authority, he "is not entitled to maintain his DEA registration." *Id.* at 3–4. The ALJ thus recommended that I revoke Respondent's registration and deny any pending renewal application. ALJ at 4.

Neither party filed exceptions to the ALJ's recommended decision. The ALJ then forwarded the record to me for final agency action. Having considered the entire record in this matter, I adopt the ALJ's recommended decision in its entirety and will revoke Respondent's registration and deny any pending applications. I make the following findings:

#### **Findings**

Respondent obtained his license to practice dentistry in the State of Pennsylvania on February 2, 1999. Gov't Mot., Ex. A. Respondent's authority to practice dentistry in Pennsylvania expired on March 31, 2009. *Id.* 

Respondent also holds DEA Certificate of Registration, BF6211762, which authorizes him to dispense controlled substances in schedules II through V as a practitioner at the registered address of 2A Old Clairton Road, Pittsburgh, Pa. Respondent's registration was last renewed on February 4, 2008, and does not expire until September 30, 2010.

#### Discussion

Under the Controlled Substances Act (CSA), a practitioner must be currently authorized to handle controlled substances in "the jurisdiction in which he practices" in order to maintain a DEA registration. See 21 U.S.C. 802(21) ("[t]he term 'practitioner' means a physician \* \* \* licensed, registered, or otherwise permitted, by \* \* \* the jurisdiction in which he practices \* to distribute, dispense, [or] administer \* \* \* a controlled substance in the course of professional practice"). See also id. section 823(f) ("The Attorney General shall register practitioners \* \* \* if the applicant is authorized to dispense \* \* \* controlled substances under the laws of the State in which he practices."). As these provisions make plain, possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration.

Accordingly, DEA has held repeatedly that the CSA requires the revocation of a registration issued to a practitioner whose state license has been suspended or revoked. David W. Wang, 72 FR 54297, 54298 (2007); Sheran Arden Yeates, 71 FR 39130, 39131 (2006); Dominick A. Ricci, 58 FR 51104, 51105 (1993); Bobby Watts, 53 FR 11919, 11920 (1988). See also 21 U.S.C. 824(a)(3) (authorizing the revocation of

a registration "upon a finding that the registrant \* \* \* has had his State license or registration suspended [or] revoked \* \* \* and is no longer authorized by State law to engage in the \* \* \* distribution [or] dispensing of controlled substances").

Moreover, the Agency has interpreted the CSA to require the revocation of a registration upon a practitioner's loss of state authority "not only where a registrant's authority has been suspended or revoked, but also where a practitioner \* \* \* has lost his state authority for reasons other than through formal disciplinary action of a State board." John B. Freitas, 74 FR 17524, 17525 (2009). Thus, even when a registrant ceases to possess authority to handle controlled substance in the State in which he practices through the expiration of a dental license or separate state controlled substances registration (when required), the Agency has revoked the practitioner's registration. Mark L. Beck, 64 FR 40899, 408900 (1999); Charles H. Ryan, 58 FR 14430 (1993).

Here, there is no dispute over the material fact that Respondent has allowed his Pennsylvania Dental License to expire and that he therefore lacks authority under Pennsylvania law to dispense control substances. Respondent is therefore not entitled to maintain his DEA registration, which will be revoked.

## Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, BF6211762, issued to James S. Ferguson, D.M.D., be, and it hereby is, revoked. I further order that any pending application of James S. Ferguson, D.M.D., to renew or modify his registration, be, and it hereby is denied. This Order is effective September 15, 2010.

Dated: July 30, 2010.

## Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–20192 Filed 8–13–10; 8:45 am]

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## **DEPARTMENT OF JUSTICE**

## **Drug Enforcement Administration**

[Docket No. 09-22]

## Robert F. Hunt, D.O. Revocation of Registration

On November 25, 2008, I, the Deputy Administrator of the Drug Enforcement

Administration (DEA), issued an Order to Show Cause and Immediate Suspension of Registration to Robert F. Hunt, D.O. (Respondent), of Fort Lauderdale, Florida. The Show Cause Order proposed the revocation of Respondent's Certificate of Registration, BH1292642, which authorizes him to dispense schedule II through V controlled substances as a practitioner, 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)." Order to Show Cause at 1. The Order immediately suspended Respondent's registration based on my conclusion that his continued registration during the pendency of the proceeding would "constitute[] an imminent danger to the public health and safety." Id. at 2 (citing 21 U.S.C. 824(d)).

More specifically, the Show Cause Order alleged that on April 10, 2008, Respondent "issued a prescription for an anabolic steroid, a Schedule III controlled substance," to a patient without referring "to the patient's medical file or conduct[ing] a medical examination of this patient." Id. at 1. The Order further alleged that Respondent "issued the prescription solely because [this] patient requested anabolic steroids," that he had "previously issued numerous prescriptions for controlled substances to this patient," and that "in some instances," he had "accepted illicit drugs as payment for these prescriptions." *Id.* at 1–2. The Order thus alleged that Respondent's conduct violated 21 U.S.C. 841(a)(1) and 844. Id.

