC received information that Respondent's Gold River clinic was dispensing amphetamine weight-loss medications to patients without a physician being present. Tr. 17. In response, on June 2, 2006, an MBC Investigator (hereinafter, Investigator I) went to

the Gold River clinic and posed as a prospective patient. Id. at 17-18. Upon meeting the receptionist, Investigator I was told that while Respondent had recently purchased the clinic, he had worked there "for quite a long time." Id. at 18. The receptionist then discussed the clinic's weight-loss programs, telling Investigator I that she would see the doctor once, and after that, she "could come back on a weekly basis" and buy the controlled substances from the receptionist. Id. The receptionist also told Investigator I that Respondent had a schedule where he rotated through the clinics, spending a day at a clinic, but that the clinics were open even when Respondent was not present and that the patients could obtain their controlled substances even when he was not physically present at the clinic. Id. at 23.

Upon returning to her office, Investigator I determined that Respondent was subject to a probationary order based on his having falsified his application for a California medical license for failing to disclose a since expunged misdemeanor conviction for fraud.[1] Id. at 19; GX 3, at 3. Thereafter, Investigator I conducted an undercover visit at the Elk Grove clinic and saw Respondent. Tr. 24. Respondent performed what Investigator I characterized as "a cursory examination" and authorized the dispensing of seven tablets of Tenuate (diethylpropion), a weight-loss medication and schedule IV controlled substance. Id. Investigator I testified that she observed Respondent "exiting out the back door" and that he had actually "left the premises" before she was given the medication, which was given to her by the clinic's receptionist. Id. at 24-25; see also id. at 140 ("I watched him walk out the door before the medication was even handed to me by the medical assistant and so he wasn't even physically inside the building when that was handed to me.").

[1] Respondent submitted the application in June 2000; he was convicted, following a no contest plea, on December 12, 1985. GX 3, at 3. According to the MBC's findings, Respondent had switched the price tag from a less expensive to a more expensive item while shopping; he was sentenced to one year of probation and to pay a fine of $100. Id.

At the hearing, Respondent vigorously denied that he had left the clinic before the medication was dispensed to Investigator I, stating "absolutely not, absolutely not." Tr. 507. He then asserted that "I clearly remember my patients, and I remember that Friday we were extremely busy" and "saw more than 70 patient [sic] that day." Id. Continuing, Respondent maintained "[t]hat Friday, definitely didn't leave. She [the Investigator] mentioned I may have left to go to lunch, but that is not true because we can pull the record for that day. I think she came sometimes toward end of the shift. Sometime - - it was 4:30 or 5:00 when she came to be examined." Id. at 508.

While the ALJ did not specifically state that she found Investigator I credible, she did find that "the medication was actually given to [her] by an unlicensed member of the Respondent's office staff." R.D. at 6 (citing Tr. 24-25; 151-52). Moreover, Respondent did not pull the record for that day, and in any event, it seems most unlikely that Respondent remembered the Investigator's undercover visit, which had occurred six years earlier. Accordingly, as ultimate factfinder, I find Investigator I's testimony on the issue credible and therefore adopt the ALJ's finding that Respondent had left the premises when the controlled substances were dispensed to the Investigator and that Respondent allowed his unlicensed staff to dispense controlled substances.

Investigator I testified that under California law, Respondent was required to offer her the option of obtaining a written prescription for the drug, which she could fill at a pharmacy. Id. at 25. However, Respondent did not do so. Id.

Investigator I further testified that the label on the vial which contained the medication did not list Respondent's name or directions for taking the drug. Id. at 26. She further testified

that Respondent did not advise her as to how to take the drug, its potential side effects, its contraindications and whether to take the drug with food. Id.

During the visit, Investigator I made an appointment for a second visit at Respondent's Gold River clinic. Id. at 27. On June 23, 2006, Investigator I went to the Gold River clinic. Id. at 28. Investigator I met an unlicensed medical assistant, who told her that her chart was not at the clinic. Id. The medical assistant weighed Investigator I and called Respondent on the phone; the medical assistant then dispensed another seven tablets of Tenuate to Investigator I. Id. However, the label on the vial neither listed Respondent's name, nor provided the correct clinic address; instead, it gave the address for his Elk Grove clinic. Id. at 29. At no point during the visit did Investigator I either see Respondent or talk with him on the phone. Id. at 30.

According to Investigator I, Respondent's medical assistant did not have authority under state law to dispense a drug to her. Id. at 31. Investigator I asserted that Respondent was aiding and abetting the unlicensed practice of medicine.[2] Id. Moreover, once again, Investigator I was not offered a written prescription for the drug. Id. Investigator I testified that under the terms of Respondent's probation, he was required to comply with all federal and state laws. Id. at 32; see also GX 3, at 4. Thereafter, Investigator I prepared her report and provided it to Respondent's probation monitor. Tr. 32. However, the probation monitor never communicated to Investigator I what action he took, if any. Id. at 32-33. On February 1, 2008, the MBC issued an order restoring Respondent medical license "to clear status and free of probation requirements," with an effective date of August 13, 2007. GX 4.

[2] Regarding his practice of allowing his receptionist and medical assistants to dispense controlled substances, Respondent justified doing so on the basis that when he purchased the clinics, he had asked the CEO (and principal owner) of the company he purchased them from about this practice. According to Respondent, he was told "that's how we've been doing it for 20 years. The medical assistants [are] only bag handlers. The medication is in the bag pre-prescribed. They don't know what's in it. All they do is just hand over the bag to the patient. Your presence may not be required." Tr. 511.

Respondent acknowledged that during a visit by his probation monitor, the latter had observed Respondent's practice of allowing his unlicensed employees to dispense medications and had discussed the issue with him. Tr. 511. According to Respondent, the probation monitor told him that he would have to consult with the MBC's attorney and get back to him. Id. Respondent admitted, however, that after the probation monitor asked the board's attorney, the monitor had told him to stop this practice. Id. at 511-12.

However, in June 2008, the MBC received another anonymous complaint regarding Respondent. Tr. 35-36. As before, the complainant alleged that a patient only had to see Respondent once, and that after that, Respondent's staff would dispense controlled substances to the patient. Id. at 36. The investigation was also assigned to Investigator I. Id. at 35.

As part of her investigation, Investigator I reviewed the reports that Respondent's probation monitor had filed after the 2006 matter was assigned to him. Id. at 36. Investigator I testified that according to the reports, Respondent had assured the monitor that he "was not allowing his staff to dispense medications," that he was following the labeling requirements, and that "he was keeping the medications under lock and key" and that only he had the key. Id.

Approximately a year later,[3] Investigator I again called one of the clinics and was told that Respondent had clinics in in Roseville, Stockton, Rancho Cordova and Elk Grove, as well as the days of the week each clinic was open. GX 6, at 6. She also discussed with the receptionist the Respondent's weight-loss program and was told that for $50, she would have a consultation and be provided with medications. Id. The receptionist further told Investigator I that after the

[3] According to her report, Investigator I had also called one of the clinics in July 2008 and discussed the two weight-loss programs offered by Respondent, including the program which used medications. GX 6, at 6. According to the report, Investigator I was told that she would see the doctor at the first two visits and get medication, but would not need to see the doctor at the third visit and would still get medication. Id.

initial consultation, the cost was $35, which included medications, and that no appointments were needed as she would not "have to see the doctor again." Id.

Investigator I then obtained approval to conduct more undercover visits, and solicited the assistance of another MBC investigator (hereinafter, Investigator II) to perform the visits. Tr. 37. Subsequently, Investigator II made an appointment, and on December 3, 2009, went to the Gold River clinic, where after filling out various forms, she saw Respondent. GX 6, at 6-7. Respondent dispensed to her seven tablets of phentermine 30mg, a schedule IV controlled substance. Id. at 7.

On December 10, 2009, both MBC Investigators returned to the Gold River clinic. Investigator II saw a medical assistant named "Pam," who asked her about her week, took her weight, and told her to meet her at the front desk. GX 6, at 7. The medical assistant then went to another room, obtained a vial of seven phentermine 30mg tablets, and upon returning to the front desk, provided them to Investigator II. Id. Investigator II paid $35 cash for the visit and medication. Id. While Respondent arrived at the clinic when Investigator II was paying for the medication, he did not speak to the Investigator about the medication that was being dispensed to her. GX 8, at 3 & 18.

Shortly thereafter, Investigator I entered the clinic to perform "a drug audit and interview" Respondent. GX 6, at 7. Investigator I observed that the door to Respondent's drug room was open and that the drugs were stored in a metal cabinet whose doors were open.[4] Tr.

[4] Respondent disputed that the medicine cabinet was open when the Inspector asked to see the drug room, testifying that "when I walked into the med room the cabinets were closed." Tr. 517. He further asserted that "the door to the med room was closed, and it has a sign on the door. It says staff only. We open and walk in and she opened the cabinets, she photographs the medication and then close[sic] the doors." Id. Respondent did, however, admit that the door to the medication room was unlocked and that he did not always keep the door locked. Id. at 518.

However, in her Investigation Report, the Investigator wrote: "On 12-10-09, I went to the clinic, performed a drug audit, and interviewed [Respondent]. I made a digital recording of [the] interview which occurred after I had looked

43. Respondent had on hand diethylpropion, phentermine, and phendimetrazine, which were in pre-labeled vials and contained in clear plastic bags. Id.

Investigator I further testified that Respondent was "required to keep the drugs in a locked, secure area that[] . . . has limited access by employees," and that while Respondent could designate an employee who had access to the room, this had "to be done formally." Id. at 44. The Investigator then explained that the room "was wide open and could be accessed by anybody in the office, including a patient." Id.

Respondent told Investigator I that his medical assistant was opening the medication room upon her arrival at the office, and that the room remained open until the clinic closed. GX

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at the drug . . . . I looked at the room where he was storing his drugs and noticed a metal cabinet with the doors open. There were clear plastic bags full of medication vials on the shelves." GX 6, at 7.

Moreover, the interview was subsequently transcribed. During the interview, Investigator I explained to Respondent that:

> With regards to the secure area of how your prescriptions are being store – your medication. It means it has to remain locked; okay? It says here . . . that's Business and Professions Code 4170 and 4172 and the regulations say that an area that is secure – I'm going to read this to you – means a locked storage area within a physician's office. The area shall be secure at all times – locked and secure at all times. The keys to the locked storage shall be available only to staff authorized by the physician to have access thereto; which means that right now it should be locked. The cabinet should be locked or that door should be locked and every time someone goes into it, the only person that should have the key should be someone who's authorized to have the key.
>
> Now, if you're seeing the patient and you've authorized . . . Pam to go in, she has a key also. You have a key. She goes in and gets the medication. You fill out the thing, the instructions and everything, and then it gets – you dispense it to the patient. Okay? Everything is done under your direct supervision. Okay? That area's not locked. Okay? It's been open since this morning obviously. And not quite like the front door. That has to be locked all the time; okay?

GX 5, at 58-59. Finally, in the Stipulated Settlement and Disciplinary Order, "Respondent admit[ted] the truth of each and every charge and allegation in" the Accusation which was attached to the Order. GX 8, at 3. On point here, the Accusation alleged that:

> On or about December 10, 2009, a Board investigator performed a drug audit of the Gold River clinic, and noticed that Respondent maintained the drugs he dispensed in a metal cabinet which was unlocked and wide open. On this date, Respondent stated to the Board investigator that his Medical Assistant opens the medication cabinet when she opens the office, and that the room where the cabinet is located stays open and unlocked from that time on for access by the Medical Assistant and Respondent, and that it is locked when they finally close for the day.

GX 8, at 16.

