

Therefore, pursuant to 21 U.S.C. § 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: July 19, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 11, 2011, and published in the **Federal Register** on April 19, 2011, 76 FR 21916, Mallinckrodt Inc., 3600 North Second Street, St. Louis, Missouri 63147, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of 4-Anilino-N-Phenethyl-4-Piperidine (8333), a basic class of controlled substance listed in schedule II.

The company plans to use this controlled substance in the manufacture of another controlled substance.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Mallinckrodt, Inc., to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Mallinckrodt, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: July 19, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09-51]

Paul Weir Battershell, N.P.; Suspension Of Registration

On May 8, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Paul Weir Battershell, N.P. ("Respondent"), of Caldwell and Meridian, Idaho. The Show Cause Order proposed the revocation of Respondent's DEA Certificates of Registration MB1090670 (for his Caldwell registered location) and MB1294711 (for his Meridian registered location), and the denial of any pending applications to renew or modify either registration, on the ground that his "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f)." ALJ Ex. 1, at 1.

The Show Cause Order specifically alleged that from "July 2005 through at least August 2006," Respondent "prescribed and dispensed Human Growth Hormone and controlled substances, including anabolic steroids, to individuals for no legitimate medical purpose and outside the course of professional practice" in violation of 21 U.S.C. §§ 333(e) and 841(a)(1), as well as 21 CFR 1306.04(a). *Id.* at 1.

The Order further alleged that from September 2005 through August 2006, Respondent "failed to maintain proper security over [his] controlled substances by not maintaining a proper key control system, failing to maintain adequate supervision over fellow employees who handle[d] [his] controlled substances and failing to monitor the distribution of [his] controlled substances in violation of 21 CFR 1301.71." *Id.* The Order also alleged that "[i]n August 2005," Respondent "failed to record the transfer of another practitioner's controlled substances into [his] inventory, when that practitioner left the clinic where [Respondent] was employed," *id.* at 2 (citing 21 U.S.C. § 827(a)(3) and 21 CFR 1304.21); that "[i]n November and December 2005," he "failed to keep records of controlled substances [he] received, specifically Phentermine 30 mg"; and that "during calendar year 2005," Respondent further "failed to properly record the date on [his] dispensing records." *Id.* (citing 21 U.S.C. § 827(a)(3) and 21 CFR 1304.21 & 1304.22).

Finally, the Show Cause Order alleged that "[d]uring 2005 and 2006," Respondent "accepted controlled

substances from non-DEA registered sources (patients) in violation of 21 U.S.C. § 844(a) and redistributed those illicitly obtained controlled substances to other patients in violation of 21 U.S.C. § 841(a)(1)." *Id.*

On June 5, 2009, counsel for Respondent timely requested a hearing, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). ALJ Ex. 2. Following pre-hearing procedures, an ALJ conducted a hearing in Boise, Idaho on December 1-2, 2009. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted post-hearing briefs.

On April 9, 2010, the ALJ issued her Recommended Decision (also ALJ). Therein, the ALJ, after considering the five public interest factors, *see* 21 U.S.C. § 823(f), recommended that Respondent be granted a restricted registration and be admonished.

As to the first factor—the recommendation of the appropriate state licensing board—the ALJ found that while the Idaho Board of Pharmacy (Board) had previously placed Respondent on probation, there was "no pending action[] against" him and "the Board has made no recommendations with regards to his registration." ALJ at 34. As to the second factor—Respondent's experience in dispensing controlled substances—the ALJ found that "Respondent's actions as well as his own statements suggest that at the time of these infractions in 2006, [Respondent] was inexperienced, or at least unaware of numerous regulations relating to the security and inventory requirements for controlled substances under the [Controlled Substances Act]." *Id.* at 34-35. She further found that while Respondent claimed that he had "sought guidance but did not receive it * * * in some instances, when [he] did receive such guidance, he was still unable to follow it." *Id.* at 35. The ALJ thus concluded that "the record demonstrates that [Respondent's] past practices demonstrate a lack of knowledgeable experience in handling controlled substances." *Id.*

As to factor three—Respondent's conviction record for offenses related to the distribution or dispensing of controlled substances—the ALJ found that the "record contains no evidence of any convictions related to the handling of controlled substances." *Id.* The ALJ thus concluded that "this factor does not fall in favor of revocation." *Id.*

With respect to the fourth factor—Respondent's compliance with applicable State, Federal or local laws related to controlled substances—the

ALJ found that Respondent had violated numerous security and record-keeping provisions of the Controlled Substances Act (CSA). These included: (1) His failure to maintain a “proper key control system to secure his controlled substances at either clinic”; (2) his receiving controlled substances from patients which were re-dispensed to other patients, in violation of 21 CFR 1304.21(a) and 1307.12(a); (3) his failure to take an initial inventory and biennial inventories, in violation of 21 U.S.C. § 827(a)(1) and 21 CFR 1304.11(b)–(c); (4) his failure to keep controlled substance dispensing records separate from records of other products his employer sold, as well as his failure to maintain those records in a form that makes them readily retrievable, in violation of 21 U.S.C. §§ 827(a)(3) and 842(a)(5), as well as 21 CFR 1304.03(d), 1304.04(a), (f)(2), (g), and 1304.21(a); (5) his failure to maintain complete and accurate records of controlled substances which the clinic had ordered, in violation of 21 U.S.C. § 827(a)(3), 21 CFR 1304.03(d), 1304.04(a), 1304.21(a), as well as Idaho Code Ann. § 37–2720; (6) his failure to maintain invoices for controlled substances received, in violation of 21 CFR 1304.22(c); and (7) his maintaining of unlabeled prescription bottles inside his controlled substances cabinet, in violation of 21 CFR 1302.03(a) and Idaho Admin. Code § 27.01.364.02. ALJ at 35–39. In addition, the ALJ noted that Respondent violated Idaho law in that he ordered controlled substances from suppliers not registered or licensed in Idaho. *Id.* at 39 (citing Idaho Code Ann. § 37–2716).

Next, the ALJ discussed the evidence supporting the Government’s allegation that Respondent had prescribed steroids to K.L., his employer, for muscle enhancement purposes, and that he did so without conducting an initial physical examination and without a legitimate medical purpose. ALJ at 40–41. Noting that “neither party introduced any patient records as evidence, nor introduced an independent expert medical opinion to substantiate their position[,]” the ALJ drew “no legal conclusions concerning the issue of whether or not [Respondent] dispensed controlled substances for a legitimate medical purpose.” *Id.* at 41. However, she concluded under factor four that the “security and record-keeping violations weigh heavily against * * * Respondent’s continued registration.” *Id.*

Under the fifth factor—such other conduct which may threaten public health and safety—the ALJ concluded that “it appears Respondent violated

Federal law,” specifically, subsection 303(e) of the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 333(e), because he is not a physician and dispensed Human Growth Hormone (HGH). ALJ at 44. While the ALJ noted that HGH is not a controlled substance under the CSA, she noted that the “plain language of 21 U.S.C. § 333(e) states that distribution of [HGH] is illegal unless pursuant to the order of a physician,” *id.* at 44, and that “violations of Federal law in distributing this drug are relevant in assessing whether * * * Respondent would comply with the” CSA. *Id.* at 41 (citing *Wonderyears, Inc.*, 74 FR 457, 458 (2009)). *See also id.* at 45.

The ALJ then discussed those facts she deemed favorable to Respondent in determining the appropriate sanction. These included that when Respondent “was informed” that it was illegal for him to prescribe HGH, he “ceased handling” it. ALJ at 45. Next, she noted that aside from Respondent’s “admission that he prescribed anabolic steroids to [his employer] prior to conducting blood work,” there was “no evidence that [he] failed to conduct physical examinations or blood work prior to prescribing any controlled substance to any other patient” and that he testified “that all new patients are given a physical exam.” *Id.* She further noted that Respondent had prescribed anabolic steroids only to this person, that he did so only “on two occasions,” and that he “credibly stated that he will not prescribe anabolic steroids again.” *Id.* at 45–46.

Next, the ALJ found that, although Respondent “had not remedied all of his record-keeping and security issues between the different audits, various witnesses stated that [he] had rectified many problems.” *Id.* at 45. Moreover, the ALJ observed that he no “longer works at [the clinic] where drug recycling was a problem.” *Id.* at 46.