Next, the Show Cause Order alleged that, on April 24, 2008, Respondent "issued two prescriptions for two brands of anabolic steroids to another patient," who was "a police detective acting in an undercover capacity," and who "presented no legitimate medical reason to justify the \* \* \* prescriptions." Id. at 2. The Order alleged that neither Respondent, nor his staff, "perform[ed] any medical tests or exams on this patient" and that Respondent "stated that [he] would list a fictitious ailment in [the patient's] medical record to justify [his] prescribing of anabolic steroids." Id. The Order alleged that "[t]hese prescriptions were not for a legitimate medical purpose in the usual course of professional practice" and that in issuing them, Respondent violated Florida Statute § 893.13(8)(a)(1), which "prohibits a prescribing practitioner from knowingly assisting a patient in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the

practice of the prescribing practitioner's professional practice," as well as 21 U.S.C. 841(a)(1). Id.

Additionally, the Show Cause Order alleged that at the same visit, Respondent also prescribed hydrocodone to this undercover detective again without "obtain[ing] a medical history, conduct[ing] a physical examination, or otherwise conduct[ing] an evaluation of the patient in violation of Florida Administrative Code §§ 64B15-14.005(3)(a) and (f)." Id. The Order further alleged that the hydrocodone prescription "was not for a legitimate medical purpose" and was not issued "in the usual course of professional practice," and thus violated both Federal law and Florida Statute § 458.33(1)(q) & (t). Id.

Finally, the Show Cause Order alleged that on July 24, 2008, the Broward County Sheriff's Office arrested Respondent on two felony counts of assisting persons in obtaining controlled substances through deceptive, untrue, or fraudulent representations, a violation of Florida Statute § 893.13-8(a)(1), and one felony count of trafficking by issuing prescriptions in excessive quantities, a violation of Florida Statute § 893.13(8)(d). Id. The Order further alleged that Respondent is "currently on pre-trial release." Id.

By letter of December 15, 2008, Respondent, through his counsel, requested a hearing on the allegations. ALJ Ex. 3. The matter was placed on the docket of the Agency's Administrative Law Judges (ALJ) and set for a hearing on January 6, 2009. Id. Thereafter, Respondent's counsel sought and was granted several continuances; 1 the hearing was finally held on April 28 and 29, 2009, in Fort Lauderdale, Florida. ALJ Exs. 4-6; ALJ at 4.

At the hearing, both parties called witnesses to testify and introduced documentary evidence. Thereafter, both parties filed proposed findings of facts, conclusions of law, and argument.

On July 2, 2009, the ALJ issued her Recommended Decision (also ALJ). Therein, the ALJ, upon analyzing the public interest factors, see 21 U.S.C. 823(f), concluded that the "continuation of [Respondent's] registration would not be in the public interest," and "that the preponderance of the evidence \*

favors revocation." ALJ at 33.
With respect to the first factor—the recommendation of the appropriate state licensing board—the ALI found that the record contained "no information of any action being taken by the Florida Medical Board \* \* \* against the Respondent's medical license" or "any recommendation from the [Florida Medical] Board regarding the outcome of this proceeding." *Id.* at 27. Likewise, with respect to the third factor— Respondent's record of convictions for offenses related to controlled substances—the ALJ found that the "record contains no evidence that the Respondent has a conviction record related to his handling of controlled substances." Id. at 30.

As to the second and fourth factors-Respondent's experience in dispensing controlled substances and his compliance with applicable laws—the ALJ made several findings. First, she found that Respondent "prescribed controlled substances to the undercover detective (UC)] to assist in pain management for his joint pain," but that his "[medical] records fail to identify this diagnosis, and do not include the amount, strength, and number of refills of the controlled substances he prescribed," in violation of Florida Statute § 458.331(1)(m).2 Id. at 27.

Next, the ALJ found that Respondent's "medical record for [the UC] fails to have any of [the] elements," such as "[a] complete medical history and physical examination \* \* \* [and documentation of the nature and intensity of the pain," as required by Florida Administrative Code r. 64B15-14.005(3)(a). Id. at 27-28. The ALJ reasoned that even if this provision, which is part of Florida Board of Osteopathic Medicine's [hereinafter, the Board] guidelines for the treatment of pain with controlled substances, does "not have the force of law in Florida, the fact that the

Respondent's medical record for [the UC fails to have any of these elements to justify the prescribing of controlled substances for pain supports a finding that \* \* \* Respondent is not handling controlled substance prescriptions and records in a responsible manner." Id. at 28. The ALJ also noted that the transcript of the UC's "April 24, 2008 visit does not contain any conversation between \* \* \* Respondent and [the UC] that would support a finding that [he] attempted to ascertain the 'nature and intensity of the pain,' or any other factor listed in Section 64B15-14.005(3)(a), in order to justify the prescribing of 100 dosage units of . Vicodin with three refills." *Id.* 