6, at 8. Respondent stated that the patients' medications were placed in envelopes which were labeled with their names, and that when a patient came in, the medical assistant would go to the drug room, obtain the vial, and write the instructions and patient's name on the label. Id. Respondent "admitted [that] he was not present while his [m]edical [a]ssistants were getting medications and dispensing them to patients," and that he allowed them to do this "with no direct supervision by him even when he was in the building." Id. Investigator I told Respondent that "he needed to dispense the medications and if he were not present, then they [the medications] could not be dispensed." Id. at 8-9.

According to Investigator I, Respondent did not "have any inventory that he could show me for his dispensing." Tr. 43. More specifically, Investigator I explained that Respondent "was unable to provide an inventory . . . of these medications, how may pills he had of each strength and each type of drug." Id. at 44. Investigator I further testified that "it was absolutely impossible to tell what his inventory should be" as "[i]t was an absolute disaster." Id. at 45.[5] When Investigator I discussed the inventory requirements with Respondent, the latter stated that "he had been doing proper inventories after he was . . . educated by his probation monitor, but it was difficult, inconvenient, and time consuming, so he stopped." GX 6, at 8. Investigator I told Respondent "to use a separate log for each strength of each mediation showing shipment and dispensing and had given him an example." Id. at 12; GX 5, at 23-25 (transcript of December 10, 2009 interview).

Investigator I also testified that she observed that some of the medication vials had labels which listed Respondent's clinics other than the Gold River location. Tr. 46. Investigator I

[5] Investigator I further testified that "[t]o keep an accurate record he would have to document when he received a shipment of these pills and what the quantity was of that particular strength, and then as these were being dispensed to the various patients he would have to mark that down, because that's what pharmacies do, so he would always have a running total of what his current inventory is." Tr. 44-45.

testified that while controlled substances were being shipped to a particular registered location (and were therefore labeled to reflect that location), Respondent acknowledged that he was taking medications from the shipments and transferring them to his other clinics. Id. at 47. However, Respondent did not document these transfers. Id.

Investigator I explained to Respondent that the labels on his vials were non-compliant, because they did not provide proper dosing instructions as they stated only "1/d." GX 6, at 8. She also told Respondent that the labels needed to list the correct address of the clinic where the drugs were being dispensed and his name as the prescribing physician. Id. Finally, she explained that the labels needed to contain the manufacturer's name, as well as the color, shape, and imprint of the medications. Id.

In the drug room, Investigator I found several post office boxes. Tr. 50. When asked what their purpose was, Respondent said that he had bought them with the idea of putting the patients' medication in them; the patients would then be given a key, which they would use to open the box, and obtain their medication. Id.; GX 6, at 9. Upon hearing this, Investigator I told Respondent that this "was a really bad idea." Tr. 50; GX 6, at 9. Investigator I also asked Respondent if he was offering his patients a written prescription. GX 6, at 9. Respondent admitted that he was not. Id.

On December 15, 2009, Investigator I received two e-mails from Respondent addressing several of the compliance issues. Id. at 11; see also RX 9. In the first e-mail, Respondent provided a copy of a memorandum he had written to his staff. RX 9, at 1. He also stated that he would address any deficiency he discovered "and make sure we are by the book." Id. The second e-mail was a copy of an e-mail Respondent sent to his distributor, addressing the labeling issues. Id. at 3. Investigator I reviewed the labels and told him that they were still missing

essential information including the manufacturer's name and a description of the medication. GX 6, at 11; RX 9, at 4. Thereafter, Respondent contacted his distributor and asked that the labels include the missing information. RX 9, at 4.

On some date before January 20, 2010, when Respondent was shot during an attempted car-jacking, Respondent called Investigator I and told her that he had got[ten] everything squared away" and to "[p]lease come and re-inspect." Tr. 87-88. On January 28, Investigator I returned to the Gold River clinic to conduct a re-inspection. GX 6, at 11. Upon arriving at the clinic, Investigator I found that a Dr. Mericle was filling in for Respondent while he recovered from his injuries.[6] Tr. 88.

Investigator I entered the drug room and inspected Respondent's drug inventory. Therein, she noted that Respondent still had numerous vials of medication which had the older non-compliant labels and was told by a clinic employee that Respondent "was using up the vials with the old labels." GX 6, at 12. While Investigator I found that Respondent had received additional medication since her previous visit, she determined that Respondent was still not accounting for the shipments in his inventory logs. Id. at 11. Moreover, Respondent had not created a separate log for each drug and strength, but rather was recording "all the medications and strengths on one piece of paper." Id. at 12. See also Tr. 143 ("The dispensing was all on one log, and all the medications were included on that same log. . . . It was still all jumbled together so I was unable to reconcile the inventory at that time . . . .").

The Investigator further found that Respondent "had no accounting for his inventory" and that vials of medication had been placed in the post office boxes, notwithstanding that she had told him it was a bad idea. GX 6, at 12. And while the Investigator was taking an inventory, a patient walked into the drug room, used "a key which was on her personal key ring" to open one

[6] Respondent did not return to the clinic until June 2010, when he resumed practicing on a part-time basis. Tr. 542.

of the post office boxes, and retrieved medication.[7] Id.; see also Tr. 51. The Investigator further testified that the medication "looked to be a controlled substance." Tr. 51.[8]

Later, Respondent's wife arrived at the clinic. GX 6, at 13. The Investigator and Respondent's wife went into Respondent office to discuss the ongoing compliance problems. Tr. 126-27. Upon entering the office, the Investigator observed that there were three drug vials on Respondent's desk. Tr. 55-56. The vials appeared to have been returned by patients as their labels bore the names of patients. Id. at 56-57. Most significantly, the medications had not been secured. Id. at 57. While the Inspector testified that the label on one of the vials indicated that it contained phentermine, she conceded that she did not know exactly what drugs were in the vials. Id. at 90-91.[9]

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[8] Regarding the use of the mailboxes, Respondent testified that at the time of the December 10, 2009 MBC inspection, he had not started using them. Tr. 527-28. Continuing, Respondent explained that the MBC Inspector wanted "the medication hand carried from me to the patient in the clinic" and did not want the medical assistants to "carry medication in their hand." Id. at 528. Respondent testified that while he agreed to "follow [the Investigator's] instruction," he then thought: "Why don't I implement a mechanism, by which medical assistant do not touch medication at all? So I came up with the idea of the mailbox." Id. at 528-29. Respondent then testified: "So I installed the mailboxes in the med room, I assigned every patient to each mailbox and I gave them explicit instruction that they need to come in, go take their vital signs, be accompanied by medical assistant, access their mailbox," sign a card indicating that they received their medication, and be escorted back to the front desk by the medical assistant. Id. at 529. Respondent explained that "[t]hat way medical assistant had nothing to do with medication. The patient comes in supervised, get their meds and they leave." Id.

Respondent then testified that after the MBC Inspector "point out that this is bad idea, it got to go, and we stop using it." Id.; see also id. at 540 (asserting that on January 28, 2010, the p.o. boxes were not being used). He further explained that "[a]t that time when [the Inspector] came back for reinspection, I was in ICU fighting for my life." Id. at 529. While it is not disputed that Respondent was hospitalized at the time of the reinspection, the incident in which the patient was observed entering the drug room unaccompanied and retrieving medication from the post office box occurred seven weeks after the Inspector told Respondent that this was a bad idea.

Moreover, the MBC Inspector testified that when she spoke with Dr. Mericle, the latter stated that "he was running the office . . . just how [Respondent] set it up. . . . He was just seeing the patients and following the office procedures that [Respondent] had put in place." Id. at 131. Consistent with Dr. Mericle's statement, Respondent testified that "Dr. Mericle wasn't fond of it [i.e., the use of the post office boxes] either." Id. at 542. And on cross-examination, Respondent testified that Dr. Mericle had "refused to refill those boxes," even after the staff told Dr. Mericle that the boxes were empty and needed to be refilled. Id. at 757.

[9] When asked about the vials, Respondent testified that they were "very old" bottles which used a different labeling format. Id. at 527. Respondent then testified that "[t]he patient brought it back saying that I want the kind of medication as I was taking it four years ago." Id. Respondent did not maintain that the bottles had been returned after he was shot. Id.

While Respondent testified that "we followed every single instruction of [the MBC Inspector] to the letter," Tr. 530, the MBC apparently thought differently. On April 13, 2010, it brought a new Accusation against Respondent based on the issues found during the December 2009 and January 2010 visits. GX 8, at 19.

The Accusation alleged five grounds for discipline. First, the Board alleged that Respondent had "fail[ed] to adequately label the medication labels as observed by [its] [I]nvestigator on" December 10, 2009 and January 28, 2010. Id. at 16. Second, the Board alleged that Respondent failed to properly secure controlled substances, noting that the medication room and drug cabinet were left open and unlocked throughout the day, as well as the incident in which a patient was allowed to enter the drug room and retrieve medication from a mailbox. Id. at 16. Third, the Board alleged that Respondent "fail[ed] to maintain a current and accurate drug inventory." Id. at 17. Fourth, the Board alleged that Respondent failed to properly consult with his patients when dispensing drugs and that he failed to offer written prescriptions. Id. at 17-18. Fifth, the Board alleged that Respondent aided and abetted the unlicensed practice of medicine by allowing his medical assistants to dispense drugs without his "direct supervision." Id. at 18.

On December 10, 2010, Respondent entered into a Stipulated Settlement and Disciplinary Order with the MBC; on April 8, 2011, the Board adopted the Order, which became effective on May 6, 2011. Id. at 1, 10. Therein, "Respondent admit[ted] the truth of each and every charge and allegation in [the] Accusation." Id. at 3.

However, in his testimony, Respondent stated that he signed the Stipulation "[p]artially unwillingly," because he "was told both by [the] deputy AG and my attorney that [it was] a good offer." Tr. 723. Respondent then testified that he felt that "[s]ome of" the allegations were

"exaggerated" by the MBC's Investigator, particularly those related to his allowing his unlicensed employees to dispense drugs when he was not present. Id. Respondent analogized his signing of the Stipulation to signing a traffic ticket to avoid being arrested and taken to jail. Id. at 731-32.

The Order suspended Respondent's medical license for thirty days and placed him on probation for three years. Id. at 5. The Order's probationary terms include that "Respondent shall maintain a record of all controlled substances ordered, prescribed, dispensed, administered, or possessed by [him], and any recommendation or approval which enables a patient or patient's primary caregiver to possess or cultivate marijuana for the personal medical purposes of the patient within the meaning of" California law. Id. The record was required to include the patient's name and address, date, "the character and quantity of controlled substance involved," and "the indications and diagnosis for which the controlled substances were furnished." Id. at 5. The Order further required that Respondent "keep these records in a separate file or ledger, in chronological order." Id. Respondent was also required to take an ethics course, "prohibited from supervising physician assistants," and required to obey all federal, state and local laws, and rules governing the practice of medicine in California. Id.

On the issue of Respondent's compliance with the 2011 MBC Order, the Government called Mr. TW, the probation monitor who had begun supervising him on April 25, 2012; Respondent called Ms. VG, his probation monitor from the effective date of the order until the case was transferred to TW. Ms. VG testified that Respondent had "been in compliance" with the terms of his probation during the period in which she was his monitor. Tr. 447. According to Ms. VG, if there was "something that I needed to have him do . . . I gave him a deadline and I believe he met them." Id. at 448. Ms. VG also testified that any such issues did not warrant

writing "a noncompliance report." Id. However, on cross-examination, Ms. VG stated that Respondent's log of his dispensings and marijuana recommendations did not include the number and street name of the patients' addresses. Id. at 453; see also GX 8, at 5.