While concluding that Respondent’s “lack of attention to the responsibilities of a registrant is extremely troublesome,” the ALJ recommended that “Respondent’s application for a DEA registration” be granted. *Id.* at 47. However, based on his recordkeeping and security violations, the ALJ recommended that his registration be restricted to allow only the prescribing of controlled substances. *Id.* In addition, the ALJ recommended that Respondent be required to file quarterly reports of his controlled substance prescribing with the local DEA office, that he be required to consent to unannounced inspections that were conducted without an Administrative Inspection Warrant, and that he be admonished. *Id.*

Finally, the ALJ recommended that these restrictions be imposed for a period of three years commencing on the effective date of this Order. *Id.*

Both parties filed Exceptions to the ALJ’s Decision. Thereafter, the record was forwarded to me for Final Agency Action.

On November 19, 2010, the Government filed a request to supplement the record. Government’s First Request to Supplement Record, at 1. In its request, the Government noted that “Respondent was the subject of a criminal case * * * regarding the same activities that were the subject of the administrative proceedings,” and that on July 28, 2010, the United States and Respondent filed a plea agreement with the U.S. District Court. *Id.* The Government further noted that on November 3, 2010, the District Court entered its Judgment. *Id.*

Having reviewed the record in its entirety and considered both parties’ Exceptions, I adopt the ALJ’s findings of fact and conclusions of law except as noted below. However, I reject the ALJ’s recommended sanction and conclude that the numerous violations established on this record mandate the imposition of a period of outright suspension. As ultimate factfinder, I make the following findings of fact.

Findings

Respondent’s License and Registration Status

Respondent is a nurse practitioner licensed by the Idaho Board of Nursing. ALJ at 4. Respondent, who has been a nurse practitioner for approximately thirty years, also holds a registration issued by the Idaho Board of Pharmacy which authorizes him to dispense controlled substances under state law. Tr. 326–27, 394. Under Idaho law, nurse practitioners (NP) are authorized to dispense the same drugs as a physician. Tr. 447.

Respondent also held two DEA Certificate of Registrations, MB1090670 and MB1294711, each of which authorizes Respondent to dispense controlled substances in schedules 3N, 4 and 5, as a mid-level practitioner, at the addresses of 5216 E. Cleveland Blvd., Caldwell, Idaho, and 27 E. Fairview Avenue, Meridian, Idaho, respectively. GX 1, at 1; Certification of Registration History, at 1 (filed April 13, 2010). Both of these registrations are for weight loss clinics, which do business under the name of Healthy Habits Wellness Clinic (Healthy Habits), and are owned by Kimball Lundahl, a chiropractor and naturopath. Tr. 20, 265, 395–96. Dr. Lundahl does not,

however, have authority to dispense controlled substances under either Idaho or Federal law. *Id.* at 20.

On March 30, 2004, Respondent first obtained the Caldwell registration. Certification of Registration History, at 1. This registration was to expire on July 31, 2009; however, on the same date, and on which date this proceeding was pending, Respondent filed a renewal application. *Id.*

On September 13, 2005, Respondent first obtained the Meridian registration. *Id.* This registration was to expire on July 31, 2008; however, on July 16, 2008, Respondent filed a renewal application. *Id.* According to the Certification of the Chief of the Registration and Program Support Section, the renewal applications for both registrations were deemed timely by him and both of these registrations remain in effect pending the issuance of this Final Order. *See id.*; *see also* 5 U.S.C. § 558(c). However, under DEA's regulation, where an Order to Show Cause has been issued to a registrant, "an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order." ¹ 21 CFR 1301.36(i). DEA has previously interpreted this regulation as requiring a registrant, who has been served with an Order to Show Cause, to file his renewal application at least 45 days before the expiration of his registration, in order for it to continue in effect past its expiration date and pending the issuance of a final order by the Agency. *Paul Volkman*, 73 FR 30630, 30641 (2008). Accordingly, I find that because Respondent had previously been served

with the Order to Show Cause, he did not file a timely renewal application for the Caldwell registration and that this registration has expired. However, I further find the renewal application for this registration is currently before the Agency. Moreover, I further find that Respondent's Meridian registration has remained in effect pending the issuance of this Decision and Final Order.

The Investigation

From January 2004 through February 2007, Respondent worked on a part-time basis at a clinic, which was owned by one Janet Green and was known as Malibu Medical Weight Loss and Nutrition (Malibu Medical). Tr. 399. At the time Respondent first started working at Malibu Medical, the clinic employed Doctor H., who was in his late eighties. *Id.* at 467. Dr. H. and Respondent alternated their days at the clinic until June 27, 2005, when Dr. H. left his employment. *Id.* at 78. On that date, Dr. H. and Respondent signed a document which stated that "all of the controlled substances on the premises were being transferred to" Respondent.² *Id.*

In December 2004, Respondent began working part-time at the Meridian location of Healthy Habits.³ Tr. 20, 97, 395, 401, 496. At the time, Dr. W. was responsible for ordering and handling the controlled substances which the clinic dispensed. *Id.* at 99–100.

On August 12, 2005, Dr. W. left the clinic and Respondent became the clinic's DEA registrant. *Id.* at 20, 77, 99–100, 194; GX 2, at 4. However, when Dr. W. left the clinic, he did not transfer the controlled substances inventory to Respondent with a signed inventory documenting the transfer. Tr. 21, 100–03; GX 2, at 4. A second DEA-registered nurse practitioner, J.B. (NP B.), worked alongside Respondent at Healthy Habits until December 12, 2005;⁴ however, the

date she began her employment at Healthy Habits is not disclosed in the record. Tr. 22, GX 2, at 3–4.

On December 6, 2005, F.C., the Chief Investigator for the Idaho Board of Pharmacy (Board), received a phone call from an FDA Special Agent (S/A), who alleged that the staff of the Health Habits Meridian Clinic was administering HGH for weight loss. GX 2, at 1. The FDA S/A also reported that he "had obtained advertisements from a Healthy Habits client," which showed that the clinic was advertising HGH "for weight loss." *Id.* Based on this information, F.C. decided to visit the clinic.

The next day, F.C. received a phone call from a Meridian police officer, who was a Healthy Habits client and "needed to know what law was violated when a doctor's employee administered or dispensed more medication to a patient than was ordered by the doctor." *Id.* at 2. F.C. went to the Meridian Police Department and interviewed the officer, who reported that Lundahl's ex-wife, who had formerly worked at the clinic but was now getting a divorce, had filed a complaint alleging that "some employees were stealing medications from the clinic." *Id.*; Tr. 15–16. The officer also told the CI that she was being given the phentermine, a schedule IV controlled substance, by a medical assistant and not a licensed practitioner. *Id.*

The same day, F.C., who was accompanied by another Board employee, went to Healthy Habits and asked to talk to a practitioner. Tr. 21. The clinic's owner, Kimball Lundahl, appeared and introduced himself. GX 2, at 3. F.C. asked Lundahl if he was a doctor; Lundahl said that he was a chiropractor and naturopath. GX 2, at 3. F.C. then asked to see where the controlled substances were kept and the controlled substances records. *Id.* When Lundahl asked what F.C.'s objective was, Lundahl told him he was going to contact his attorney before saying more. *Id.* F.C. then told Lundahl that as a chiropractor and naturopath, he was not authorized to handle controlled substance and that F.C. needed to talk with the nurse practitioners who had ordered the controlled substances. *Id.* Lundahl told F.C. that one of the nurse practitioners (NP B.) "was seeing patients" and that Respondent "would be in at 2:00 p.m." *Id.*

Lundahl then took F.C. and the Board employee to another room and showed him both NP B.'s and Respondent's DEA registration. *Id.* F.C. then told Lundahl

² 2005, she had left the clinic by December 12th. GX 2, at 22.

¹ This regulation further provides that "[t]he Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety." 21 CFR 1301.36(i). However, given the allegation that Respondent had prescribed anabolic steroids without a legitimate medical purpose, and that he had failed to maintain proper security and keep proper records for the controlled substances he ordered and dispensed, ALJ Ex. 1, at 1–2; I find that an extension of his registration would have been "inconsistent with the public health and safety." 21 CFR 1301.36(i).