The ALJ further found that "Respondent recorded a history of osteoporosis in [the UC's] medical record, while simultaneously stating that it was not true," and that "[t]his chart notation was used to justify issuing prescriptions for two anabolic steroids to" the UC. Id. Based on this finding, the ALJ concluded that Respondent violated Florida Statute § 893.13(8)(a)(1), which prohibits "a prescribing practitioner" from "knowingly assist[ing] a patient \* \* \* in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice." Id.

Having found that "Respondent's asserted belief that [the UC] had HIV and osteoporosis is not credible, and his purported diagnoses false," the ALJ further concluded that Respondent "knew or should have known that [the UC] was seeing him to obtain anabolic steroids for the purpose of body building," and thus, in issuing the steroid prescriptions to the UC, he also violated the prescription requirement of 21 CFR 1306.04(a). Id. (citing Edmund Chein, M.D., 72 FR 6580, 6590 (2007) ("prescribing anabolic steroids for body building or strength enhancement under a false diagnosis is not [prescribing] for a legitimate medical purpose")).

The ALJ further found that Respondent "prescribed Subutex" (buprenorphine), "a Schedule III controlled substance \* \* \* approved by the FDA for use by authorized practitioners for detoxification or maintenance treatment," 3 to a patient "on multiple occasions to treat him for the effects of the other controlled substances [the patient] was consuming." Id. at 28–29. Because Respondent did not hold a separate registration to prescribe "this drug for narcotic abuse treatment" as required by

<sup>&</sup>lt;sup>1</sup> In his letter which requested a hearing, Respondent's counsel also requested a continuance from the scheduled date of the hearing of January 6, 2009. ALJ Ex. 3, at 1. The hearing was then rescheduled for February 23, 2009. See ALJ Ex. 4, at 2. On January 28, 2009, Respondent's counsel requested a second continuance on the grounds that he sought the actual recordings of the transcribed undercover visits at issue, that he sought to depose the confidential informant, and that he was "interviewing prospective expert witnesses to testify on the doctor's behalf." Id. at 1–2. In ruling on the second request for continuance, the ALJ noted that "Respondent argued that any prejudice stemming from an additional continuance is suffered only by the Respondent." ALJ Ex. 6, at 2. The ALJ therein canceled the February 23, 2009 hearing. Id. at 3. In her Prehearing Ruling of February 27, 2009, the ALJ rescheduled the hearing for April 28 and 29, 2009. ALJ Ex. 7, at 4; see also ALJ Ex. 8 (Notice of Hearing; Instructions (April 8, 2009)).

 $<sup>^{2}</sup>$  This statute provides for disciplinary action against a medical doctor for "[f]ailing to keep legible

\* \* medical records that \* \* \* justify the course of the treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations." Fla. Stat. § 458.331(1)(m). However, as discussed below, Respondent is a doctor of osteopathy; his license is subject to the provisions of Florida Statutes Chapter 459, which provide grounds for disciplinary action against an osteopath's license in Fla. Stat. § 459.015.

<sup>3</sup> See 21 CFR 1308.13(c)(2)(i).

21 U.S.C. 823(g), and "was admittedly not authorized by the DEA to prescribe this substance for this purpose," the ALJ concluded that Respondent "clearly violated the Controlled Substances Act." *Id.* at 29. Ultimately, the ALJ concluded that under these two factors, "the preponderance of the evidence weighs against allowing Respondent to maintain his DEA registration." *Id.* at 29–30.

As to the final factor—such other conduct which may threaten the public health and safety—the ALJ explained that "[t]he gravamen of this case is the Respondent's lack of candor, in both his recordkeeping and in his testimony before this tribunal, as well as his apparent lack of appreciation for the serious responsibilities of a DEA registrant." Id. at 30. Noting that "Respondent falsely entered 'osteoporosis' as a diagnosis in [the UC's] medical record," and "then testified under oath that he genuinely believed his diagnosis to be true," the ALJ found—based on the transcript of the April 24 undercover visit—that "this testimony lacked credibility." Id. The ALJ thus concluded that this "lack of candor further supports [the] conclusion that revocation of Respondent's registration is appropriate." Id.

The ALJ further noted that Respondent had "issued the prescriptions for anabolic steroids notwithstanding the fact that he had no test results to support his purported diagnosis of osteoporosis, and despite his admission that such test results would determine whether or not his basis for issuing the prescriptions was valid." Id. at 31. The ALJ thus concluded that "Respondent's attitude toward prescribing controlled substances under these circumstances \* \* was so cavalier as to create a substantial risk of diversion" and that "Respondent's conduct therefore falls below the level of responsibility expected of a DEA registrant." Id. Thus, under the fifth factor, the ALJ found that "the preponderance of the evidence \* \* \* supports a conclusion that continuation of [Respondent's] DEA registration would not be in the public

interest." Id.