Ms. VG subsequently testified that in "trying to refresh her recollections," she had reviewed Respondent's drugs logs and "noticed there was no street number or street name" and that she "did not send [Respondent] a letter advising him he needed to correct that." Tr. 454. Ms. VG then acknowledged that she did not have "a good" reason for failing to notify Respondent that he was not in compliance. Id. at 455.

Mr. TW testified that on May 24, 2012, he met with Respondent and reviewed his marijuana recommendation log. Id. at 176. Mr. TW testified that upon reviewing the logs, he noticed that they did not "have the full address of the patient" and included only "the city, state and zip code." Id. According to Mr. TW, Respondent stated that Ms. VG "had reviewed" his log and "told him that he no longer had to keep the address of the patients on the controlled substance log." Id. at 178. When Mr. TW asked Ms. VG about this, she explained that while she had notice that the address was not being kept in the log, "she allowed for that to occur in a sense [that] she would not put him out of compliance with it, but not that it was okay to not complete the log in its entirety."[10] Id. at 179.

Mr. TW told Respondent that "he need[ed] to actually keep the log in full as per the wording in the order." Id. The next day, Mr. TW sent Respondent a letter "inform[ing] him that he would be considered to be out of compliance by not keeping that information up to date." Id. at 179-80.

[10] While Ms. VG's statement to Mr. TW was clearly hearsay, Respondent called Ms. VG to testify and could have questioned her (but did not) about whether she made the statements to which Mr. TW testified. Tr. 179.

On or about May 30th, Respondent sent Mr. TW an email, to which he attached scanned copies of his marijuana logs. Id. at 180. Mr. TW testified that upon looking at the logs, "they still didn't include all the information that was necessary" under the Board's order. Id. Mr. TW then sent Respondent an email, in which he "cited the verbiage in the order to let [Respondent] know exactly what we needed to have as far as his controlled substance log." Id. Mr. TW clarified that the missing information was the "address information for the patient." Id. at 181. Explaining his continued failure to comply with the order, Respondent again cited the information he claimed to have received from Ms. VG. Id. He further testified that he did not include that information in the log because "[h]is patients didn't really want to release their information to the Medical Board." Id. However, following an exchange of emails, Respondent stopped working at the marijuana facility. Id. at 183.

The DEA Investigation

On May 23, 2011, the Sacramento DEA field office received a copy of the MBC's Order. Tr. 206. After verifying that Respondent's medical license had been suspended, on May 25, 2011, two DEA Diversion Investigators (hereinafter, DI or DIs) went to Respondent's Roseville office. Id. at 210. Upon their arrival, the DIs met Ms. GA, one of Respondent's medical assistants. Id. at 210-11. Ms. GA told the DIs that Respondent "was out of the country." Id. at 211. The DIs asked Ms. GA if there was another doctor with whom they could talk and met Dr. Stephen Fisher, who also said that Respondent was out of the country. Id. Dr. Fisher then explained that he was working for Respondent on a temporary basis and had started on May 16th. Id. The DIs then told Ms. GA and Dr. Fisher that they needed to speak with Respondent and eventually they spoke to him by phone. Id. at 212.

One of the DIs told Respondent, who was still in the country, that because his state license had been suspended, he did not "have authority to handle controlled substances." Id. at 213. Respondent agreed to meet the DIs later that day at his Roseville clinic; the DIs brought to the meeting four voluntary surrender forms, one for each of his registrations. Id. at 214.

Upon meeting Respondent, the DIs again explained that in order to hold a DEA registration, he was required to have state authority to handle controlled substances, and because his license had been suspended, he did not have current authority. Id. The DIs then told Respondent that he could either surrender his registration or they would pursue the issuance of an Order to Show Cause to revoke his registrations. Id. Respondent agreed to voluntarily surrender his registration and signed the four forms manifesting his consent. Id. at 214-15; see also GX 9.

The DIs then asked Respondent if he had controlled substances at any of his clinics. Id. at 216-17. Respondent acknowledged that he had controlled substances at the Roseville and Elk Grove clinics. Id. at 217. Because controlled substances must be stored at a registered location, and following the surrendering of his registrations, the clinics were no longer registered locations, the DIs allowed Dr. Fisher to transfer his registration to the Roseville clinic and Respondent to transfer the controlled substances located at the clinic to Dr. Fisher. Id. However, because Respondent was no longer registered at his Elk Grove clinic, and had no doctor who could become registered there, the DI's told Respondent that they would have to take possession of these controlled substances and arranged to meet at the Elk Grove clinic the following day. Id.

The next day, the DIs went to the Elk Grove clinic, met another of Respondent's medical assistants, Michelle Garcia, who showed them the controlled substances. Id. at 218. The drugs,

which included phentermine, phendimetrazine,[11] and diethylpropion, were stored in a locked closet, on a seven to eight-foot high bookshelf. Id. at 219. The DIs also found that nutritional products such as protein shakes and bars were stored in the closet, but they were not intermingled on the same shelf with the controlled substances. Id.

According to the DI, the manner in which the controlled substances were stored did not comply with the Agency's regulations. First, the closet was not a secure and substantially constructed cabinet as required by 21 CFR 1301.75(b). Id. at 220. Second, non-controlled substances were stored in the closet with the controlled substances. Id.

The DI further testified that while at the Elk Grove clinic, he and his partner took a physical inventory of the controlled substances on hand, which they then compared to the daily medication log maintained by Respondent and which provided a running inventory. Id. at 222. Ms. Garcia provided the DIs with the "inventory sheet" for the close of business on May 21, which was the last day the Elk Grove clinic had been open. Id. The DIs counted the drugs on hand, with Ms. Garcia witnessing the count, and determined that the numbers "were not at all close" to those on the inventory sheets. Id. at 223. However, having reviewed the data, the counts for two of the drugs were off by only four dosage units each, one was off by nine dosage units, one was off by thirteen dosage units, and the remaining three were off by twenty-four, thirty-four and thirty-five dosage units respectively.[12] GX 10, at 3-5.

On May 31, the DIs went to the Roseville clinic and counted the controlled substances on hand. GX 10. Upon comparing the counts with Respondent's daily inventory record, four of the

[11] The DI testified that there was also a small amount of Bontril, which is a branded form of phendimetrazine. Id. at 219.

[12] The actual count for phentermine 37.5mg (3194) was off by only nine dosage units. See GX 10, at 3, 5.

six drugs had discrepancies of seven dosage units or less; the remaining two drugs had discrepancies of twenty-seven and thirty-three dosage units. Id. at 6-7

While at the Roseville clinic, the DIs also found a box labeled "Gold River," which contained more controlled substances and were told that the drugs had been moved to the Roseville clinic because the Gold River clinic had "recently . . . closed for business." Tr. 229. There was, however, no documentation for the transfer. Id. at 229-30. Upon counting these drugs and comparing them with the daily inventory for the last day that the Gold River clinic had been open for business, the DIs determined that there were substantial shortages of three drugs: 3,000 dosage units of phentermine 37.5mg; 1,011 dosage units of phentermine 30mg; and 1,021 dosage units of phendimetrazine 35mg.[13] See Tr. 229, GX 10, at 1-2.

Subsequently, the DIs decided to perform an audit of Respondent's controlled substance activities at the Elk Grove, Roseville and Gold River clinics. The DIs issued a subpoena for two years of Respondent's records, obtained his daily inventory logs, his dispensing logs, and his receipts from distributors. Tr. 390, 392-93. Using Respondent's daily inventory logs for various dates in late November 2010[14], a DI added the controlled substances Respondent had received from his distributor to arrive at the total amount Respondent was accountable for of each drug by dosage unit strength at each of his registered locations; using the closing inventory figures, the DI added the amounts of each drug which Respondent had either dispensed or transfered to calculate the total amount he could account for. Tr. 391-94. The DI then compared the total amounts for each drug Respondent was accountable for, with the totals for which he

[13] Two other drugs found in the Gold River box had discrepancies of seven and sixteen dosage units; the remaining drug had no discrepancy. See GX 10, at 1-2.

[14] The opening and closing dates of the audits were November 20, 2010 and May 26, 2011 for the Elk Grove clinic; November 22, 2010 and May 31, 2010 for the Roseville clinic; and November 23, 2010 and May 31, 2011 for the Gold River clinic. See GX 11.

could account, and prepared a chart for each of the three clinics. Id. at 387. In addition, a senior DI then reviewed the DI's audit. Id. at 391.

According to the DI, at Elk Grove, Respondent had shortages of 8,410 dosage units of phentermine 37.5mg; 2,316 dosage units of phentermine 30mg; 6,637 dosage units of phendimetrazine 35mg; 252 dosage units of phendimetrazine 105mg; and 906 dosage units of diethylpropion 25mg. GX 11, at 1.[15] At Gold River, Respondent was short 3,915 dosage units of phentermine 37.5mg; 1,046 dosage units of phentermine 30mg; 313 dosage units of phendimetrazine, and 390 tablets of phendimetrazine 105mg.[16] GX 11, at 1. And at Roseville, Respondent was short 10,740 tablets of phentermine 37.5mg; 3,535 tablets of phentermine 30mg; 5,361 tablets of phendimetrazine 35mg; 812 tablets of phendimetrazine 105mg, and 595 tablets of diethylpropion 25mg.[17] Respondent thus had shortages totaling more than 40,000 dosage units.

In his testimony, Respondent challenged the accuracy of the DEA audit and offered two charts into evidence.[18] See RXs 14 & 15. The first chart (RX 14), which is labeled

[15] At Elk Grove, Respondent had small overages of thirty-five dosage units of diethylpropion 75mg and four dosage units of Bontril 105mg. GX 11, at 1.

[16]At Gold River, Respondent also had a shortage of fourteen dosage units of diethylpropion 25mg, and seven dosage units of dielthylpropion 75mg. GX 11, at 2.

[17] At Roseville, Respondent had a small overage of seven dosage units of Bontril 105mg. GX 11, at 3.

[18] At the hearing, Government counsel objected to the introduction of the charts because they were not disclosed prior to the hearing, and thus he had "no effective way of cross-examining" Respondent on them. Tr. 771. When Respondent's counsel subsequently sought to enter the exhibits, Government counsel renewed his objection. Id. at 851. The ALJ overruled the Government's objection, reasoning that because the Government opened the door, it could not claim prejudice. Id.

I conclude that the ALJ properly overruled the Government's objection. A review of the record shows that in response to Respondent's testimony that he believed the DEA audit had "tremendous inaccuracies," Government counsel asked if he had a chart and if he had brought it to the hearing. Id. at 760. Respondent answered affirmatively, and after the exhibits (RX 14 and 15) were marked, Government counsel proceeded to ask Respondent several questions regarding the charts, including how his figures compared with those on two DEA forms, a receipt for seized items (RX 11), and the closing inventory form (GX 10), before moving on. Tr. 768-70.

"Dispensing/Inventory Log," purports to list for each clinic, Respondent's monthly dispensings of each drug (by strength), the shipments received (presumably during the audit period), and closing inventory. [19] The second of these exhibits (RX 15), lists on a monthly basis for the years 2010 and 2011, the quantities for each drug (and strength) that he received from his distributor, but does not break down the quantities distributed to each clinic. As for the list of Respondent's receipts (RX 15), which only lists the month, drug, and quantity, and not the actual date of receipt; with respect to several of the drugs (phentermine 37.5, phentermine 30, and phendimetrazine 35), the DI's figures actually charged him with receiving smaller quantities than are listed on this document.[20]

Having proceeded to question Respondent regarding these exhibits, the Government opened the door to their admission and the ALJ properly denied the objection.