² Based on Respondent's testimony, the ALJ found that Dr. H. left the clinic "sometime around December 2005," and that when he "left, he transferred his inventory to" Respondent. ALJ at 22 (citing Tr. 468). However, the ALJ also noted that "[o]n June 27, 2005, [Respondent] took over as the medical practitioner for Malibu * * * from Dr. [H.], the previous DEA registrant." *Id.* (citing GX 3, at 2; Tr. 78, 467). The latter finding is supported by the January 11, 2006 Report of Investigation submitted by F.C. of the Idaho Board of Pharmacy which related that, on December 29, 2005, Ms. Green told him that the transfer had occurred on June 27, 2005, and that Respondent had taken over the practice on that date. GX 3, at 1–2. Based on the contemporaneous nature of the Report of Investigation, I find that the transfer of the controlled substances occurred on June 27, 2005. GX 3, at 1–2.

³ At some point, Respondent also began working at the Caldwell location, and at the time of the hearing, he was working at both locations. Tr. 397.

⁴ According to a note written by NP B., although she was working at Healthy Habits on December 7,

that Respondent's "DEA number had been changed to another location" and that NP B. "was the only individual we had registered at his address." *Id.* However, as found above, Respondent had been registered at the Meridian clinic since September 13, 2005.

NP B. then met with F.C. and stated that both she and Respondent "had two controlled substances registrations" and that "she ha[d] never ordered any controlled substances to that address." *Id.* F.C. then asked Lundahl to get the controlled substance records; he also asked NP B. to show him the controlled substances but she did not have the key to the cabinet in which they were stored. GX 2, at 3; Tr. 21–22. Upon obtaining the key from another employee, the cabinet was opened and F.C. observed manufacturer-size bottles of phentermine,⁵ as well as "a large number of prescription bottles in which the phentermine had been transferred," but that "[n]one of the prescription bottles had labels on them." GX 2, at 3. F.C. told Lundahl and NP B. that the prescription bottles must be labeled. *Id.*

After being shown the cabinet that was used to store phentermine in another exam room, F.C. asked NP B. to explain the procedures used to dispense the controlled substances. NP B. stated that she would write a "prescription" and that the "medical assistant" would then "get[] the medication from the cabinet and give[] it to the patient." GX 2, at 4. Clinic staff would then take the form and enter the information into the clinic's computer. *Id.* F.C. then told NP B. that such an order was not a prescription, as it was not "intended to be taken to a pharmacy to have the medication dispensed." *Id.* F.C. then reviewed records which were computer generated reports of what the clinic had sold that day; however, the reports listed all items that had been sold and "not just controlled substances." *Id.*

Respondent arrived at the clinic and explained that he was now the practitioner in charge and had become the clinic's DEA registrant upon Dr. W.'s departure. GX 2, at 4. When F.C. told Respondent that upon the latter event, he and Dr. W. should have done an inventory and that a record should have been created to document the transfer, Respondent indicated that no such inventories or documented transfers were done.⁶ *Id.*; Tr. 21. F.C. told Respondent that the clinic's dispensing records included both controlled and

non-controlled drugs and that controlled substance records "needed to be maintained either separately from * * * other records * * * or in such form that the [controlled substance] information * * * is readily retrievable from [the clinic's] ordinary business records." GX 5, at 4–5.

F.C. also learned that the clinic staff was not signing and dating invoices when controlled substances were being received and was not notating the quantity received. Tr. 22; GX 2, at 5. When F.C. asked to see the controlled substance invoices, he found that Healthy Habits had received phendimetrazine (a schedule III controlled substance, 21 CFR 1308.13(b)), phentermine, and HGH (a schedule III controlled substance under Idaho but not Federal law) from two companies that were not licensed to distribute drugs in Idaho. GX 2, at 5, 7–10; Tr. 23. However, the company which distributed the Phendimetrazine and Phentermine was a DEA registrant. GX 2, at 7–9.

F.C. then asked Respondent if "he personally took care of the records." *Id.* at 5. Respondent said "no." *Id.* F.C. then determined that the records were maintained by the medical assistant. *Id.* Respondent also said that he did not review the controlled substance records to determine whether they were accurate and that he did not know where they were kept. *Id.*; Tr. 22–23. Upon determining that neither Respondent nor NP B. locked up the controlled substances at the end of the day, F.C. advised them that "they need[ed] to insure[sic] that the [controlled] substances [were] secured and that no one [had] access to them when there is no practitioner on duty." GX 2, at 5. At the end of the visit, F.C. told Lundahl that he would prepare a letter to Respondent identifying the deficiencies and require [him] to respond in writing listing the corrective actions taken." *Id.*

On December 16, 2005, F.C. received a letter from Healthy Habits' counsel enclosing four letters executed by the clinic's employees including Respondent⁷ which "outlin[ed] the meeting on the 7th and propos[ed] in a very general way, corrections to problems identified on the 7th." *Id.* at 6, 11–13, 15–22; *see also id.* at 12–23; RXs 3 & 5. In his letter, Respondent acknowledged the various deficiencies found by F.C. and stated that the clinic "is currently doing all we can to comply with all laws and regulations of the state of Idaho," that the clinic "wish[ed] to

completely comply with all laws and regulations," and that the clinic was "currently making the above * * * changes told to us." GX 2, at 15–16.

On December 29, 2005, F.C., accompanied by a DEA Diversion Investigator (DI), visited Malibu Medical, where they were greeted by its owner, Janet Green, and her son, Joe Green. GX 3, at 1; Tr. 27, 123–24. Ms. Green took the Investigators to an exam room and opened up a locked closet in which there was a locked metal cabinet which contained various controlled substances and records. GX 3, at 1–2. However, the clinic's staff had access to the controlled substances cabinet when Respondent was not on the premises. GX 3, at 1–2; Tr. 29–30; Tr. 125, 128 (testimony of DI).

F.C. counted the controlled substances on hand and compared them with a daily count sheet maintained by the clinic; none of the five items he counted matched the items on the report. F.C. then proceeded to audit four controlled substances (diethylpropion⁸ in both 25 and 75 mg strength, and phendimetrazine in 35 and 105 mg strength) for the period June 27, 2005⁹ through December 28, 2005. Tr. 27–28; GX 3, at 2. According to F.C., he used computer generated reports for the quantity received, which he compared to the actual invoices and found them to be accurate; however, F.C. noted that the invoices did not indicate the date of receipt and were not initialed. GX 3, at 2. He also used a computer generated report for the quantity dispensed.¹⁰ F.C. stated that he compared one day of the computer generated list of dispensings to the sign out log and found it to be accurate. *Id.*

F.C. found that Respondent was short 212 capsules of diethylpropion 75 mg and 685 capsules of diethylpropion 25 mg. GX 3, at 2. F.C. also found that Respondent was short 2,056 capsules of phendimetrazine 105 mg and 8,115 capsules of phendimetrazine 35 mg. In total, F.C. found that Respondent was short approximately 11,000 dosage units of schedule III and IV controlled substances. *Id.*; Tr. 27–28. These

⁸Diethylpropion is a schedule IV stimulant. 21 CFR 1308.14(e).

⁹As found above, on June 27, 2005, Respondent had assumed control of the clinic's controlled substance inventory when Dr. H. left the clinic. GX 3, at 2. Ms. Green provided the Investigators with documentation of the transfer, which included inventories signed by both Respondent and Dr. H., the previous DEA registrant. *Id.*

¹⁰F.C. stated in his Supplemental Report of Investigation (GX 3) that he and Ms. Green had compared one day of the dispensing report with "the sign out log and found the * * * information to be accurate." GX 3, at 2.

⁵Phentermine is a schedule IV controlled substance. 21 CFR 1308.14(e)(9).

⁶F.C. also told Respondent that the State Board's rule requires that an inventory of controlled substances be performed annually and DEA's rule requires that it be performed bi-annually.

⁷The letters were from Respondent, NP B., Dr. Lundahl, and one K.S. *See* GX 2, at 13–23.

shortages were significant in size. *Id.* at 29.