Having concluded that the
Government had made out a prima facie
case for revocation, the ALJ turned to
whether Respondent had "accept[ed]
responsibility for his misconduct" and
demonstrated that his misconduct
would not recur. Id. at 32. The ALJ
noted that Respondent had refused the
UC's request for a prescription for HGH
and had declined the UC's request to
refer other persons, stating that he
would not "usually" prescribe to men

who were seeking anabolic steroids for body building. *Id.* However, the ALJ also found that "[i]nstead of admitting his mistake in prescribing steroids for [the UC] and presenting evidence to reassure [the Agency] that he would cease this practice, \* \* \* Respondent chose to build upon the falsifications." *Id.* at 33. Concluding that Respondent had failed "to take responsibility for his past misconduct, and [had] fail[ed] to provide assurances regarding his future conduct," the ALJ concluded that Respondent's registration should be revoked. *Id.* 

Neither party timely filed exceptions to the ALJ's decision, which were due no later than July 27, 2009. On July 30, 2009, the ALJ forwarded the record to me for final agency action. Thereafter, on September 3, 2009, Respondent filed exceptions. However, because Respondent's exceptions were filed out-of-time, I have not considered them.

However, I have considered the rest of the record in its entirety including Respondent's brief containing his proposed findings of fact and conclusions of law. Having done so, I adopt the ALJ's findings of fact and conclusions of law except as specifically noted herein. I further adopt both her ultimate conclusion that Respondent's continued registration is inconsistent with the public interest and her recommendation that Respondent's registration be revoked. I make the following findings.

#### **Findings of Fact**

Respondent is a doctor of osteopathic medicine, and is board-certified in family practice. Tr. 408–09. At the time of the hearing, Respondent had practiced as a general practitioner in Broward County, Florida for approximately 21½; years. <sup>4</sup> Tr. 408–09.

Respondent is also the holder of DEA Certificate of Registration, BH1292642, which authorizes him to dispense controlled substances as a practitioner in schedules II through V. GX 1. According to the certificate, Respondent's registration was to expire on October 31, 2008. *Id.* However, on September 18, 2008, Respondent filed a

renewal application. GX 2. In accordance with the Administrative Procedure Act and DEA regulations, I find that Respondent's registration remains in effect (albeit in suspended status) pending the issuance of the Final Order in this matter. See 5 U.S.C. 558(c); 21 CFR 1301.36(i).

In February of either 2006 or 2007, one of Respondent's patients was arrested by an officer with the Hollywood, Florida police department and charged with the state law offense of trafficking in hydrocodone. Tr. 123. At the time of his arrest, the patient had in his possession 150 tablets of a controlled substance containing hydrocodone, which he had obtained through a prescription issued by Respondent.<sup>5</sup> Id. at 23, 25, 75. In either December 2007 or January 2008, the patient, who was facing a lengthy prison sentence, accepted a plea bargain under which he entered into a "substantial assistance agreement" with the Broward County, Florida Sheriff's Office and became a confidential informant (CI). Id. 23, 27, 87, 364.

Thereafter, the CI told the authorities that Respondent had prescribed hydrocodone,<sup>6</sup> testosterone,<sup>7</sup> Deca-Durabolin,8 and Xanax 9 for him. Id. at 27. While the CI testified that Respondent had legitimately treated him for anxiety and had referred him to several specialists for heart and joint issues, Respondent also gave him prescriptions for anabolic steroids. Id. at 28-29. According to the CI, he initially obtained the steroid prescriptions "just because I asked him for them," id. at 29, and did so at either the second or third visit after his initial visit. Id. at 31. However, "after awhile [the CI's] body was [not] producing enough testosterone" and "it became medically necessary to have some testosterone." Id.

<sup>&</sup>lt;sup>4</sup>Respondent has been "involved with" two organizations, Community Healthcare Center One and Broward House, which are community resource centers for patients with HIV in Broward County. *Id.f* at 413, 417–18. At the Children's Medical Services Program, he helped create Broward County's clinic for infectious diseases for the pediatric HIV population; at the Children's Diagnostic and Treatment Center, he has volunteered one afternoon a week seeing HIV patients and waiving payment. *Id.* at 421. He has also been "involved with" the Gay and Lesbian Community Center, where he has given free lectures on topics "related to living with HIV." *Id.* at 416.