[19] While the closing inventories were taken after Dr. Fisher took over Respondent's Roseville clinic, Respondent testified that after his suspension became effective, medication was no longer being dispensed at the clinic. See Tr. 569 ("The period where [the DI] audited the clinic is to the point that the medication was basically last day dispensed, which is prior to my suspension at the end of May of 2011. From the time of my suspension thereon to this date, they do not carry medication in the office. They issue prescription pad to the patient and the patient goes to the pharmacy.").

Notably, Respondent makes no claim that Dr. Fisher diverted any of the drugs at the Roseville clinic and the counts taken during the closing inventory were typically off only by a small number of tablets from the figures listed in this clinic's Daily Inventory.

[20] More specifically, the Government's audit found that Respondent received 39,941 dosage units of phentermine 37.5, see GX 11, while the shipments listed in Respondent's chart for November 2010 through May 2011, total 42, 821 dosage units. See RX 15. The discrepancy may be explained by the fact that according to Respondent's chart, 5,995 dosage units of this drug were received in November 2010. RX 15, at 2-3. However, Respondent's chart does not set forth what quantities may have been received prior to the starting date (November 21, 2010) of the Government's audit. See RX 15.

With respect to phendimetrazine 35, the shipments listed on RX 15 for November 2010 through May 2011 total 16,996 dosage units, of which 3,996 dosage units were received during the month of November. RX 15. By contrast, the Government found that Respondent received 10,118 dosage units during the audit period.

With respect to phentermine 30, Respondent's chart lists no shipments as having been received in November 2010 and the shipments received between December 2010 and May 2011 total 13,997 dosage units. RX 15. By contrast, the Government's audit found that Respondent received 11,997 dosage units. See GX 11.

With respect to phendimetrazine 105 and diethylpropion 25, the Government's figures match the shipments listed on RX 15.

In his testimony, Respondent disputed the accuracy of the Government's figures for the amounts of the various drugs he dispensed. Tr. 808-09. Regarding the Elk Grove clinic, Respondent maintained that he had dispensed 11,207 dosage units of phentermine 37.5, and that this was based on his dispensing records. Id. at 809. By contrast, the Government's audit found that he had dispensed only 2,754 dosage units. GX 11, at 1. Regarding the discrepancy, Respondent testified:

> I mean, how could in six months in such a busy office only 2,754 pills be dispensed? That's only two bags of medication in six months while I in that same office handed over 11,207 pills. Not only are [sic] patient charts and logs show that, also the expense log in the patient's chart where the patient paid for it, and it matches with that, our revenue matched with that. So we did sell that many pills.

Tr. 842. Indeed, for many of the drugs, Respondent's figures for the amounts dispensed (which are listed on his "Dispensing/Inventory Log") were three to five times greater (and sometimes more) than the Government's.[21] Compare GX 11 with RX 14.

Moreover, on the Dispensing/Inventory log, Respondent listed the shipments he had received during the audit period for each of the drugs, including the total he had received for all three clinics.[22] With respect phentermine 37.5, Respondent listed his total receipts as 5547 dosage units. RX 14. Yet even subtracting out all of the 5,995 dosage units Respondent received in November 2010, RX 15 still lists shipments totaling 36,826 dosage units. See RX

[21] As other examples, Respondent asserted that at his Elk Grove clinic, he dispensed 3,990 dosage units of phentermine 30 and 4,872 dosage units of phendimetrazine 35; the DI found that he dispensed only 850 dosage units of phentermine 30 and 213 dosage units of phendimetrazine 35. Compare GX 11, at 1, with RX 14. At the Roseville clinic, Respondent asserted that he dispensed 17,500 dosage units of phentermine 37.5; 4,956 dosage units of phentermine 30; and 5,397 dosage units of phendimetrazine 35 mg . RX 14. By contrast, the Government's audit found that he dispensed only 4,965 dosage units of phentermine 37.5; 909 dosage units of phentermine 30 mg; and 377 dosage units of phendimetrazine 35mg. GX 11.

At Gold River, Respondent assert that he dispensed 7,630 dosage units of phentermine 37.5; 2,590 dosage units of phentermine 30; and 3,339 dosage units of phendimetrazine 35. RX 14. By contrast, the Government's audit found that he dispensed only 2,103 dosage units of phentermine 37.5; 822 dosage units of phentermine 30mg; and 355 dosage units of phendimetrazine. GX 11.

[22] Respondent testified that the "[s]hipment in" lines on RX 14 reflects "the amount of shipment they [Calvin Scott, his distributor] made to the office," and that these figures were "based on" RX 15. Tr. 805.

15. As for phentermine 30, Respondent listed his total receipts as 1,852 dosage units. See RX 14. Yet, according to RX 15, Respondent received a total of 13,997 dosage units during the audit period. RX 15.

With respect to phendimetrazine 35, on the Dispensing/Inventory log, Respondent listed his total receipts as 664 dosage units. See RX 14. Here again, even subtracting out all of the 3,996 dosage units Respondent received in November 2010, he still received a total of 13,000 dosage units during the audit period. RX 15. And as for phendimetrazine 105, Respondent listed his total receipts as 390 dosage units. See RX 14. Yet, according to RX 15, Respondent received a total of 3,000 dosage units during the audit period. See RX 15.

While, on cross-examination, Respondent admitted that he had never previously conducted an audit, he nonetheless maintained that "my math is good." Tr. 807. However, the disparities between the total of quantities of the monthly shipments listed on RX 15 and the quantities Respondent listed on the Dispensing/Inventory log (RX 14) as his incoming shipments suggest the opposite. Indeed, the inconsistencies between these figures are of such a magnitude as to call into question the reliability of any of the data contained in Respondent's Dispensing/Inventory logs. RX 14. I therefore decline to give any weight to the dispensing data offered by Respondent and adopt the findings of the audit performed by the DI.

As found above, upon the suspension of his medical license, Respondent initially hired Dr. Stephen Fisher to cover his practice. However, according to Respondent, following the MBC's adoption of the Stipulated Settlement and Disciplinary Order, the MBC Probation Monitor (Ms. VG) met with him to discuss the "dos and don'ts" while his medical license was suspended. Tr. 552. For whatever reason, Ms. VG only allowed Dr. Fisher to work at the clinic for "three days . . . from [the] beginning of [Respondent's] suspension" after which Respondent

was required to find "a bona fide locum tenens company." Tr. 553.[23] Respondent then contracted with a company known as Staff Care to provide a locum tenens physician for the remainder of his suspension. Id.

On June 22, 2011, after the suspension of his state license ended, Respondent resumed practicing medicine. Id. at 576. On that day, Respondent "saw almost [thirty-six] patient[s]." Id. at 577. Having surrendered his DEA registrations, Respondent could not lawfully either dispense or prescribe controlled substances to his patients. GX 1, at 1.

The Government introduced into evidence copies of thirteen phentermine prescriptions for Respondent's patients which were called in to pharmacies on that day. See GX 12; Tr. 373, 385. Each of the prescriptions listed Dr. Fisher as the prescriber. See GX 12. All but two of the prescriptions, however, listed the name of one of Respondent's employees as the person who had called in the prescription; each prescription also listed the phone number of one of Respondent's clinics.[24] See id. ; see also Tr. 413-14.

The next day, the DI received a phone call from Dr. Fisher. Id. at 364. After reporting that his prescription pad had been stolen, Dr. Fisher explained that Respondent had seen the patients and that prescriptions had been called in under his (Dr. Fisher's) DEA registration; Fisher then "asked if this was legal." Id. The DI told him to "stop immediately." Id.

[23] There was testimony suggesting that Dr. Fisher was on probation at the time of Respondent's suspension, and that because a probationer cannot supervise another probationer, the former could not work for Respondent, who remained the owner of the clinic. Tr. 365, 370. However, according to Ms. VG, she "advised Dr. Fisher that a non[-]licensed physician cannot pay, cannot hire a licensed physician, and during the time of [Respondent's] suspension, Dr. Fisher could not work for him hourly." Id. at 458.

[24] The DI subsequently testified that to his knowledge, Respondent did not "call in any prescriptions himself." Tr. 415.

The DI further testified that he had received a phone call that same morning from Ms. VG, who was then also Respondent's probation monitor.[25] Id. at 366. VG told the DI that "she had also gotten a call from Dr. Fisher stating that [Respondent] had used his . . . DEA registration" without his authorization. Id.

In her testimony, Ms. VG corroborated that she had received a phone call from Dr. Fisher "the day after [Respondent's] suspension was lifted." Id. at 457. VG further testified that Fisher told her that Respondent "had come into his office with some drug logs of patients, that he had used Dr. Fisher's DEA . . . number to prescribe for them, and he asked me if that was okay." Id. VG then "asked Dr. Fisher if she had seen those patients that day"; Fisher "said no" and that he had been at the 420 clinic "that whole day." Id. at 458. Moreover, Fisher told VG "that the first he had . . . heard of it was when" Respondent apparently brought the drug logs to Fisher's office and "told him he" had "used his number." Id. When asked how she interpreted Fisher's statement, VG testified that "[i]t seemed he was unaware." Id.; see also id. at 463 ("I feel that he [Fisher] was unaware. I would testify to that.").

Later that morning, Respondent showed up at the DEA office. Id. at 360. According to the DI, while initially Respondent asked whether the DIs "could expedite his DEA registration," he then told the DIs that the day before, "he had seen patients at his Roseville clinic and that Dr. Fisher had called in the prescriptions under Dr. Fisher's DEA number." Id.; see also id. at 398. However, later in the conversation, Respondent stated that the prescriptions were called in by both his medical assistants and Dr. Fisher. Id. at 361.

During the meeting, Respondent mentioned that physician assistants and nurse practitioners can "see patients on behalf of a doctor and write prescriptions." Tr. 403. The DI

[25] The DI testified that he received the phone call on June 22, before he received a visit from Respondent. Tr. 366. However, all of the prescriptions were dated June 22. GX 12.

testified that while physician assistants and nurse practitioners can do this, "they have to be an agent of the practitioner," as well as have their own DEA registration and be "authorized to handle controlled substances." Id. The DI then maintained that Respondent could not act in this manner as he was not registered and because he owned the clinics, "he was not an agent of Dr. Fisher." Id. at 405.

The DIs then went to interview Dr. Fisher, who was working at an entity (Sacramento 420 Evaluations), which provided medical marijuana evaluations. Id. at 408. Upon their arrival, Fisher told the DIs that he had just spoke with Respondent, and that Respondent had told him that he had talked to the DIs and "that it was okay to continue using his DEA number." According to the DI, when they initially "asked Dr. Fisher if he had personally called in all the prescriptions," Fisher denied having called in any of them and said that Respondent's medical assistant did so. Id. at 366-67. Fisher further told the DIs that while he may have previously treated some of the patients, the day before he was working at the 420 clinic and not at Respondent's Roseville clinic. Id. at 367. However, the DI did not determine whether Dr. Fisher had ever actually seen these patients. Id. at 420-21.

The DI testified, however, that subsequently, Dr. Fisher's story as to whether he had authorized the prescriptions changed "back and forth." Id. at 368; see also id. at 415 (testimony of DI that Fisher changed his story "multiple times").[26] Moreover, during the interview, VG called and was placed on the speaker phone. Id. at 368-69. However, Fisher then stated that "he did authorize" the prescriptions the day before, "but from that point on, they were no longer authorized." Id. at 369. The DI – in response to the Government's question – then acknowledged that Fisher had changed his story. Id. Moreover, when asked by the Government

[26] Regarding the interview, the DI further testified that "it was pretty obvious that he was being deceptive, as in he was trying to change [his story] based on whatever we wanted to hear or whatever wouldn't get him in trouble. Just being honest, it seemed like he was making up a story." Tr. 416.

whether Fisher appeared coherent, the DI replied "No" and explained that when Fisher was asked about the prescriptions, he could not recall whether this incident had occurred the day before or several days earlier. Id. The DI also testified that there were "other things that happened . . . that had given us the impression that he [Fisher] wasn't completely aware of what was going on." Id.