When Respondent arrived at the clinic, the DEA DI presented him with a Notice of Inspection, which he signed. GX 3, at 3. F.C. asked Respondent if he remembered what he had been told about locking up the controlled substances at the end of the work day and allowing persons, who lacked legal authority to handle controlled substances, to have access to them when he was not present. GX 3, at 3. Respondent acknowledged that he remembered. *Id.* When F.C. then asked why Ms. Green had access to the controlled substances in his absence, Respondent stated he did not “have a key to the cabinet or the office.” *Id.*

F.C. “then told [Respondent] that he was short approximately 11,000 dosage units of” controlled substances, and when asked by the DI “where he thought the missing substances were,” Respondent “had no answer.” *Id.* Respondent denied having taken any for his personal use and again stated “that he did not have a key to the cabinet.” *Id.*

F.C. then asked Respondent how long he had been a controlled substance registrant; Respondent stated “two years.” *Id.* When F.C. asked Respondent whether he had explained controlled substance recordkeeping and security requirement to the clinic’s staff; Respondent stated that he did “not know what the requirements” were. *Id.*; Tr. 30, 126. F.C. then told Respondent that the shortages provided grounds for the Board to revoke or restrict his state registration. GX 3, at 3. When Respondent said that he wanted to keep his registration, F.C. told him that he had until January 10, 2006 to “review the records to identify any record-keeping errors that might account for the missing medication.” GX 3, at 3; Tr. 31.

On January 10, 2006, F.C. and the DI met with Respondent, his attorney at the time (who also represented Dr. Lundahl and Healthy Habits), and Ms. Green. GX 3, at 3; Tr. 31, 33, 129. Ms. Green maintained that the reason the audit found shortages was because it did not include the drugs dispensed the day before the audit. GX 3, at 3; Tr. 32.

F.C. then suggested that a new audit be performed covering the period from June 27, 2005 through January 10, 2006. GX 3, at 3. F.C. used the same beginning inventory (as was used for the first audit), took an inventory with Ms. Green of the controlled substances then on hand, and used the clinic’s computer generated reports for the quantity received and dispensed. *Id.*

The audit found an overage of thirty-six dosage units of phendimetrazine 105 mg and a shortage of 161 dosage units of phentermine 35 mg. GX 3, at 3–4. The audit also found that another drug, which was not specified on the record, had an overage of 681 capsules. *Id.* at 4; Tr. 33.

Ms. Green stated that the overage was caused “probably because of the recycled medications.” GX 3, at 4; Tr. 34, 129–30. She then explained that patients would return drugs to the clinic and that the clinic would re-dispense the drugs to a different patient. GX 3, at 4; Tr. 34. F.C. told Respondent and Ms. Green that the clinic “could not accept medications from patients and reuse them.”¹¹ GX 3, at 4. In his testimony, Respondent maintained that he did not know that the clinic was re-dispensing drugs and that when he found out, he told her the practice was illegal.¹² Tr. 464, 466.

F.C. then asked Respondent whether “he had restricted the access to the controlled substances”; Respondent stated that “he [had] the only keys to the drug cabinet.” GX 3, at 4; Tr. 34. F.C. testified that at the conclusion of the visit, he felt that Malibu Medical “was probably squared away.” Tr. 34, 131; *but see* GX 3, at 4 (“I said that the audit at Malibu Medical seems to have been corrected but that I don’t understand how.”).

On January 11, 2006, F.C. and the DI went back to Healthy Habits and met with Respondent, his then attorney, and Dr. Lundahl. GX 3, at 4. The DI presented Respondent with a Notice of Inspection, which Respondent signed. *Id.* Respondent showed the Investigators where the controlled substances were kept and stated that he was the only one with a key to the cabinet. *Id.* Upon opening the cabinet, the Investigators again found that there were controlled substances in unlabeled prescription bottles. *Id.* F.C. again told Respondent (and the others) that the “bottles needed to be labeled.” *Id.* They stated that “they understood.” *Id.*

Respondent provided an annual inventory that he had completed on December 12, 2005, and Lundahl stated

¹¹ F.C. told Ms. Green and Respondent that if a patient returned medication, the clinic should “flush the medications down the toilet in the presence of the patient.” GX 3, at 4. To make clear, this is not a proper method of disposing of controlled substances.

¹² According to F.C., when Ms. Green explained that the overages were “most likely” caused by the re-dispensing of the drugs, Respondent nodded his head in agreement thus suggesting that he was aware of the practice. Tr. 194–96. While it is not entirely clear in the decision, the ALJ apparently resolved this factual dispute in favor of Respondent. *See* ALJ at 24.

that the clinic had “opened for business on 12/17/04.” GX 3, at 4. The Investigators then audited the clinic’s handling of six controlled substances for the period of December 17, 2004 through December 12, 2005. *Id.*

The audit found that there were overages of 1,807 dosage units of phendimetrazine 35 mg, 184 dosage units of phendimetrazine 105 mg, 7,036 dosage units of diethylpropion 25 mg, and 74 dosage units of phentermine 15 mg, and a shortage of 3,028 dosage units of phentermine 37.5 mg. *Id.* While the Investigators also attempted to audit the phentermine 30 mg, they could not do so because the only dispensing records available were for November and December 2005. *Id.* Moreover, the clinic staff estimated that it would “take three weeks to create the reports necessary to complete th[e] audit.” *Id.*

F.C. further determined that the clinic “did not have all the invoices” showing its purchases and that “no one knew where any other invoices were.” GX 3, at 4–5; Tr. 37. Moreover, “the computer generated report listing the medication dispensed was off by seven days.” GX 3, at 4. In addition, a dispensing report for one of the drugs “listed only a few months of transactions” because “someone had misspelled the name of the drug” and the report had to be run twice to get the total number of dosage units that had been dispensed. *Id.* at 5.

F.C. found it significant that the clinic’s recordkeeping did not allow for the completion of the phentermine 30 mg audit and that three of the audits found overages/shortages of over 1,000 dosage units. Tr. 36. F.C. testified “[d]espite any computer deficiencies, it is still [Respondent’s] responsibility * * * to maintain complete and accurate records of his controlled substance handling.” *Id.* at 135. At the conclusion of the visit, the Investigators gave Healthy Habits until January 20, 2006 to get its records in order. *Id.* at 38.

On August 28, 2006, an FDA Special Agent obtained a federal search warrant, which authorized a search of Healthy Habit’s Meridian clinic for evidence relevant to violations of the Food, Drug and Cosmetic Act, specifically 21 U.S.C. 333(e). GX 6, at 1. The warrant authorized the seizure, *inter alia*, of records pertaining to the clinic’s purchases and distributions of HGH, as well as any HGH. *Id.* at 4; Tr. 136.

On August 30, 2006, F.C., the DI, and FDA Agents executed the warrant. Tr. 38–39, 136, 217. Initially, only one employee, the receptionist, was on site when the warrant was served. *Id.* at 41, 43.

As found above, although F.C. had previously instructed Respondent that

he alone should have the key to the controlled substances cabinet, and that during the January 11 inspection, Respondent had stated that he was the only person with the key, "one of the assistants[] had the key." *Id.* at 137. Moreover, in an unlocked refrigerator in an examination room, the DI found several vials in a small box, all approximately 1.5 inches tall and labeled "Nandralone Decaloid," an anabolic steroid and schedule III controlled substance.¹³ *Id.* at 138, 141. The labels identified the prescriber as "Dr. Paul Battershell," the patient as "Kimball Lundahl," and the pharmacy as "'Applied Pharmaceuticals'"¹⁴ of Mobile, Alabama, a compounding pharmacy which was suspected of unlawfully distributing HGH and anabolic steroids. *Id.* at 138–39; 215–16. However, because the warrant did not authorize the seizure of anabolic steroids, the DI left the vials of nandrolone decaloid in the refrigerator. *Id.* at 139.

Pursuant to the warrant, law enforcement officers seized medical records for patients receiving HGH, records documenting the clinic's receipt and distribution of HGH, as well as four vials of HGH, which had labels listing "Dr. Battershell" as the prescriber. *Id.* at 217–18. Subsequently the FDA tested the vials and confirmed that it was HGH. *Id.* at 219.

During the search, the lead FDA S/A interviewed Dr. Lundahl, who said that the HGH was distributed for anti-aging purposes. *Id.* at 223. Dr. Lundahl stated that Respondent prescribed both HGH and nandralone, an anabolic steroid also known as Deca-Durabolin to him. *Id.* However, Lundahl stated that the clinic had not distributed anabolic steroids to anyone else.¹⁵ *Id.*

Later that day, the FDA Agent (and another FDA Agent) went to Malibu Medical and interviewed Respondent. *Id.* at 224. Initially, Respondent denied prescribing anabolic steroids to Dr. Lundahl. However, when the Agents confronted him with Lundahl's statement and warned him "that lying to a federal agent was a criminal offense," Respondent admitted that he had lied

and that he had "prescribed Deca-Durabolin" to Lundahl "because * * * Lundahl had asked him to do it." *Id.* at 225. Respondent also said that "he wasn't exactly sure what Decadurabolin even was, but [that] it was similar to" HGH. *Id.*

While Respondent did not perform bloodwork on Lundahl prior to prescribing HGH to him, *id.* at 511, there is no evidence establishing when Respondent first prescribed Deca-Durabolin to Lundahl. Moreover, the Government did not introduce Lundahl's patient file into evidence.¹⁶

According to Respondent, Lundahl "had degenerative deterioration of his cervical spine," and he had a document from Lundahl's physician, who was "a specialist in this area," as well as an MRI to support this. *Id.* at 402. At the hearing, Respondent testified that he prescribed Deca-Durabolin to Lundahl because he had inflammation and "pain in his neck," and denied that he had prescribed the steroid for muscle building purposes. *Id.* at 402–03.