<sup>&</sup>lt;sup>5</sup> The patient had been treated by Respondent since at least January 2002, GX 7A, at 70; and initially saw Respondent for anxiety and a heart palpitations and explained that he was concerned that his heart problems were caused by his prior use of steroids. Tr. 31. The CI maintained that Respondent had told him that "if I wanted to do it the right way under [a] doctor's care[,] to come see him. *Id.* 

<sup>&</sup>lt;sup>6</sup> Hydrocodone in combination with another active pharmaceutical ingredient is a Schedule III narcotic controlled substance. 21 CFR 1308.13(e)(iv). Stipulated Facts, ALJ at 5.

<sup>&</sup>lt;sup>7</sup> Androgen 1% is an injectable brand of testosterone, an anabolic steroid, a Schedule III controlled substance. 21 CFR 1300.01(b)(4)(lvii), 21 CFR 1308.13(f); Stipulated Facts, ALJ at 5. Delatestryl is a brand of testosterone, and Testim 1% is a brand of testosterone gel. ALJ at 5.

<sup>&</sup>lt;sup>8</sup> A brand of nandrolone decanoate, an anabolic steroid. Tr. 170; 21 CFR 1300.01(b)(4)(xl); 21 CFR 1308.13(f).

<sup>&</sup>lt;sup>9</sup> Xanax, or alprazolam, which is a Schedule IV depressant controlled substance. 21 CFR 1308.14(c)(1); Stipulated Facts, ALJ at 5.

at 29. According to the CI, when he asked for the steroid prescriptions, Respondent did not hesitate to prescribe them. *Id.* at 30.

According to the CI, Respondent prescribed the anabolic steroids "off and on," and the CI made the decision as to when to cycle on, and off of, the drugs. Id. at 32, 34. The CI also testified that Respondent wrote him a prescription for Human Growth Hormone (HGH) because he asked for it, id. at 35, as well as prescriptions for Percocet 10 for his knees; Respondent subsequently referred the CI to an orthopedist who diagnosed him as having "a slight torn meniscus." Id. at 34-35. Finally, the record also establishes that Respondent wrote the CI at least twenty-six prescriptions for Subutex (buprenorphine), a schedule III controlled substance, as well as prescriptions for both Testim and Androgel, which are gel forms of testosterone and also a schedule III controlled substance. See GX 7C, at 1-3, 5-6, 9-10, 14-15, 18-19, 22-23, 30-32, 37, 61–62, 64, 66, 71, 78, 83–84, 87– 90, 95–96, 105–06 (Subutex Rxs); id. at 2, 24, 31, 33, 62, 67, 81, 82 (Testim and Androgel Rxs).

The CI's medical record (GXs 7A & 7D) contains various documents including blood tests, radiology reports, as well as evaluations by specialists including an orthopedist, cardiologist, and endocrinologist. See GX 7A, at 60 (orthopedist's report); 65-69 (cardiologist's report); GX 7D, at 13-14 (endocrinologist's report). The medical record contains ample evidence (including blood tests and endocrinologist's report) establishing that the CI had low testosterone levels and had been diagnosed with hypogonadism, which was caused by the presence of a small tumor (adenoma) on his pituitary gland. Id. at 444-455; GX 7A, at 9, 13-14; GX 7D, at 1, 3-4, 7-12, 16-18, 21, 25, 39-41, 43-49, 54-57; GX 7D, at 13-14. In its brief, the Government does not challenge the medical appropriateness of any of the controlled substance prescriptions Respondent wrote for the CI with the exception of an April 10, 2008 prescription for Testim, and his prescribing of Subutex. See Gov. Br. at 8-9; 31-35.

As for the Subutex prescriptions, Respondent testified that after the CI told him that he had also been going to a pain clinic (run by a Dr. Weed) to obtain additional quantities of narcotics

and "had actually been taking much higher quantities of narcotics that I had suspected [and] had been doing this for quite some time," he recommended that the CI "see a psychiatrist who specializes in detox patients." Tr. 486. While Respondent was "not sure" as to whether the CI went to this doctor "or another detox specialist," the CI went back to Respondent, showed him the Subutex prescription and apparently other documents showing that he had seen the detox specialist "a couple of times." Tr. 486, 488. The CI told Respondent said that the Subutex "was working well for him," but complained that the detox specialist charged "\$250 or \$275 a visit, insisted on seeing [the CI] every month, and would not accept his" insurance. Id. at 488. Respondent then agreed to write Subutex prescriptions for the CI. Id. As found above, the CI's patient file indicates that between November 16, 2004, and April 10, 2008, Respondent authorized at least twenty six prescriptions for Subutex. See generally GX 7C, at 1-3, 5-6, 9-10, 14–15, 18–19, 22–23, 30–33, 37, 61–62, 64, 66, 71, 78, 83-84, 87-90, 95-96, 105-06; GX 7D, at 19 & 33.