Regarding this allegation, Respondent testified that upon arriving at his clinic on the morning of June 22, he called Dr. Fisher and asked him if he could come in and cover the clinic. Tr. 576. However, Dr. Fisher told Respondent that he could only cover the clinic until 11 a.m. because his shift at the 420 clinic started at 11:30. Id. After Fisher suggested that Respondent cover the clinic himself, Respondent stated that that would not work. Id. Respondent then proposed that he would see the patients, and that while he could not "prescribe appetite suppressants to them," Fisher had "seen some of" them; Respondent would then report the patients' conditions to Fisher, and if the latter agreed, "then [Fisher would] authorize [Respondent's clinic] to call [a prescription] in for [Fisher] or [Fisher could] call it in" himself. Id. at 576-77.

According to Respondent, Dr. Fisher "agreed" to the arrangement. Id. at 577. Respondent told Fisher that when he was "done seeing these patient[s]," he would call Fisher and report the patient's condition and "have the staff run the vital sign of the patient with you, and then you authorize them to call it in for you." Id. Respondent testified that when they were done with the patients, he called Fisher and "informed [him] of these patients" and Fisher then spoke with Genevieve, one of the medical assistants, and told her that because he was "on probation, a log of these patients must be made" and "must be done on the board probationary unit forms." Id. Respondent then testified that his medical assistants "reported the patients to" Fisher, id. at

578, that Fisher "recalled some of them," id.. at 577, and Fisher "authorized them to call in the" prescriptions. Id. at 578. Respondent also testified that his staff created a log of the prescriptions on probation unit forms and gave them to VG the following day. Id. at 579.

When asked whether he was trying to circumvent his lack of a DEA registration, Respondent testified that he "deeply" regretted his actions and that it "was a big mistake done that day by me." Id. He added that "[i]t should not have ever have happened, and it is not going to happen." Id.

Additional Testimony of Respondent

Regarding the MBC Investigations, Respondent acknowledged that prior to the December 10, 2009 visit, sometimes he was not onsite when medication were dispensed. Tr. 535. He further stated that after that visit, he changed that practice so that at "lunchtime the clinic's completely closed . . . and nobody would see any patients because the doctor . . . would not be in the premises." Id. at 536. Regarding his recordkeeping, Respondent testified "that we should have had the daily inventory of what is in and what [was] going out," and that "we were in error or it was not complete enough." Id. Respondent further stated that he began to implement this change "immediately after" the inspection and that he kept the logs "in the office" where "the staff did not have access to it [sic] because I was afraid [of] any tampering or loss of logs." Id. at 536-37.

Respondent testified that when the MBC Inspector returned on January 28, 2010, the staff did not have the logs "because I had them with me." Id. at 537. However, he then testified that implementing everything "was work in progress." Id. Subsequently, Respondent testified that the inventory sheets were "sitting on top of the cabinet in the med room" and that "it's easy for anybody who wants to inspect [to] walk in there and see those inventory sheets." Id. at 845.

Later in his testimony, Respondent denied that he bore responsibility for the MBC's finding that on January 28, 2010, his logs did not indicate the different drug strengths. Id. at 824; GX 8, at 17. Respondent asserted that "[w]homever covers the shift that day is responsible, and by that time Dr. Mericle was covering the shift for almost a week." Tr. 824-25.

Respondent also asserted that upon returning to practice, he "reimplemented the strict inventory control [of] scheduled substances shipped to us, logging it side by side with the medication dispensed, and keep [sic] track of daily inventory to make sure we are balanced and in compliance." Id. at 544. He also apologized for having medications, which were labeled for clinics other than the clinic where they were to be dispensed, explaining that when they "were short in one office . . . we brought medication from another office." Id. Respondent further testified that while he complied with the Inspector's labeling recommendation, he "still had existing medications with the label from another clinic." Id. at 545. While Respondent testified that the Inspector told him to print new labels and place them on the bottles, he then acknowledged that this "probably" did not happen until "after [he] resume[d] working" and "the bottles were dispensed." Id. at 546-47. Respondent explained that he "noticed that that's what they're doing, but as long as it was labeled, I didn't see anything wrong with that." Id. at 547. And when asked whether, "[i]n hindsight, [he saw] anything wrong with that," Respondent answered:

> I think . . . if the inspection is taking place, anybody coming to inspect the med room and look at those drugs and don't have label on it, it may relay impression that we still have this big mess going on, you know? Should not have been there. They should be properly labeled and in there.

Id.

More generally regarding his compliance issues, Respondent testified that he had "learned quite a bit" and that "this is a very humbling experience." Id. at 584-85. He further

stated that "I definitely ask question first and then commit to an action, and until I don't have a clear answer, I don't have clear path that is in accords with the laws of the land . . . I would not commit to it." Id. at 585. Respondent added that he was "still learning and I'm going to commit myself to a better process." Id.

When asked if he had trouble understanding the statutes, and what he would do to aid in himself in this regard, Respondent bemoaned that "[i]t is very difficult" and that "legal language or all these quotes are not easy to understand[]" and "need[ed] little further elaboration and explanation." Id. He then stated that this was "not the excuse," and that if he did not "understand," he would "have to refer to sources that . . . do know it." Id. at 585-86. When asked what other changes he would make, Respondent testified that he "will not be doing weight management anymore" and "will not have local pharmacy," meaning that he would not have "scheduled drug[s] in the office" because there is "too much paperwork" and "too much responsibility." Id. at 586. Respondent then stated that he only wanted authority to write prescriptions. Id. at 587.

Respondent further testified that he was "uninformed" about the rules, but that it was his own "fault." Id. at 592. He then asserted that he will "take every measure to make sure I'm in compliance with" the MBC and DEA's rules, and that "there is a time that one has to admit to his guilt and move on, you know?" Id.

On cross-examination, Respondent admitted that in 2006, his then-probation monitor had discussed with him his use of unlicensed personnel to dispense controlled substances. Id. at 716-17. He further admitted that he told the first probation monitor that he would change his clinics' days and hours of operation to ensure that the clinics were open only when a physician was present and that he would no longer allow his staff to dispense medications. Id. at 718. Later, he

answered "yes" when asked whether he had assured his first probation monitor that he would supervise the dispensing of medications. Id. at 782. However, he subsequently testified that while he understood the probation monitor's advice to mean that he must be physically "present in the office," this did not mean the same as "direct supervision" of the medical assistant. Id. at 815-16. Respondent then maintained that the probation monitor had never told him that he needed to be in the same room or watch his assistants as they dispensed medications. Id. at 816. Respondent asserted that he "made sure that [he was] in the office," but that in 2009, there were, in the words of his counsel, "a couple of occasions that slipped through in Gold River." Id. at 817. Respondent also denied telling his first probation monitor that he had the only key to the drug room. Id. at 719.

As for the allegations that gave rise to the second MBC investigation (that Respondent was allowing his unlicensed staff to dispense medication when he was not present), Respondent only "partially" agreed with them. Id. at 720. More specifically, he asserted that the unlicensed staff was not free to dispense medication and that he had pre-dispensed the medication by placing it a manila envelope which was sealed, and that there was a notation written on the back. Id. He also disputed the testimony of the MBC Investigator that he was not present when medication was dispensed to Investigator II on December 10, 2009 visit, testifying that he was in the clinic when she received the medication. Id. at 721-22. According to Respondent, the allegation was exaggerated, id. at 723, and that he directed his receptionist to ask the patient to count the medications and had "video to show" this.[27] Id. at 780. While Respondent eventually, but reluctantly, admitted that his clinics were dispensing drugs when he was not present, id. at 727, he continued to deny that he was not present when the MBC Investigator obtained controlled substances on December 10, 2009. Id. at 780.

[27] Respondent did not, however, produce any such video. Tr. 780.

Respondent also disputed the MBC's findings that he failed to properly secure controlled substances. Id. at 735. Indeed, Respondent asserted that MBC Investigator had "opened the [drug] cabinet, photographed it . . . and later she presented to the board that this is how she found it." Id. at 736. Respondent then asserted that "the door to the hallway is always closed," and that "[w]e never leave the door to the med room wide open, the cabinet wide open." Id.

Respondent also denied that at the time of the May 2011 inspection, he was still violating regulations that required him to store his controlled substances in a substantially constructed and securely locked cabinet. Id. And when asked by the Government whether he was familiar with the Code of Federal Regulations, Respondent answered "[n]o." Id. at 737.

Regarding whether he had discussed with the MBC Investigator the use of the mail boxes and her having told him that it was a bad idea, Respondent testified that he did not recall the conversation. Tr. 752. Moreover, he did not recall whether he told anyone about the boxes. Id . at 753. Regarding the January 28, 2010 incident, in which a patient entered the drug room unescorted and retrieved medication from one of the boxes, Respondent initially testified that the patient "was never left alone," and that to his knowledge the boxes were not being used when he was not present. Id. at 756. However, he then acknowledged that he had set up the practice and that it was still in place when he was shot. Id. And still later, Respondent testified that he "knew from the staff . . . that the patient went to the boxes and there was nothing there because those things need to be replenished after each visit." Id. at 833.

While Respondent admitted that he failed to maintain accurate drug inventories as alleged in the 2010 MBC Accusation, he denied that the problem was still ongoing at the time of the May 2011 DEA inspections. Id. at 759. Moreover, even though he was not physically present when the DEA Investigator took a physical inventory, which was witnessed by one of his

employees, Respondent asserted that the DEA counts were inaccurate, id. at 762, and that "my inventory is much more accurate than what [the DI] did." Id. at 787. However, he then admitted that one of his employees had verified the DEA counts. Id. at 762.

Respondent further denied that he had ever told the MBC Inspector that maintaining inventories was difficult, inconvenient and time consuming. Id. at 773-74. When confronted with his having stipulated to the truth of the allegation in the MBC Order, Respondent stated that agreed to sign the Order because as part of a "package offer" and that this "was minor compared to the big picture." Id. at 774. However, Respondent then acknowledged that inventories must be done "accurately," that he "made a mistake" and asserted that he was "willing to take any action" to "remedy . . . the oversight." Id. at 775.

Respondent testified that he had not taken any courses on the proper handling of controlled substances, stating that "[i]t was not required." Id. at 796-97. He also stated that he had never inquired as to whether there were any such courses available. Id. at 797.

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that "[t]he Attorney General may deny an application for [a practitioner's] registration . . . if [he] determines that the issuance of such registration . . . would be inconsistent with the public interest." 21 U.S.C. 823(f). In making the public interest determination, the CSA directs that the following factors be considered:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing . . . controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

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

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

Id.

"[T]hese factors are . . . considered in the disjunctive." Robert A. Leslie, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to deny an application for a registration. Id. Moreover, I am "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 v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

Where the Government has met its prima facie burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest, the burden then shifts to the applicant to "present sufficient mitigating evidence" to show why he can be entrusted with a new registration. Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008) (quoting Samuel S. Jackson, 72 FR 23848, 23853 (2007) (quoting Leo R. Miller, 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' ALRA Labs, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." Medicine Shoppe, 73 FR at 387; see also Jackson, 72 FR at 23853; John H. Kennedy, 71 FR 35705, 35709 (2006); Cuong Tron Tran, 63 FR 64280, 64283 (1998); Prince George Daniels, 60 FR 62884, 62887 (1995). Because of the authority conveyed by a registration and the extraordinary potential for harm caused by those who misuse their registrations, DEA places significant weight on an applicant/registrant's candor in the proceeding. See Hoxie v. DEA, 419 F.3d at 483

("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination).