Respondent also testified that Dr. Lundahl was the only person to whom he had prescribed anabolic steroids and that he was no longer prescribing them to him. *Id.* at 422. Moreover, Respondent prescribed the steroids to Lundahl for approximately one year, writing two prescriptions, each with two refills. *Id.* at 506. The Government did not introduce any evidence refuting any of Respondent's testimony regarding the propriety of the steroid prescriptions.¹⁷

On October 2, 2007, the Idaho Board adopted a Stipulation and Order, which Respondent entered into with the Board's Executive Director; the Order resolved the various security and recordkeeping issues that were found during the inspections of both the Healthy Habits and Malibu Medical clinics. GX 9, at 1–2. In the Stipulation, Respondent admitted to "violating Idaho Code § 37–2718(a)(4) by failing to obtain prior approval from the Special

Agent in Charge of DEA before storing other non-medical materials (a cash box) with schedule III–V controlled substances as required by 21 CFR 1301.72(b)(8)(i) & (ii)."¹⁸ *Id.* at 2. Respondent also admitted to "violating Idaho Code § 37–2720"¹⁹ by failing to keep records and maintain inventory by having inventory in excess of that recorded as required by 21 CFR 1304.04[.]” *Id.*

The Stipulation and Order placed Respondent's state controlled substance registration on probation for one year subject to certain conditions including that he pay a \$250.00 fine and agree to notify his employer and any subsequent employers of the Stipulation's terms. *Id.* at 3. In addition, Respondent agreed to "comply with all state and federal laws and rules regulating controlled substances" and to be prepared to "show evidence of such compliance upon request of the Board of Pharmacy." *Id.* Finally, Respondent agreed to "develop a protocol for security" and "a protocol for maintenance of records and inventory," both which were subject to the Board's review and approval, and which he agreed to follow for "so long as he maintains" a state controlled substance registration. *Id.*

On August 11, 2009, a Federal grand jury indicted Respondent along with Kimball Lundahl and Healthy Habits. GX 10. While Respondent was initially charged with one count of conspiracy to unlawfully distribute HGH, in violation of 18 U.S.C. 371 and 21 U.S.C. 333(e); five counts of unlawful distribution of HGH on various dates, in violation of 21 U.S.C. 333(e); one count of conspiracy to unlawfully distribute nandralone, a schedule III controlled substance, in violation of 21 U.S.C. 846; and four counts of unlawfully distributing nandralone, *id.* at 12–15; according to the plea agreement, at some point, the Government filed a superseding information. Rule 11 Plea Agreement, at 1. The information charged Respondent with one count of "causing the introduction into interstate commerce of a misbranded drug, in violation of" 21

¹⁸ Under 21 CFR 1301.72(b)(8)(ii):

Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas, provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of the DEA for the area in which such storage is situated.

¹⁹ Idaho Code § 37–2720 provides as follows:

[Persons] registered to manufacture, distribute, or dispense controlled substances under this act shall keep records and maintain inventories in conformity with the recordkeeping and inventory requirements of federal law and with any additional rules the board issues.

¹³ 21 CFR 1308.13(f)(1).

¹⁴ Subsequent testimony of the FDA Agent revealed that this company was named Applied Pharmacy Services ("APS"). Tr. 319.

¹⁵ The Government elicited extensive testimony from both the FDA Special Agent and Respondent regarding the latter's prescribing of HGH. It also introduced various documents showing that Respondent had ordered HGH from a compounding pharmacy, which was not an FDA approved product. However, for the reasons stated in *Tony T. Bui*, 75 FR 49979, 49989 (2010), I deem it unnecessary to make detailed findings regarding Respondent's prescribing of HGH.

¹⁶ Respondent maintained that he later tested Lundahl and found that his Insulin-like Growth Factor-1 test ("IGF-1") levels were low. *Id.* at 511. He also stated that because Lundahl had previously been prescribed HGH by his father, who is "a doctor," he had simply renewed the prescriptions. *Id.* at 502, 511. However, earlier in his testimony, Respondent stated that Lundahl's father was "a chiropractor" and thus would not have had authority to prescribe any drug under Idaho law. *Id.* at 502.

¹⁷ While the Government introduced a copy of the Indictment which charged Respondent with unlawfully distributing Nandralone on various dates to include August 31 and December 29, 2005, as well as April 24 and August 23, 2006, *see* GX 10, at 12–15, it is fundamental that an indictment is only an accusation and not proof that Respondent committed the acts alleged.

U.S.C. 331(a) and 333(a)(1). *Id.* at 4. The factual recitation made clear that the basis of Respondent's liability was that Respondent had purchased HGH from APS that FDA had "not approved for any purpose," and as such, "did not include any approved labeling and * * * did not contain adequate directions for use by a layperson." *Id.* Notably, the information did not charge Respondent with any offenses under the Controlled Substance Act. *See id.*

At the hearing, Respondent voluntarily testified as a Government witness. Tr. 394. He testified that he has not prescribed HGH since the time he was told by the FDA Agent that only a physician could prescribe this substance. *Id.* at 409, 418, 479, 494. He also testified that the reason the nandralone was stored in the unlocked refrigerator and not with the other controlled substances was because Dr. Lundahl thought it was best to store it at cooler than room temperature. *Id.* at 424.

Although Respondent stopped prescribing HGH, he maintained that it was legal for him to do so because under Idaho law a nurse practitioner can prescribe anything that a medical doctor can.²⁰ Tr. 447, 491. He stated, "I can prescribe [HGH] because it's on my formulary." *Id.* at 448.

As to the Malibu Medical's practice of re-dispensing medications that were returned by its patients, Respondent testified that he did not know that the staff was doing that. *Id.* at 464. He further maintained that when Ms. Green mentioned this to the Investigators, he told her it was illegal. *Id.*

As to the violations found during the inspection of Healthy Habits, Respondent testified that he no longer used the computer to track controlled substances; instead, he uses paper records. *Id.* at 471. He maintained that the reason why the audit could not be completed on the phendimetrazine 35 mg was because of an irreparable computer problem. *Id.* at 472. He also

²⁰ See Idaho Admin. Code § 23.01.01.315.05 ("All authorized advanced practice professional nurses may dispense pharmacologic and non-pharmacologic agents pursuant to applicable state and federal laws * * *"); *see also* Idaho Code Ann. § 54-1402(1) & (1)(a) (defining "advanced practice professional nurse" to include "nurse practitioners" and defining "nurse practitioner"); Idaho Admin. Code § 23.01.01.271.02 (defining "advanced practice professional nurse" as including "nurse practitioners").

He also testified that he did not prescribe HGH off-label and was prescribing it for Adult Growth Hormone Deficiency, which is an FDA-approved indication, and pointed to the IGF-1 tests he had done on his patients and a protocol of the American Academy of Anti-Aging Medicine as proof. *Id.* at 449, 452, 460-61, 550.

explained that the clinic no longer packed the prescriptions it dispensed, but instead obtained pre-packed bottles. *Id.* at 472. He further testified that he counted his inventory of controlled substances every day.²¹ *Id.* at 559.

Although Respondent ultimately acknowledged that as a registrant, it was his responsibility to know the law and regulations applicable to controlled substances, he nevertheless asserted that if one did not "have any experience with this," the regulations did not provide "the answers" and that "they need to have a class and tell you * * * what's expected of you with this controlled substance license." Tr. 567-68, 569. Similarly, he testified that "it's the Board of Pharmacy's obligation to inform nurse practitioners exactly of * * * what the conditions you're working in, and how to maintain records, how to do what is correct." *Id.* at 569. He stated his belief that "the Board of Pharmacy is negligent" for not having provided more instruction to controlled substance registrants. *Id.* at 570.