In his testimony, Respondent maintained that he was unaware until "only recently" that there was a special course that he had to take to prescribe Subutex, that he did know exactly when this requirement "went into effect," and that he was unsure as to whether the course was required at the time he wrote the CI's prescriptions. *Id.* at 488–89. He also maintained that no pharmacist had told him that he needed a special registration to prescribe Subutex for detoxification. *Id.* at 488–89.

The ALJ observed that "the Government presented no expert medical testimony to suggest that the Respondent's treatment of [the CI] was inappropriate." ALJ at 9. She therefore "decline[d] to make any specific findings concerning the legitimacy of Respondent's treatment decisions in [the CI's] case." *Id.* at 9 n. 5. As noted above, the ALJ did, however, find that Respondent violated Federal law by prescribing Subutex to the CI. ALJ at 28–29

Pursuant to his substantial assistance agreement, the CI agreed to introduce a Detective from the Broward County Sheriff's Office to Respondent. Tr. 39. Accordingly, the CI phoned Respondent and left a message in the latter's personal voicemail indicating that he would be dropping by Respondent's office and bringing a friend that he wanted to refer to him. *Id.* at 38, 39, 40. The CI testified that he did not make any further phone calls to Respondent. *Id.* at 40. Furthermore, according to the

Detective, the CI was required to report any contact he had with Respondent, and the Detective stated that he believed the CI would have reported any such contact. Tr. 374. Moreover, had the CI otherwise contacted Respondent and not reported it, the CI would have violated the substantial assistance agreement. *Id.* at 371.

In his testimony, Respondent asserted that either "a few days," or "a few weeks" before April 10, 2008, Respondent and the CI talked on the phone for some five to ten minutes regarding the friend's alleged medical issues. *Id.* at 493–94, 531. However, on cross-examination, Respondent testified that the call could have taken place on April 10, 2008. Tr. 530. Respondent's recollection was that the conversation occurred when he answered the CI's phone call. *Id.* at 531.

Respondent maintained that during this conversation, the CI told him that his friend experienced problems with fatigue and that he had a "history of \* \* \* joint pain, shoulder problems with surgery, fractures in his back, etc., and that he was, his workout partner \* \* \* and that he felt he would benefit from the same testosterone therapy and the steroids that he was taking." *Id.* at 404

In his testimony, Respondent claimed that he told the CI that there was a "difference" between him and his friend because "You [the CI] have a medical reason \* \* \* to be on testosterone replacement therapy [and] I can't just prescribe this for a patient who wants it." Id. at 494–95. According to Respondent, the CI "continued to badger me," and asked: "Well, couldn't we put down something else as a diagnosis?" Id. Respondent maintained that he answered: "No, that's not the way this works. This is a controlled substance and I need to document why it's being used." Id.

Respondent asserted that the CI then told him that his friend was HIV positive, that he "had a serious problem maintaining [his] weight [and] with fatigue and weakness," and that he was in paramedic training and needed to "beef up" to complete it. *Id.* Respondent testified that he thought it "was admirable" that the CI's friend had decided not to go on disability and collect Medicaid or work under the table. *Id.* at 495–96. On crossexamination, however, Respondent acknowledged that the CI had not said when his friend was diagnosed with HIV or by whom. Id. at 532. Nor did he discuss what treatment the CI's friend was receiving for HIV. Id. at 533.

According to Respondent, he "felt a little bit of compassion" on hearing that

<sup>&</sup>lt;sup>10</sup> Percocet is a combination oxycodone product. Oxycodone is a Schedule II narcotic controlled substance. 21 CFR 1308.12(b)(1)(xiii); Stipulated Facts, ALJ at 5.

the CI's friend "was HIV positive," but he "reiterated" that "[a]nabolic steroids are out of the question unless there is a medical reason." *Id.* at 496. Respondent further claimed that the CI told him that his friend was "really touchy about" his being HIV positive and did not want anyone to know because they would think that he was either gay or an "IV drug addict." *Id.* Respondent next asserted that the CI had said that he [Respondent] could not tell his friend that the CI had told him about the friend's HIV positive status. *Id.* 

Respondent then testified that he asked the CI to "tell [him] more about these fractures [the friend] had" and that the CI related that his friend had fractured his shoulder and two vertebrae. Id. at 497. Respondent maintained that based on this information he concluded that the CI's friend "may have some bone loss" and "some osteoporosis." Id. Respondent then asserted that he told the CI that if he could "establish that as a diagnosis, then I can at least justify giving him a prescription and then when he comes back to see me for [a] follow up[,] I will try to get him to admit that he knows that he's HIV positive and proceed with the appropriate testing." Id. Finally, Respondent asserted that he discussed with the CI that the latter's friend did not have insurance and that there would be "cost issues" as to whether he "could do all the testing on him like the bone density study to show that he had osteoporosis." Id.