Having considered all of the factors, I hold that the Government has met is prima facie burden of showing that Respondent has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 823(f). I further hold that Respondent has not rebutted the Government's prima facie case and reject the ALJ's recommendation that I grant Respondent a restricted registration. Accordingly, Respondent's applications will be denied.

Factor One – The Recommendation of the State Licensing Authority

While not specifically citing this factor, the Government argues that it "has established a basis for the denial of Respondent's pending applications . . . under [21 U.S.C.] 824(a) based upon . . . the previous suspension of his state medical license." Gov. Post-Hrng. Br. 28. The Government is mistaken, because to exercise the authority granted under section 824(a)(3), the Agency must find not only that a registrant or applicant "has had his State license or registration suspended, revoked, or denied by competent State authority," but also that the registrant/applicant "is no longer authorized by State law to engage in the . . . distribution[] or dispensing of controlled substances." 21 U.S.C. 824(a)(3). As the Government subsequently acknowledges, Respondent's state license has been reinstated, and while he is subject to various probationary terms, none of those terms either prohibit or limit his authority to dispense controlled substances in the course of professional practice. Gov. Post-Hrng. Br. 28. Respondent therefore meets the CSA's prerequisite for obtaining a practitioner's registration. See 21 U.S.C. 823(f) ("The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. 823(f).

However, while Respondent now satisfies the condition that he hold authority under state law to dispense controlled substances, this conclusion "'is not dispositive of the public interest inquiry.'" George Mathew, 75 FR 66138, 66145 (2010), pet. for rev. denied Mathew v. DEA, No. 10-73480, slip op. at 5 (9th Cir., Mar. 16, 2012); see also Patrick W. Stodola, 74 FR 20727, 20730 n.16 (2009). As the Agency has long held, "the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest." Mortimer Levin, 57 FR 8680, 8681 (1992). Accordingly, this factor is not dispositive either for, or against, the granting of Respondent's applications. Paul Weir Battershell, 76 FR 44359, 44366 (2011) (citing Edmund Chein, 72 FR 6580, 6590 (2007), pet. for rev. denied Chein v. DEA, 533 F.3d 828 (D.C. Cir. 2008)). [28]

Factors Two and Four – Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Relating to Controlled Substances

In support of its contention that Respondent's registration would be inconsistent with the public interest, the Government points to the multitude of violations found during both the MBC and DEA investigations. With respect to the state violations, the Government cites to the testimony and findings of the MBC that: 1) Respondent failed to offer written prescriptions to the undercover officers; 2) allowed his unlicensed staff to dispense medications to his patients; 3) failed to properly label the controlled substances; 4) failed to provide proper security for his controlled substances; and 5) failed to maintain accurate drug inventories. Gov. Post-Hrng. Br.

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

29-31 (citations omitted). With respect to the federal violations, the Government points to the testimony of the DI regarding the May and June 2011 investigation, which found that Respondent was still failing to properly secure controlled substances, that he was still not properly documenting the receipt and transfer of controlled substances, and that he failed to maintain accurate drug inventories. Id. at 30-31. The Government also argues that the results of the DEA audit "weigh[] against" granting Respondent's application. Id. Finally, the Government argues that Respondent engaged in the unauthorized use of Dr. Fisher's registration, when he "caused controlled substance prescriptions to issue" under the latter's registration and that these prescriptions violated 21 CFR 1306.04 because Dr. Fisher never saw any of the patients that day. Id. at 32.

With respect to the state violations, each of these is established by the MBC's 2011 disciplinary order, in which Respondent admitted the truth of each and every allegation contained in the accusation filed by the Board. See GX 8, at 3; id. at 11-19. Respondent's admissions to the Board's allegations constitute substantial evidence that he committed the respective violations. That being said, this does not mean that each of the underlying violations established by the MBC's order is properly considered under these factors.

As originally enacted, the Controlled Substances Act did not authorize the denial of an application for a practitioner's registration (nor revocation of an existing practitioner's registration) on public interest grounds, but was limited to those instances in which a practitioner had materially falsified an application, had been convicted of a state or federal felony relating to controlled substances, or did not possess state authority to dispense controlled substances. See Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, §§ 303(f), 304(a), 84 Stat. 1254 (1970). Over time, Congress came to recognize that the "[i]mproper

diversion of controlled substances by practitioners is one of the most serious aspects of the drug abuse problem. However, effective Federal action against practitioners ha[d] been severely inhibited by the limited authority in [the then] current law to deny or revoke practitioner registrations." H.R. Rep. No. 98-1030, at 266 (1984), reprinted in 1984 U.S.C.C.A.N. 3182, 3448. Continuing, the House Report explained that:

> The current limited grounds for revoking or denying a practitioner's registration have been cited as contributing to the problem of diversion of dangerous drugs. In addition, because of a variety of legal, organizational, and resource problems, many States are unable to take effective or prompt action against violating registrants. Since State revocation of a practitioner's license or registration is a primary basis on which Federal registration may be revoked or denied, problems at the State regulatory level have had a severe adverse impact on Federal anti-diversion efforts. The criteria of prior felony drug conviction for denial or revocation of registration has proven too limited in certain cases as well, for many violations involving controlled substances which are prescription drugs are not punishable as felonies under State law. Moreover, delays in obtaining conviction allow practitioners to continue to dispense drugs with a high abuse potential even where there is strong evidence that they have significantly abused their authority to dispense controlled substances.
>
> Clearly, the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest.

Id.

Accordingly, Congress amended section 823(f) "to expand the authority of the Attorney General to deny a practitioner's registration application." Id. Thus, "[u]nder 21 U.S.C. [823](f), as amended, . . . the Attorney General would be required to register a practitioner authorized under State law to dispense or conduct research with controlled substances unless he made a specific find[ing] that registration would be 'inconsistent with the public interest.'" Id. After noting the five public interest factors, the House Report then explained that while "[t]he amendment . . . will continue to allow the Attorney General to routinely register most practitioner applicants, . . . in those case in which registration is clearly contrary to the public

interest, the amendment would allow a swift and sure response to the danger posed to the public health and safety by the registration of the practitioner in question." Id. at 267, 1984 U.S.C.C.A.N. at 3449.

The House Report thus makes clear that Congress's primary purpose in authorizing the denial of an application based on the public interest was to provide an additional means for the Attorney General to address diversion by practitioners. However, the mere fact that a violation of a state rule occurs in the context of the dispensing of controlled substances does not necessarily mean that the violation has a sufficient nexus to the CSA's core purpose of preventing the diversion and abuse of controlled substances.

As noted above, the Government contends that Respondent's violations of Cal. Bus. & Prof. Code § 4170(a)(6) & (7) are properly considered in assessing his experience in dispensing controlled substances or his compliance with applicable laws related to controlled substances. See Gov. Post-Hrng. Br. 29. Notably, these provisions apply to all prescription drugs (and not just controlled substances) which a prescriber dispenses to his patients. See Cal. Bus. & Prof. Code §§ 4022, 4170(a). As the MBC Investigator testified, these provisions require that: 1) a prescriber, who dispenses drugs in his practice, offer to his patient the option of obtaining a written prescription "that the patient may elect to have filled by the prescriber or by any pharmacy," and 2) provide a "written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice." Cal. Bus. & Prof. Code § 4170(a)(6) & (7). In short, these provisions are not directed at preventing diversion, but rather at protecting consumers. As such, Respondent's violations of them have little to no probative value in assessing his experience in dispensing controlled substances and compliance with applicable laws related to controlled substances.

Next, the Government points to Respondent's practice of allowing his office staff, who were unlicensed, to dispense controlled substances without being directly supervised by him. Gov. Post-Hrng. Br. 30. The MBC found that Respondent's conduct constituted the aiding and abetting of the unlicensed practice of medicine. GX 8, at 19 (citing Cal. Bus. & Prof. Code § 2238, 2264, and 4170(a)). While these provisions apply to the practice of medicine generally and are not restricted to the dispensing of controlled substances,[29] there is a sufficient nexus between the CSA's purpose of preventing diversion to consider this conduct under factor two.

More specifically, the unsupervised dispensing of controlled substances by unlicensed individuals creates a heightened risk that those individuals will divert the drugs. See Margy Temponeras, 77 FR 45675, 45677-78 (2012) (considering physician's practice of allowing unlicensed individuals to dispense controlled substances in violation of state law under factor two). So too, allowing unlicensed persons, who likely have no training in identifying persons engaged in drug abuse or diversion, to dispense controlled substances without supervision, increases the opportunity for those persons who are self-abusing or engaged in diversion to obtain controlled substances. Cf. Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)) ("the [CSA's] prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse).

[29] See Bus. & Prof. Code § 2264 ("The employing, directly or indirectly, the aiding, or the abetting of any unlicensed person or any suspended, revoked, or unlicensed practitioner to engage in the practice of medicine or any other mode of treating the sick or afflicted which requires a license to practice constitutes unprofessional conduct."); id. § 4170(a)(1) ("No prescriber shall dispense drugs . . . to patients in his . . . office or place of practice unless all of the following conditions are met: . . . The dangerous drugs . . . are dispensed to the prescriber's own patient, and the drugs . . . are not furnished by a nurse or physician's attendant.").

By contrast, section 4170(a) (8) provides, inter alia, that "a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol," and "a physician assistant who functions pursuant to Section 3502.1 . . . may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer . . . or a pharmacist."

Most disturbingly, Respondent admitted that following the 2006 incidents, his probation monitor had observed his practice of allowing unlicensed personnel to dispense controlled substances. Tr. 511-12. While according to Respondent, the monitor stated that he would have to consult the MBC's attorney, after the monitor consulted the attorney, he told Respondent to stop this practice. Id. at 512. Yet, during the 2009 investigation, Respondent was still allowing his unlicensed medical assistants to dispense controlled substance without being supervised by him.[30] And as further evidence that Respondent had failed to discontinue the practice, Investigator I testified that when she called one of Respondent's clinics and discussed his weight loss program with the clinic's receptionist, she was told that after the initial consultation, she would be able to get medication without "hav[ing] to see the doctor again[31]" and that no appointments were needed. GX 6, at 6.

Respondent also admitted that he failed to properly label the controlled substances that he dispensed. GX 8, at 3 & 15-16. The evidence shows that some of the medication vials did not list Respondent's name as the dispenser, did not have the correct clinic address, did not provide adequate directions for taking the medication, and were missing other essential items of information such as the manufacturer's name, as well as the color, shape and identification code of the medication. Id.; Tr. 46-47. See Cal. Bus. & Prof. Code § 4076 (setting forth labeling requirements for prescriptions); id. § 4170(a)(4) (requiring a prescriber who dispenses drugs to

[30] While there is evidence that during the MBC's December 10, 2009 undercover visit, Respondent arrived at the clinic while the Investigator was paying for the medication, the drugs had already been furnished to the Investigator and Respondent did not discuss the medication with the Investigator. GX 8, at 18.

[31] Indeed, the receptionist's statement was corroborated by the MBC's December 10, 2009 undercover visit, where Investigator II saw a medical assistant, who after asking her about her week and weighing her, told her to meet her at the front desk, and then provided a vial containing seven tablets of phentermine 30mg to the Investigator. GX 6, at 7. I thus conclude that Respondent had resumed his practice of allowing his unlicensed employees to dispense controlled substances.