Discussion

Section 304(a) of the CSA provides that a "registration pursuant to section 823 of this title to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would make his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In determining the public interest, Congress directed 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. 21 U.S.C. 823(f).

"[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

²¹ Respondent also provided unrefuted testimony regarding his compliance with the State Board's order. *Id.* at 557-558.

revoke an existing registration or 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).

With respect to a practitioner's registration, the Government bears the burden of proving, by a preponderance of the evidence, that Respondent has committed acts which render his registration inconsistent with the public interest. 21 CFR 1301.44(e). However, where the Government satisfies its *prima facie* burden, the burden then shifts to the registrant to demonstrate why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough*, 73 FR 363, 380 (2008).

Having reviewed the record in its entirety, I conclude that the evidence relevant to factors two (Respondent's experience in dispensing controlled substances), four (Respondent's compliance with applicable laws related to controlled substances) and five (such other conduct which may threaten public health and safety) establishes that Respondent has committed acts which render his "registration inconsistent with the public interest." 21 U.S.C. 824(a)(4). While I have considered Respondent's evidence, I conclude that the record supports the suspension of his registration. I further reject the ALJ's recommendation that Respondent's application "be granted at this time." ALJ at 47. However, in the event Respondent complies with the condition set forth below, his applications will be granted.

Factor One—The Recommendation of the State Licensing Board

As found above, Respondent entered into a Stipulation and Order with the Idaho Board of Pharmacy which placed his state registration on probation for a period of one year subject to various recordkeeping and security conditions. The Board did not, however, make a recommendation to DEA as to the disposition of this matter.

While Respondent apparently retains authority under Idaho law to dispense controlled substances, DEA has repeatedly held that a practitioner's possession of state authority "is not dispositive of the public interest inquiry." *George Mathew*, 75 FR 66138, 66145 (2010) (citing *Patrick W. Stodola*, 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie*, 68 FR at 15230). "[T]he 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). Consistent with Agency precedent, this factor is not dispositive either for, or against, the continuation of Respondent’s registration. *See also Edmund Chein*, 74 FR 6580, 6590 (2007), *aff’d*, *Chein v. DEA*, 533 F.3d 828 (D.C. Cir. 2008), *cert. denied*, ___ U.S. ___, 129 S.Ct. 1033 (2009).

Factors Two and Four: Respondent’s Experience in Dispensing Controlled Substances and His Compliance With Applicable State, Federal, and Local Law

While Respondent has been a licensed nurse practitioner for more than thirty years, his experience as a dispenser of controlled substances is of considerably shorter duration. Moreover, his experience is characterized by a stunning lack of knowledge of the applicable requirements of Federal law, as well as his numerous failures to comply with the CSA and DEA regulations and to properly supervise those persons who performed these functions at the clinics where he worked.

Under Federal law, “every registrant * * * shall * * * as soon * * * as such registrant first engages in the * * * dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand.” 21 U.S.C. § 827(a)(1); *see also* 21 CFR 1304.03(a) & (b); 1304.11. Moreover, “every registrant * * * dispensing a controlled substance or substances, shall 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); 21 CFR 1304.21(a) & (d); 1304.22(c). Finally, “[e]very inventory or other record required under this section * * * shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and * * * shall be kept and be available, for at least two years, for inspection and copying.” 21 U.S.C. 827(b); *see also* 21 CFR 1304.04(a) & (g).

As found above, when, upon Dr. W.’s departure, Respondent became the practitioner-in-charge and the DEA registrant at Healthy Habit’s Meridian Clinic, he failed to take an inventory and document the transfer of the controlled substances on hand. This was a violation of 21 U.S.C. § 827(a)(1) and 21 CFR 1304. Moreover, the clinic’s staff

was not signing and dating the invoices for the controlled substances that it purchased to reflect the date on which the drugs were actually received. This is a violation of 21 CFR 1304.22(c), which incorporates by reference the requirement of 21 CFR 1304.22(a)(2)(iv) that a registrant maintain records documenting “[t]he number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory.” (emphasis added).

In addition, upon examining the clinic’s dispensing records, which were maintained in a computer, the State Board Inspector was provided a record that included both controlled and non-controlled drugs. While Federal law allows for nonnarcotic controlled substance records to be maintained electronically, a recordkeeping system must be able to “separate out” the controlled substance records “from all other records in a reasonable time and/or [that the] records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.” 21 CFR 1300.01(38). The clinic’s dispensing records thus did not comply with Federal law. In addition, while Respondent did not maintain the records, he admitted that he did not review them and did not even know where they were kept.

Neither Respondent, nor the other nurse practitioner (who also held a DEA registration), locked up the controlled substances at the end of the day and clinic staff had access to the drugs even where there was no registrant on duty. Under a DEA regulation, all “registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 CFR 1301.71(a); *see also id.* 1301.71(b)(8) (authorizing Agency to consider “[t]he adequacy of key control systems”); *id.* 1301.71(b)(11) (authorizing Agency to consider “[t]he adequacy of supervision over employees having access to * * * storage areas”); *id.* 1301.71(b)(14) (authorizing Agency to consider “[t]he adequacy of the registrant’s * * * system for monitoring the receipt, * * * distribution, and disposition of controlled substances in its operations”).

Notwithstanding that Respondent was specifically instructed during the inspection of Healthy Habits that the controlled substances needed to be secured and that no one should have access to them when there was no practitioner on duty, during the

inspection of Malibu Medical (which occurred only three weeks later), the Investigators found that the clinic’s staff had access to the controlled substances when Respondent was not on the premises.²² Moreover, here too, the clinic was not recording the actual date it received the controlled substance it purchased. 21 CFR 1304.22(c).

Upon auditing Malibu Medical, the Investigators found significant shortages of several controlled substances including 685 capsules of diethylpropion 25 mg, 2,056 capsules of phendimetrazine 105 mg, and 8,115 capsules of phendimetrazine 35 mg. In total, Respondent was short approximately 11,000 dosage units. These shortages are especially significant given that the audit covered only a six-month period and are indicative (in the best case scenario) of serious record keeping failures. Moreover, when asked during this visit, whether he had explained the controlled substance recordkeeping and security requirements to the clinic staff, Respondent replied that he did “not know what the requirements” were.

It is true that at a subsequent audit of Malibu, the clinic’s owner maintained that the initial audit had not included drugs that had been dispensed the day before,²³ and that upon doing a new audit, the clinic had overages of thirty-six dosage units of phendimetrazine 105 mg and 681 dosage units of another drug, as well as a shortage of 161 dosage units of phentermine 35 mg. Moreover, the clinic’s owner maintained that the overages were probably caused by the clinic’s practice of accepting drugs that were returned by patients and re-dispensing them.

Citing DEA regulations (21 CFR 1304.21(a) and 21 CFR 1307.12(a)), the ALJ concluded that the re-dispensing of the drugs violated Federal law. However, 21 CFR 1304.21(a) merely requires that a registrant maintain “a complete and accurate record of each”

²² Respondent admitted to F.C. that he remembered that he had been told this.

²³ There is ample reason to be skeptical of Ms. Green’s claim that the failure to count a single day’s worth of dispensings accounted for most of the shortages, given the size of the shortages and typical dosing of these drugs (which seems quite large to be only one day’s worth of dispensings) and that she should have known at the time of the original audit that the dispensing logs were not up to date. Moreover, Respondent, who ultimately is responsible for the maintenance of accurate records, “had no answer” as to why the controlled substances could not be accounted for.

However, even assuming the validity of the results of the second audit, the audit still found both shortages and overages. Also, as found above, when Investigators audited the Healthy Habits clinic, here too, there were major issues with the accuracy of Respondent’s records.

controlled substance it receives or disposes of. Moreover, 21 CFR 1307.12(a) provides in relevant part, that “[a]ny person lawfully in possession of a controlled substance * * * may distribute (without being registered to distribute) that substance to the person from whom he/she obtained it.” The provision thus expressly allows for a patient to return a controlled substance to a dispensing practitioner and neither the Government nor the ALJ cite to any other provision of the CSA or DEA regulations which expressly prohibits this practice.