The ALJ found it unnecessary to make a specific finding as to whether the phone conversation—as testified to by Respondent—took place. ALJ at 12 n.12. However, as ultimate factfinder, I reject Respondent's testimony pertaining to the conversation in its entirety. See 5 U.S.C. 557(b); Reckitt & Colman, Ltd., v. DEA, 788 F.2d 22, 26 (DC Cir. 1986). I do so for the following reasons: (1) I accept the CI's testimony that the only call he made involved his leaving a voice mail message noting that the Detectives testified that the CI made only one call and that if the CI had made another a call and had not notified the Detectives, he would have violated the assistance agreement and could have received substantial prison time; (2) in his testimony, Respondent gave three possible dates (or ranges of) for when the conversation took place including a few weeks before, a few days before, or on the day that the visit actually occurred; (3) other evidence in the case (which is discussed below) showed that Respondent falsified medical records, thus casting serious doubt on his truthfulness as a witness; (4) much of Respondent's testimony regarding the

phone call is patently self-serving and implausible; <sup>11</sup> and (5) during the Detective's two visits, Respondent never questioned the Detective (despite his elaborate story regarding his reason for diagnosing the Detective as having osteoporosis) about the purported fractures of the Detective's shoulder and two back vertebrae. <sup>12</sup> See ALJ at 31; see also GXs 9 & 10.

On April 10, 2008, the CI and the Detective, who used the name "Bill Rix," [hereinafter, either "Rix" or "UC"] went to Respondent's office; the UC wore a wire, and the entire visit was taperecorded and transcribed. *Id.* at 132; *see* GX 9. The CI introduced Bill Rix to Respondent, and indicated that Rix was looking for a doctor. Tr. 39, 125.

At the visit, the CI complained of a swollen gland, GX 9, at 2. Respondent examined his neck and wrote him a prescription for an antibiotic, Augmentin. Id. at 2-3; GX 5, at 1. The CI then asked whether Respondent had "any more samples \* \* \* of Andro Gel." GX 9, at 4. Respondent asked the CI "[w]hich one" he took? The CI responded: "Testim." Id. at 4. Respondent then gave the CI a coupon for a debit card that gave a \$40 discount off of each monthly co-pay for the drug for a year, *id.* at 4–5, and wrote him a prescription for Testim 1%, a brand of testosterone gel, which is an anabolic steroid and schedule III controlled substance. GX 5, at 2; Stipulated Facts, ALJ at 5. Respondent did not document the April 10, 2008 visit in the CI's medical record.<sup>13</sup> Tr. 181–82; GX 7A–D.

At the April 10 visit, the UC (after indicating that he did not have insurance) stated that he had "had shoulder surgery," that his joints were "shot," that "everything" hurt, that he was "just losing strength and \* \* \* getting older," and that he wanted to 'get the physical done \* \* \* and just see what [his] body's doing." GX 9, at 9-10. When Respondent mentioned getting blood tests done, the UC indicated that he did not want blood work done, asked if it "that [was] necessary," and stated that he was "just worried about [his] joints." Id. at 10. Respondent then asked the UC if he

thought "anything is bad like you're going to need x-rays or an MRI scan or anything like that?" *Id.* The UC answered "no," and that he did not "think so." *Id.* 

In his testimony regarding the April 10 visit, Respondent alleged that he made his diagnosis in part that day because Bill Rix had "a slight figure" and "ha[d] very deep lines on either side of his face. That to me is a sign of lipodystrophy \* \* \* when he smiled and I saw these deep indentations in either side of his face, it just corroborated for me that this guy \* \* \* not only is \* \* \* definitely HIV positive but that he's had some problems with muscle wasting and fat loss and muscle loss." 14 Tr. 499, 571.

Regarding the April 10 visit, Respondent also testified that the fatigue and joint pain of which the UC complained would be consistent with osteoporosis. Tr. 510; RX 13. While Respondent testified that in normally evaluating a patient's complaint of fatigue he would conduct blood tests to check a patient's testosterone level, Tr. 510, at neither of the UC's visits did Respondent require the UC to undergo a blood test. See GXs 9 & 10. According to Respondent, this was because the UC had indicated he did not want them. Tr. 510.

At the April 24th visit, the UC first completed several forms for the patient file, including one in which he provided his "Patient Information," one for his "Adult Health History," and one in which he provided his consent "to undergo all necessary tests \* \* \* and any other procedure required in the course of study, diagnosis, and treatment of" his condition. GX 8, at 6-7, 9–11, 13–14; GX 10, at 1; Tr. 184–188. On the "Patient Information" form, the UC indicated that he was "selfemployed" and not that he was training to become a paramedic. GX 8, at 6. On the medical history form, the UC indicated that he was sexually active with more than one female partner, that he drank four to five times per week, and that he smoked marijuana "socially." GX 8, at 11. He also indicated that the purpose of his visit was "Fatigue/Muscle Loss," and that he had undergone shoulder surgery in "02." Id. at 10. The UC did not, however, indicate that he had a history of any other

<sup>&</sup>lt;sup>11</sup> See, e.g., Tr. 495 ("I can't just prescribe this [testosterone] for a patient who wants it."); ("This is a controlled substance and I need to document why it's being used.")