"fulfill[] all of the labeling requirements imposed upon pharmacists by Section 4076"). Here again, while the state's labeling requirements apply to the dispensing of all prescription drugs and not just controlled substances, providing accurate directions for taking a controlled substance has a clear nexus to the CSA's purpose of preventing drug abuse and diversion.[32] Cf. 21 CFR 1306.24(a) ("The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.").[33]

Here again, the evidence shows that while Respondent was fully advised as to the State's labeling requirements, and assured the MBC Investigator that he had come into compliance, during the January 28, 2010 re-inspection, the Investigator found that Respondent still had numerous vials of medication which bore the older, non-compliant labels. Tr. 88-89. Indeed, one of Respondent's employees told the Investigator that Respondent "was using up the vials with the old labels."[34] GX 6, at 12.

The MBC also found that Respondent failed to properly secure his controlled substances, noting that during the December 10, 2009 inspection at the Roseville clinic, the Investigator found that the drug room was unlocked and that the drug cabinet was unlocked and wide open.

[32] So too, the requirement that the label contain the dispenser's name and address provides information that can be used to determine the source of the drugs and whether the drugs were lawfully dispensed or have been diverted.

[33] Pursuant to the Food, Drug, and Cosmetic Act, "[a]ny drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title [the misbranding provisions], except paragraphs (a), (i)(2) and (3) . . . if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription." 21 U.S.C. 353(b)(2).

[34] The ALJ found that "when informed about the labeling violations, the Respondent took prompt action to remedy the problem." R.D. at 23. The ALJ's finding ignores that during the re-inspection, the Investigator found that Respondent had continued to dispense his older and improperly labeled stock of controlled substances.

GX 8, at 16. The Investigator further found that Respondent's staff unlocked the drug room at the beginning of the day and that the room was kept unlocked until the clinic closed for the day. Id. Moreover, the MBC found that during the January 28, 2010 re-inspection, a patient was allowed to enter the drug room unaccompanied and retrieve medication from one of the post-office boxes. Id. While Respondent was then in the hospital, and the clinic was being overseen by Dr. Mericle, a locum tenens physician, Respondent testified that Dr. Mericle had "refused to refill those boxes" even after the clinic's staff had told him that the boxes were empty and needed to be refilled. Tr. 757. Moreover, Respondent admitted that the MBC Investigator had told him the boxes were a really bad idea. The evidence thus supports a finding that Respondent disregarded the MBI Investigator's advice and commenced using the boxes.

Under California law, "[a] prescriber who dispenses drugs pursuant to Section 4170 shall store all drugs to be dispensed in an area that is secure." Cal. Bus. & Prof. Code § 4172. By regulation, the MBC has defined "the phrase 'area which is secure' [to] mean[] a locked storage area within a physician's office. The area shall be secure at all times. The keys to the locked storage areas shall be available only to staff authorized by the physician to have access thereto." Cal. Code Regs. Tit.16, § 1356.3. The MBC thus found that Respondent violated Cal. Bus. & Prof. Code §§ 2238 and 4172, as well as the afore-cited regulation. GX 8, at 3, 16.

Finally, the MBC found that Respondent violated California law by failing to maintain accurate drug inventories. See id. at 17 (citing Cal. Bus. & Prof. Code §§ 2238 and 4081). More specifically, the Board found that Respondent did not record the drugs that he transferred from one clinic to another of his clinics, as well as the incoming shipments, and that he only kept a log of what he dispensed each day. Id. Moreover, during the 2009 inspection, Respondent admitted that in 2006, his probation monitor had instructed him as to how to do proper inventories. Id.

Respondent then admitted that he had stopped maintaining proper inventories because he found doing so to be "too difficult, inconvenient, and time consuming." Id.[35] Also, Respondent was not creating a separate log for each medication by its strength, but rather, he was recording all of the dispensings on a single piece of paper.

Here again, while the MBC Investigator instructed Respondent that he had to maintain a separate log for each strength of each medication and record the shipments, GX 5, at 23-25; during the January 2010 re-inspection, she found that notwithstanding his assurance that "he had got[ten] everything squared away," he was still not accounting for the incoming shipments in his inventory logs and still recording all of the dispensings in a single log, rather than creating a separate log for each strength of a medication. GX 6, at 12; Tr. 143.

The evidence does show that at the time of the May 2011 DEA inspection, Respondent was maintaining a daily inventory log which listed each drug by its strength. See GX 10, at 2, 5, 7. As found above, the DEA Investigators took an inventory of the controlled substances on hand at the three clinics and compared their counts with Respondent's daily inventory logs. While the discrepancies between the counts and the daily inventory logs for the Elk Grove and Roseville clinics were relatively small, the DIs found substantial discrepancies when they counted the drugs which had been transferred from the Gold River clinic (and which were counted separately) and compared the counts with the daily inventory sheet for the last day that clinic had been open. More specifically, Respondent was short 3,000 dosage units of phentermine 37.5mg; 1,011 dosage units of phentermine 30mg; and 1,021 dosage units of phendimetrazine 35mg.[36] See GX 10, at 1-2; Tr. 229.

[35] While in his testimony, Respondent disputed that he ever made this admission, Tr. 773-74, he had previously stipulated to the MBC's finding that he did. GX 8, at 17.

[36] Based on this evidence, the Government argues that "Respondent's failure to maintain an accurate drug inventory" was a violation of both state and federal law. Gov. Post-Hrng. Br. 31 (citing Cal. Bus. & Prof. Code §§

Also, Respondent had no documentation for the transfer of the controlled substances from the recently closed Gold River clinic to his Roseville clinic. Tr. 229-30. This was also a violation of federal law, which requires that "every registrant . . . maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him." 21 U.S.C. 827(a)(3). Moreover, pursuant to DEA regulations, "[s]eparate records shall be maintained by a registrant for each registered location." 21 CFR 1304.21(b). Thus, I also conclude that Respondent violated Federal law by failing to document the transfer of controlled substances between his various clinics.[37]

As found above, the DI performed an audit of Respondent's handling of controlled substances at the three clinics for the period beginning on November 20, 2010 through May 26, 2011 for the Elk Grove clinic; November 22, 2010 through May 31, 2011 for the Roseville

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2238 and 4081; 21 CFR 1304.11). However, federal law explicitly provides that a registrant is not required to maintain "a perpetual inventory." 21 U.S.C. 827(a)(3). Accordingly, I note this evidence only to show Respondent's continuing failure to comply with the State's requirements.

Federal law does, however, require that a registrant maintain "a complete and accurate record of all stocks . . . on hand" upon a registrant's "first engag[ing] in the . . . dispensing of controlled substances, and every second year thereafter." 21 U.S.C. 827(a)(1). As for whether the inventory logs that were used for the opening dates of the audits were "complete and accurate," short of having actually counted the drugs on those days, there is no way of knowing. The Government is not, however, required to establish which of the specific records (initial/biennial inventories, receipts, dispensing/disposals) were incomplete or inaccurate. Rather, it suffices to show that upon auditing all of the required records, Respondent could not account for a material portion of the controlled substances he handled during the audit period.

As for the ALJ's reasoning that Respondent's failure "to maintain an accurate drug inventory . . . made it impossible for the DEA . . . to conduct a meaningful drug audit," R.D. at 21, as explained above, short of performing an actual count of the drugs on the opening date of the audit period, there is no way of determining whether the data provided in the daily inventory logs for the opening date of the audits were inaccurate, and the evidence showed that the DI used the figures obtained during the actual counts at each clinic for the closing inventories. In any event, the fact that a registrant fails to maintain accurate records does not render it "impossible" to do a "meaningful" audit, whatever that means. Indeed, it is not uncommon that DEA Investigators will find that a particular registrant is entirely missing required records.

[37] The Government also maintains that during the June 2011 DEA inspection of Respondent's Roseville clinic, he was failing to properly secure the controlled substances. Gov. Post-Hrng. Br. at 30. The evidence cited by the Government as support for this contention actually involved the Elk Grove clinic, where Respondent was storing the controlled substances in a locked closet, rather than a substantially constructed cabinet as required by 21 CFR 1301.75(b). See id. at 17 (citing Tr. 218-19). While I find this to also be a violation, I give it only nominal weight given the absence of evidence that the closet was not secure.

clinic; and November 23, 2010 through May 31, 2011 for the Gold River clinic. At Elk Grove, Respondent had shortages of 8,410 dosage units of phentermine 37.5mg; 2,316 dosage units of phentermine 30mg; 6,637 dosage units of phendimetrazine 35mg; 252 dosage units of phendimetrazine 105mg; and 906 dosage units of diethylpropion 25mg. GX 11, at 1. At Gold River, Respondent was short 3,915 dosage units of phentermine 37.5mg; 1,046 dosage units of phentermine 30mg; 313 dosage units of phendimetrazine 35mg, and 390 tablets of phendimetrazine 105mg. Id. at 2. And at Roseville, Respondent was short 10,740 tablets of phentermine 37.5mg; 3,535 tablets of phentermine 30mg; 5,361 tablets of phendimetrazine 35mg; 812 tablets of phendimetrazine 105mg, and 595 tablets of diethylpropion 25mg. Id. at 3. Thus, between the three clinics, Respondent had shortages totaling more than 40,000 dosage units.

These are material shortages and at a minimum, they support the conclusion that Respondent violated federal law by failing to maintain "complete and accurate record[s]" of the controlled substances he handled. 21 U.S.C. 827(a)(1)-(3). As the ALJ correctly noted, Respondent's "inability to account for this significant number of dosage units creates a grave risk of diversion." R.D. at 21. Indeed, even were there no other proven violations, the audit results alone are sufficient to satisfy the Government's prima facie burden of establishing that Respondent's registrations would be "inconsistent with the public interest." 21 U.S.C. 823(f). See Medicine Shoppe – Jonesborough, 73 FR 364, 386 (2008).

The Government also argues that Respondent violated federal law because, upon the restoration of his state license, he impermissibly used Dr. Fisher's DEA registration to issue controlled substance prescriptions. Gov. Post-Hrng. Br. 32. It further argues that these

prescriptions were unlawful because Dr. Fisher was working at a different clinic the day the prescriptions were issued and never saw the patients. Id. (citing 21 CFR 1306.04(a)).

As for the contention that Respondent impermissibly used Dr. Fisher's DEA number, the Government's proof rested entirely on the testimony of a Diversion Investigator and an MBC Probation Monitor regarding the hearsay statements of Dr. Fisher. While hearsay statements are admissible in administrative proceedings, and can even constitute substantial evidence under certain circumstances, to do so the statements must bear sufficient indicia of reliability. See Hoska v. United States Dep't of the Army, 677 F.2d 131, 138 (D.C. Cir. 1982); Calhoun v. Bailar, 626 F.2d 145 (9th Cir. 1980). The factors to be considered include the independence or possible bias of the declarant, whether the statements are signed and sworn or oral and unsworn, whether the statements are consistent, whether they are contradicted by direct testimony, whether the declarant is available to testify, and whether the statements are corroborated. See Hoska, 677 F.3d at 139; Calhoun, 626 F.2d at149.

Here, in an order denying Respondent's motion to exclude the proposed testimony regarding Dr. Fisher's hearsay statements, the ALJ explained that the admissibility of the evidence would be assessed based on various judicially-created standards, including the Ninth Circuit's Calhoun decision. See Order Denying In Part Respondent's Motion to Exclude a Portion of the Government's Proposed Testimony and Exhibits, at 6-7. Nonetheless, the Government produced no evidence to demonstrate that Dr. Fisher's statements are sufficiently reliable to constitute substantial evidence of the material fact for which they were offered – namely, that Respondent used Fisher's registration to call in prescriptions without Fisher's permission. To the contrary, through the DI's testimony, the Government made clear that Fisher's statements are inherently unreliable.