The Idaho Board of Pharmacy’s Rules do, however, prohibit the re-dispensing of controlled substances in the manner that occurred here. More specifically, the Board’s rule provides that:

In the interest of public health, drugs, medicines, sickroom supplies, devices, and items of personal hygiene shall not be accepted for return by any pharmacist or pharmacy after such drugs, medicines, sickroom supplies, devices, and items of personal hygiene have been taken from the premises where sold, distributed, or dispensed, except that medications for in-patients of residential or assisted living facilities, licensed skilled nursing care facilities, and hospitals may be returned to the dispensing pharmacy for credit if the medications are liquid medications that have been supplied in manufacturer sealed containers and remain unopened, or the medications are in unopened “unit dose” packaging.

IDAPA 27.01.01(156)(05).²⁴ The clinic where this practice occurred clearly does not fall within the limited exceptions for certain in-patient facilities provided by the regulation. As even Respondent acknowledged when confronted during the inspection, the practice was illegal. Moreover, beyond the fact that the clinic did not maintain accurate records documenting the return of the drugs, 21 CFR 1304.21(a), as the State’s rule expressly recognizes, the practice poses a serious risk of harm to patients because the drugs may have been adulterated by the person to whom they were dispensed. Even accepting the ALJ’s apparent crediting of

Respondent’s testimony that he was unaware that the clinic was engaged in this practice, *see* ALJ at 36, it is particularly disturbing that once again, Respondent was oblivious to the clinic’s engaging in an illegal practice.

Thereafter, the Investigators returned to the Healthy Habits clinic and conducted an audit of its handling of six controlled substances from December 17, 2004, the date the clinic opened for business, and December 12, 2005, the date on which Respondent had taken an annual inventory as required under Idaho law. The audit found substantial overages of multiple drugs including 1,807 dosage units of phendimetrazine 35 mg and 7,036 dosage units of diethylpropion 25 mg. Moreover, the audit found a shortage of 3,028 dosage units of phentermine 37.5 mg, and the Investigators could not complete their audit of phentermine 30 mg, because the clinic had dispensing records for only November and December 2005 and the staff stated it would take three weeks to create the necessary reports. In addition, the clinic was missing invoices for its purchases.

Here again, Respondent violated the CSA and DEA regulations by failing to maintain proper records.²⁵ *See* 21 U.S.C. 827(a)(3); 21 CFR 1304.21(a) & (d); 1304.22(c). Moreover, while the clinic’s inadequate recordkeeping was attributed to computer problems, as the DEA registrant, Respondent was responsible for ensuring that the records were being properly maintained.

In addition, while Respondent now assured the Investigator that he was the only person with a key to the controlled substance cabinet, the Investigator again found controlled substances in unlabelled prescription bottles. Under DEA regulations, “[e]ach commercial container of a controlled substance * * * shall have printed on the label the symbol designating the schedule in which such controlled substance is listed.”²⁶ 21 CFR 1302.03(a). Thus, Respondent was in violation of this requirement.

Finally, during the execution of the search warrant at Healthy Habits, F.C. found that notwithstanding his previous instruction to Respondent that he alone

should have the key to the controlled substance cabinet, as well as Respondent’s assurance to him during the January 11 inspection that he alone had the key, one of the clinic’s assistants had the key. This reinforces the conclusion that Respondent does not take seriously his responsibilities as a registrant.

Under factor four, the ALJ also considered the Government’s contention that Respondent prescribed anabolic steroids to his employer (Dr. Lundahl) for no legitimate medical purpose because he initially did so “without conducting the necessary physical examination and exhibited a lack of understanding as to when the prescribing of steroids is medically and legally appropriate.” Gov. Proposed Findings at 6. According to the testimony of the FDA S/A, when he questioned Respondent as to whether he had prescribed nandralone to Dr. Lundahl, Respondent denied doing so. Tr. 225. However, upon the S/A’s telling Respondent that either he or Lundahl were lying and that lying to a federal agent is a criminal offense, Respondent admitted to doing so. *Id.*

The FDA S/A testified that Respondent “wasn’t exactly sure what [nandralone] even was, but it was similar to” HGH. *Id.* The S/A further stated that it was his “impression” that [Respondent] had not done a “good faith medical exam that would justify the prescription of [n]a[n]dralone.” *Id.* at 226.

The ALJ, however, credited Respondent’s testimony that he prescribed the nandralone to treat a degenerative condition in Lundahl’s neck which was causing inflammation and pain and that he had both a document from Lundahl’s physician and an MRI to support the prescription. While Respondent’s denial to the FDA Agent raises a strong suspicion that the prescriptions lacked a legitimate medical purpose, the Government did not produce Lundahl’s medical record to show what documentation of Lundahl’s condition existed at any point of Respondent’s prescribing. 21 CFR 1306.04(a). As for the FDA Agent’s testimony that it was his “impression” that Respondent had not performed a physical exam, such equivocal testimony does not meet the substantial evidence test. Beyond this, the Government did not produce any evidence (such as either expert testimony or state medical practice standards) which, when coupled with the medical record, might have established that Respondent exceeded the bounds of professional practice in issuing the prescriptions. *United States*

²⁴ The Board’s rule further states that:

Medications that have been outside the custody and control of the hospital or facility for any reason are not eligible for return. To be considered as having been in the custody and control of the hospital or facility, the medications must have been delivered by the dispensing pharmacy directly to the hospital or facility or to an agent thereof who is authorized and qualified to accept delivery, and the medications must then be held by the hospital or facility in an area suitable for storing medications and not accessible to patients. Once a medication has passed from the hospital or facility storage area to the patient or to the patient’s designee for any reason, the medication is no longer eligible for return.

IDAPA 27.01.01(156)(05)(d).

²⁵ This conduct also violated Idaho Code § 37–2720. *See* GX 9, at 2. This statute provides that persons “registered to manufacture, distribute, or dispense controlled substances * * * shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and with any additional rules the board issues.” Idaho Code Ann. § 37–2720.

²⁶ Under a DEA regulation, “[t]he term *commercial container* means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user.” 21 CFR 1300.01(b)(6) (emphasis in original).

v. *Moore*, 423 U.S. 122, 142–43 (1975). I thus agree with the ALJ that the Government did not meet the burden of proof on this issue.²⁷

However, the numerous violations of both the CSA and state rules pertaining to recordkeeping, security, and re-dispensing of controlled substances, which are proved on this record are sufficient to satisfy the Government's *prima facie* burden of showing that Respondent's continued registration is "inconsistent with the public interest." 21 U.S.C. 823(f).

Sanction

Under Agency precedent, where the Government has made out *prima facie* case that a registrant has committed acts which render his "registration inconsistent with the public interest," he must "'present[] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'" *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)).

²⁷ The Government also argues that Respondent distributed HGH in violation of 21 U.S.C. § 333(e) for two reasons: (1) he prescribed HGH for anti-aging purposes, a use which has not been approved by the FDA, and (2) because the statute requires that the drug be distributed pursuant to "the order of a physician" and "he is not a licensed physician." Gov. Prop. Findings at 5.

In her decision, the ALJ concluded that "[t]he plain language of 21 U.S.C. § 333(e) states that distribution of [HGH] is illegal unless [done] pursuant to the order of a physician." ALJ at 44. Concluding that because "Respondent is not authorized to handle HGH," the ALJ declined to reach the issues of whether Respondent had prescribed HGH for unapproved uses or whether the actual product he dispensed had been approved by FDA.

In *Tony T. Bui*, 75 FR 49979, 49989 (2010), I explained that because DEA is not charged with administering the Food, Drug and Cosmetic Act, the Agency lacks authority to definitively interpret 21 U.S.C. § 333 and to declare the practice of prescribing HGH for anti-aging purposes to be a violation of Federal law. I conclude that this holding likewise bars the Agency from deciding whether Respondent violated the statute by prescribing the drug, because, even though he has authority under state law to prescribe HGH, he is not a physician. Indeed, the question of whether Congress intended to criminalize all prescribing of HGH by non-physicians, including those who can lawfully prescribe the drug under state law, is quintessentially one for judicial cognizance. Notably, while this question could have been resolved in the criminal proceeding, the U.S. Attorney dismissed the charges that Respondent violated 21 U.S.C. § 333.

Respondent's plea agreement does, however, establish that he violated the FDCA by causing the introduction of a misbranded drug into interstate commerce. While this violation of Federal law is a factor to be considered under factor five (such other conduct which may threaten public health and safety), by itself it is not dispositive. Rather, it is relevant only for the limited purpose of assessing the likelihood of Respondent's future compliance with the CSA. See *Wonderyears, Inc.*, 74 FR 457, 458 (2009).

"Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that [he] will not engage in future misconduct." *Medicine Shoppe-Jonesborough*, 73 FR 364 (2008).

The record here paints a mixed picture as to whether Respondent has rebutted the Government's *prima facie* case. In Respondent's favor, it is undisputed that he has complied with the Idaho Board's Order to develop protocols for maintaining proper security and recordkeeping of controlled substances. He also testified that he no longer uses a computer to track controlled substances and instead uses paper records. Moreover, he now orders controlled substances which have been pre-packaged and labeled. In addition, while I have declined to make findings as to whether Respondent's prescribing of HGH violated 21 U.S.C. § 333, it is undisputed that upon being told by the FDA Agent that his conduct was illegal, he stopped doing so.

Yet other evidence in the record raises a serious question as to whether Respondent can be trusted to responsibly discharge his obligations as a registrant. For example, Respondent failed to properly supervise the clinic staff to ensure that they were maintaining proper records. However, as the registrant, he is the person ultimately responsible for the numerous recordkeeping failures found during the audits of the various clinics including both missing, incomplete and irretrievable records, as well as the audit results which found substantial overages and shortages including one of more than 3,000 tablets. It is especially troubling that these conditions were found—at both the Healthy Habits and Malibu clinics no less—even after the Board Inspector had discussed with Respondent (during the first inspection at Healthy Habits) his responsibility for maintaining proper records and Respondent had signed a letter to the Inspector assuring that he "wish[ed] to completely comply with all laws and regulations" and that the clinic was "currently making the above * * * changes told to us." GX 2, at 15–16.

To similar effect, the evidence shows that even after Respondent was told that he, as the registrant, must maintain the key for the controlled substances cabinet and ensure that non-practitioner employees did not have access to the drugs when he was not on duty, in

several subsequent inspections, the Investigators found that other individuals had the key to the cabinet when he was not present. Moreover, during the search of Healthy Habits, the Investigators again found this to be the case even though Respondent had previously assured the Investigators that he was the only person with the key. Likewise, Respondent further claimed that he was unaware that the staff of the Malibu Clinic was re-dispensing controlled substances that had been returned by patients.

Were the evidence limited to the recordkeeping and security violations found at the first inspection, these acts would not necessarily warrant a lengthy sanction. However, the evidence is not so limited and manifests a disturbing pattern of indifference on the part of Respondent to his obligations as a registrant.

In her decision, the ALJ noted Respondent's testimony that "he was ill-informed of many of the record-keeping and security requirements." ALJ at 46. She further suggested that Respondent's having undergone the various audits and this hearing "have undoubtedly been educational." *Id.* However, the instruction provided at the various inspections by the Board's Inspector should also have "been educational," and yet, Respondent ignored it.

While Respondent acknowledged at the hearing that he was ultimately responsible for knowing the law and regulations applicable to controlled substances, he then maintained that if one did not "have any experience," the regulations did not provide "the answers" and that "they need to have a class to tell you * * * what's expected of you with this controlled substance license." Tr. 567–68. He also contended that the Board of Pharmacy was obligated "to inform nurse practitioners exactly of * * * what the conditions you're working in, and how to maintain records, [and] how to do what is correct." *Id.* at 569.

The language of the CSA and DEA regulations is sufficiently clear as to the scope of the recordkeeping obligations that any responsible registrant could find "the answers" if he bothered to read the statutes and regulations. Beyond that, having been personally informed (on two occasions no less) that he had to maintain custody of the controlled substance key and ensure that non-practitioners did not have access to the drugs when he was not on duty, Respondent cannot claim that the applicable rules are unclear. However, given that his conduct manifests that he is not a quick study, it probably would be beneficial for Respondent to take a

continuing medical education course on controlled substance recordkeeping and security.

I therefore conclude that Respondent's Meridian registration should be suspended for a period of six months and that his applications to renew the Meridian and Caldwell registrations should be held in abeyance during this period. Provided Respondent completes a continuing medical education course²⁸ which covers controlled substance recordkeeping and security (and commits no other acts which would warrant the denial of his applications), his renewal applications will be granted upon conclusion of this period and new registrations shall issue subject to the following conditions.

1. Respondent shall consent to unannounced inspections by DEA personnel and that such personnel shall not be required to obtain an administrative inspection warrant.

2. Respondent shall perform audits semi-annually for all controlled substances handled by any clinic at which he is the practitioner-in-charge and shall file reports with the local DEA field office within ten business days of having completed the audit. Such reports shall show, for each controlled substance, the beginning and ending inventory, the quantity of each controlled substance received (which shall be supported by a document listing by date each receipt and the quantity received) and the quantity disposed of (which shall be supported by a copy of the clinic's dispensing log and other records documenting the disposal of controlled substances). Respondent shall certify that each report is a true and accurate audit of the clinic's handling of controlled substances.

3. Respondent's failure to comply with either condition shall constitute an act which renders his registration inconsistent with the public interest.

4. These conditions shall remain in effect for three years following the issuance of a new registration and shall apply to any registration granted by the Agency.

In the event Respondent fails to complete a course in controlled substance recordkeeping and security, his registration will be revoked and both of his pending applications will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well

²⁸ Such course shall be accredited by a state medical board.

as 28 CFR 0.100(b), I hereby order that DEA Certificate of Registration, MB1294711, be, and it hereby is, suspended for a period of six months to begin on the effective date of this Order. I also order that Respondent's applications to renew DEA Certificates of Registration, MB1294711 and MB1090670, shall be held in abeyance pending the completion of the period of suspension. I further order that upon completion of the period of suspension and Respondent's presentation to the Agency of proof that he has completed a Continuing Medical Education course which covers the subjects of controlled substance recordkeeping and security, Respondent's applications to renew the above Certificates of Registration shall be granted subject to the conditions set forth above. Finally, I order that if Respondent fails to complete the aforesaid course, Certificate of Registration MB1294711 shall be revoked and his pending applications to renew his registrations shall be denied. *This Order* is effective August 24, 2011.

Dated: July 14, 2011.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Training and Related Assistance for Indian Country Jails

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections (NIC) Jails Division is seeking applications for the provision of training and related assistance for Indian Country jails, including those operated by tribes and by the Bureau of Indian Affairs (BIA). The project will be for a three-year period and will be carried out in conjunction with the NIC Jails Division. The awardee will work closely with NIC staff on all aspects of the project.

To be considered, the applicant team collectively must have, at a minimum, (1) In-depth knowledge of the purpose, functions, and operational complexities of jails, (2) experience in working with Indian Country jails, (3) in-depth knowledge of the key elements of jail administration, as taught in NIC's Jail Administration training program, (4) expertise and experience with jail

standards and inspections, (5) expertise and experience in conducting jail staffing analyses, and (6) experience in conducting training programs based on adult learning principles, specifically the Instructional Theory Into Practice (ITIP) model. The applicant team must include a curriculum specialist with expertise and experience in ITIP. The curriculum specialist will have a significant role in developing, reviewing, and revising the curriculum for the Jail Administration training program, as specified under "Scope of Work."

DATES: Applications must be received by 4 p.m. (EDT) on Friday, August 12, 2011.

ADDRESSES: Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street, NW., Room 5002, Washington, DC 20534. Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date as mail at NIC is sometimes delayed due to security screening.

Applicants who wish to hand-deliver their applications should bring them to 500 First Street, NW., Washington, DC 20534, and dial 202-307-3106, ext. 0, at the front desk for pickup.

Faxed or e-mailed applications will not be accepted. Electronic applications can be submitted only via <http://www.grants.gov>.

FOR FURTHER INFORMATION CONTACT: A copy of this announcement and Links to the required application forms can be downloaded from the NIC Web site at <http://www.nic.gov/cooperativeagreements>.

Questions about this project and the application procedures should be directed to Ginny Hutchinson, Jails Division Chief, National Institute of Corrections. Questions must be sent via e-mail to Ms. Hutchinson at vhutchinson@bop.gov. Ms. Hutchinson will respond via e-mail to the individual. Also, all questions and responses will be posted on NIC's Web site at <http://www.nic.gov> for public review. (The names of those submitting the questions will not be posted.) The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation.

SUPPLEMENTARY INFORMATION:

Background: The NIC Jails Division offers technical assistance, training, and information to jails nationwide, including Indian Country jails. NIC now wishes to target training and related services to Indian Country needs on jail administration, staffing analysis, and