More specifically, the DI testified that when he and his supervisor interviewed Fisher, the latter's story as to whether he had authorized the prescriptions changed "back and forth" and "multiple times." Tr. 368, 415. Later during the interview (with the MBC's Probation Monitor having called-in and been placed on the speaker phone), Fisher stated that "he did authorize" the prescriptions the day before, but henceforth, "they were no longer authorized." Id. at 369. The DI further testified that "it was pretty obvious that [Dr. Fisher] was being deceptive" and "trying to his change [his story] based on whatever we wanted to hear or whatever wouldn't get him in trouble." Id. at 416. And earlier in his testimony, the DI explained that Fisher did not appear to be coherent and gave "the impression that he wasn't completely aware of what was going on." Id. at 369.

When evaluated under the applicable factors, Fisher's statement implicating Respondent in the unauthorized use of his registration is clearly unreliable. Fisher, whose statements were oral and unsworn, clearly admitted that he had authorized the prescriptions, only to change his story and tell the DIs whatever he thought they wanted to hear to keep himself out of trouble. Thus, to the extent Fisher was even aware of what was going, he was in no way an unbiased observer, but rather a clearly interested participant, and one who provided contradictory statements. In short, Fisher's statement implicating Respondent is so inherently unreliable that the allegation must be rejected.

As for the Government's further contention that these prescriptions violated 21 CFR 1306.04(a)[38] because Dr. Fisher did not see the patients that day, in neither the Show Cause Order nor either of its pre-hearing statements did the Government provide notice that it intended to litigate the issue. See ALJ Ex. 1 (Show Cause Order); Gov. Pre-Hrng. Statement, at 5-6

[38] Pursuant to 21 CFR 1306.04(a), "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual acting in the usual course of his professional practice."

(discussing DI's proposed testimony), Gov. Supp. Pre-Hrng. Statement, at 6 (discussing DI's proposed testimony). Indeed, the Government did not even raise the contention that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice until its post-hearing brief. See Gov. Post-Hrng. Br. 32. Thus, even if Respondent could have been be charged with violating this regulation under a conspiracy theory, raising the issue for the first time in a post-hearing brief is simply too late to provide fair notice.[39] See Margy Temponeras, 77 FR 45675, 45677 (2012) (discussing cases). I therefore reject the contention.

However, as explained above, the audit results, which establish that Respondent failed to maintain complete and accurate records, are, by themselves, sufficient to satisfy the Government's prima facie burden of showing that Respondent's registrations would be inconsistent with the public interest. This conclusion is buttressed by the numerous other violations proven on the record, including the state violations of allowing his unlicensed staff to dispense medications to his patients; failing to properly label the controlled substances; failing to provide proper security for his controlled substances; and failing to maintain accurate drug inventories, as well as the federal violations of failing to document the transfers of controlled substances between his clinics.

SANCTION

Under Agency precedent, where, as here, "the Government has proved that [an applicant] has committed acts inconsistent with the public interest, [the applicant] must '"present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility

[39] Even had I concluded otherwise on the issue of notice, and assuming that Respondent and Fisher entered into an agreement, the Government produced no evidence establishing that Fisher had never seen, or established a valid doctor-patient relationship with, the patients whose prescriptions were entered into evidence. Nor did it produce any evidence that it was outside the scope of professional practice for Fisher to issue prescriptions to the patients.

carried by such a registration."'" Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008) (quoting Samuel S. Jackson, 72 FR 23848, 23853 (2007) (quoting Leo R. Miller, 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' ALRA Labs, Inc. v. DEA, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where [an applicant] has committed acts inconsistent with the public interest, the [applicant] must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." Medicine Shoppe, 73 FR 387; see also Jackson, 72 FR 23853; John H. Kennedy, 71 FR 35705, 35709 (2006); Prince George Daniels, 60 FR 62884, 62887 (1995). See also Hoxie v. DEA, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination). So too, in making the public interest determination, "this Agency places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding." Robert F. Hunt, 75 FR 49995, 50004 (2010) (citing The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy, 72 FR 74334, 74338 (2007) quoting Hoxie, 419 F.3d at 483 ("Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.")).

While an applicant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. See, e.g., Joseph Gaudio, 74 FR 10083, 10094 (2009); Southwood Pharmaceuticals, Inc., 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. See Jacobo Dreszer, 76 FR 19386, 19387-88 (2011) (explaining that a respondent can

"argue that even though the Government has made out a prima facie case, his conduct was not so egregious as to warrant revocation"); Paul H. Volkman, 73 FR 30630, 30644 (2008); see also Gregory D. Owens, 74 FR 36751, 36757 n.22 (2009).

Moreover, as I have noted in several cases, "'[n]either Jackson, nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be revoked'" or an application should be denied. Gaudio, 74 FR 10094 (quoting Southwood, 72 FR 36504 (2007)); see also Robert Raymond Reppy, 76 FR 61154, 61158 (2011); Michael S. Moore, 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. See Gaudio, 74 FR 10095 (quoting Southwood, 71 FR at 36504). Cf. McCarthy v. SEC, 406 F.3d 179, 188-89 (2d Cir. 2005) (upholding SEC's express adoptions of "deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions").[40]

[40] Thus, in Gaudio, "I explained that 'even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts.'" 74 FR 10094 (quoting Southwood, 72 FR 36504) (citing Butz v. Glover Livestock Commission Co., Inc., 411 U.S. 182, 187-88 (1973)); cf. McCarthy, 406 F.3d at 189 ("Although general deterrence is not, by itself, sufficient justification for expulsion or suspension, we recognize that it may be considered as part of the overall remedial inquiry."); Paz Securities, Inc., et al. v. SEC, 494 F.3d 1059, 1066 (D.C. Cir. 2007) (agreeing with McCarthy). In Gaudio, I further noted that the "[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest, see 21 U.S.C. 801, and the broad grant of authority conveyed in the statutory text, which authorizes the [suspension or] revocation of a registration when a registrant 'has committed such acts as would render [his] registration . . . inconsistent with the public interest,' id. § 824(a)(4), and [which] specifically directs the Attorney General to consider ['such other conduct which may threaten public health and safety,' id. § 823(f)]." 74 FR 10094 (quoting Southwood, 72 FR 36504).

Unlike factors two ("[t]he applicant's experience in dispensing") and three ("[t]he applicant's conviction record"), neither factor four ("Compliance with applicable laws related to controlled substances") nor factor five ("Such other conduct which may threaten public health and safety") contain the limiting words of "[t]he applicant." As the Supreme Court has held, "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." Russello v. United States, 464 U.S. 16, 23 (1983). Thus, the text of factors four and five suggest that these factors are not limited to assessing the applicant's compliance with applicable laws and whether he has engaged in "such other conduct," but rather authorizes the Agency to also consider the effect of a sanction on inducing compliance with federal law by other practitioners.

The ALJ found that "respondent took prompt action to remedy" the labeling violations, that he "implemented new security procedures" and that "he also began a procedure whereby he kept a daily running inventory log of his controlled substances on hand." R.D. at 23. She also found that "Respondent credibly expressed his remorse for his past misconduct." Id.

Yet the ALJ also found that "the record demonstrates that he was never able to dispense controlled substances and remain in compliance with the Board's and the DEA's regulations." Id. Remarkably, the ALJ then concluded that "Respondent has sustained his burden to accept responsibility for his past misconduct and has successfully demonstrated that he will not engage in future misconduct related to his handling of controlled substances." Id. at 24. While characterizing Respondent's various violations as "mistakes in his dispensing of controlled substances," which she nonetheless deemed to be sufficiently "egregious" to warrant placing restrictions on his registration, the ALJ concluded "that the outright denial of his application is too severe a resolution." Id. She therefore recommended that I grant Respondent a restricted registration, pursuant to which he would be authorized only to prescribe controlled substances. Id.

I reject the ALJ's recommended sanction, because even assuming, without deciding, that Respondent has credibly accepted responsibility for his misconduct, this is a case where actions speak louder than words. Indeed, as the ALJ herself noted, "the record demonstrates that [Respondent] was never able to dispense controlled substances and remain in compliance with the Board's and [this Agency's] regulations." R.D. at 23 (emphasis added). As the Seventh Circuit has noted, "past performance is the best predictor of future performance," ALRA Labs, Inc. v. DEA, 54 F.3d at 452, and the evidence here shows that even when Respondent was provided information – on the proverbial silver platter – as to how to comply with various state

requirements (i.e., by not allowing unlicensed employees to dispense, by correcting all improperly labeled controlled-substance vials, by properly securing controlled substances, and by maintaining a daily inventory log which listed the drugs by their strengths), he still frequently failed to comply. Moreover, even when he did eventually start maintaining a daily inventory log which listed each drug by its strength, the DI found major discrepancies between the amounts which the logs stated as his inventories and the actual amounts Respondent had on hand.

Most significantly, the DI's audit found that Respondent had shortages of 40,000 dosage units over a six-month period. While there is no evidence in the record that the controlled substances were being diverted, as the ALJ also noted, Respondent's "inability to account for this significant number of dosage units creates a grave risk of diversion." R.D. at 21. And even if the shortages are only attributable to Respondent's poor recordkeeping, "'[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.'" Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy, 76 FR 51415, 51416 (2011) (quoting Paul H. Volkman, 73 FR 30630, 30644 (2008)).

These shortages are substantial and reflect a massive failure on Respondent's part to comply with the CSA's requirements that he maintain complete and accurate records of the controlled substances he received and dispensed in his practice. See 21 U.S.C. 827(a). And while Respondent maintained that "it is very difficult" for him to understand the various statutes, the CSA's recordkeeping provisions clearly provided Respondent with fair notice that he was required to maintain complete and accurate records of the controlled substances he handled. See id. Indeed, no court has ever held that the CSA's recordkeeping provisions fail to provide clear

notice as to what records must be maintained and that those records must be complete and accurate.

Thus, while Respondent testified that this proceeding had been "a very humbling experience" and promised he was "going to commit myself to a better process," that he was "uninformed" about the rules but that he was at fault, and that he would "take every measure to make sure [he is] in compliance" with the MBC's and DEA's rules, this is a refrain which he previously sung for the MBC's Investigators. See Tr. 584-85, 592; see also GX 3, at 4 & 6 (agreeing to comply with the terms of the MBC's 2003 Order, including that he "obey all federal, state and local laws, [and] all rules governing the practice of medicine in California"); GX 8, at 6 & 10 (May 2011 order).[41] And when asked if he had taken any courses on the proper handling of controlled substances, Respondent answered that he had not because "it was not required." Tr. 796-97.

Accordingly, notwithstanding his expressions of remorse, I conclude that Respondent's record of substantial non-compliance with both State and Federal laws and regulations related to the dispensing of controlled substances, (along with his failure to take any courses on the handling of controlled substances) leaves me with no confidence that he will responsibly handle controlled substances in the future. See ALRA Labs, 54 F.3d at 452. As for the ALJ's recommended sanction that I grant Respondent a registration which restricts his activities to prescribing, while there is no evidence establishing that Respondent issued prescriptions which violated 21 CFR 1306.04(a), his conduct is sufficiently egregious as to warrant the outright denial of his applications. Moreover, the ALJ's recommendation fails to consider the Agency's

[41] While the MBC did not adopt the Stipulated Settlement and Disciplinary Order until April 8, 2011, notably, Respondent agreed to the Order's terms and conditions on December 10, 2010. GX 8, at 1 & 10. Yet as found during the May 2011 DEA Inspection, Respondent was still failing to comply with the State's recordkeeping rules.

need to deter similar misconduct on the part of other registrants. Accordingly, I reject the ALJ's recommended sanction and will deny Respondent's applications.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the applications of Fred Samimi, M.D., for DEA Certificates of Registration as a practitioner be, and they hereby are, denied. This Order is effective immediately.

Dated: March 25, 2014.

Michele M. Leonhart,
Administrator.

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