<sup>&</sup>lt;sup>12</sup> At the second visit, Respondent, after looking at charts filled out by the Detective, asked: "what was the shoulder, rotator cuff?" GX 10, at 8. He then asked the Detective: "Any other problems other than the shoulder?" *Id.* at 10. Notably, he did not ask the Detective any questions about the purported fractures.

<sup>&</sup>lt;sup>13</sup> On July 24, 2008, the Broward County Sheriff's Office executed a search warrant at Respondent's office and seized the medical records. Tr. 321–22.

<sup>&</sup>lt;sup>14</sup> The ALJ found credible Respondent's testimony that lipodystrophy is a sign of HIV status. ALJ at 16. However, the record contains no evidence establishing whether the UC actually has deep lines on his face. Moreover, according to the UC's patient file, on April 24, 2008, the UC was measured as being 5 feet, 10 inches tall and weighing 182 pounds. The UC's height and weight do not appear consistent with that of a person who has a slight build.

conditions such as the purported fractures of his shoulder or vertebrae. Id.

On cross-examination, Respondent testified that he does not usually read the "demographic" portion of the forms his patients complete (where the UC had indicated that he was selfemployed), and that he reads only the medical history. Tr. 560. Respondent further maintained that he was "operating on the assumption that this man w[i]ll be trying to use my medical records to reflect a normal physical within reason so that he could get a job as a paramedic," notwithstanding that at no time during the visit did the UC indicate that he was in training for a paramedic position. *Id.* at 559, 564–65. He also maintained that he believed that Bill Rix had been infected with HIV since 2002. Id. at 561-62.

Upon entering the exam room, Respondent recognized the UC and asked him if he had been with the CI "the other week, right?" GX 10, at 8. After the UC answered affirmatively, Respondent asked him: "What was the shoulder, rotator cuff?" *Id.* The UC mentioned "Mumford," an apparent reference to a surgical procedure, but then stated that he had no problems other than aging, losing strength, and

aching joints. Id. at 9-10.

The UC then complained that things were different when he could get Winstrol and Testosterone Enthanate, which are both anabolic steroids, through Powermedica, a pharmacy which arranged for persons to get prescriptions which were written by doctors who never saw the persons for whom they prescribed. 15 Id. The UC also related that he had gone to Powermedica "one day to pick up my order and there were cops everywhere."

After discussing the side effects of HGH, the UC told Respondent that he had used Deca Durabolin "back in college" when he "played college baseball." Id. at 12. Respondent stated it was "too bad they stopped making" Deca. Id. When the UC expressed surprise at this, Respondent indicated that "we can still get [Deca] at Comcare Pharmacy[.] [T]hey're compounding their own." Id.

After discussing some of the side effects of using anabolic steroids and how these substances are metabolized, Respondent noted that Deca provided

"more bang for your buck" than other steroids. Id. at 12-14. Respondent advised the UC that while there was an "association" between Deca and necrosis of the hip, he "would have no problem prescribing it for anybody" and that necrosis was caused by using too much. *Id.* at 14.

Respondent then advised the CI that Deca was the "safest one as far as your liver is concerned," and "you get good results with it especially when you combine it with testosterone," but that "you just have to combine it with testosterone cause if you just start using the Deca[,] [its] chemical structure is very similar to testosterone so your body sees it as testosterone." Id. "So if you start injecting all that extra Deca[,] your own testosterone production is going to drop." Id. at 15. Respondent then told the CI that "you really have to combine the two together," (Deca and testosterone) and "that's not a problem cause" "injectable testosterone is cheap and they're both oil base[d] so you can put it in the same syringe and you're done." Id. Respondent did advise the UC that he would need to get a liver function test "every two to three months" that he took the steroids. Id.

The CI then told Respondent that "all I'm concerned with" is "I need to get strong again." Id. at 16. Respondent then asked the CI: "What was the blood work that you last had done or anything?" Id. The CI answered: "it was about two years ago." Id. Upon being asked by Respondent if he ever "had any liver enzyme problems?," the CI answered "No," and added that "actually," his "testosterone levels [were] high." Id.

After discussing the relative effects of testosterone (which would improve his strength) and Deca (which would give him more size), Respondent declared: "Just to cover my ass I'm going to put down you got a history of osteoporosis." Id. at 17. Respondent then explained that "[i]t's just brittle bones, it's common actually \* \* \* in women after menopause but men do get it who have low testosterone levels." Id. The UC then asked Respondent: "Do you want me to say my Mom or Dad had it?" Id. Respondent answered "No," and the UC stated: "Okay." Id.

Respondent then stated: "Just so that you know when I write osteoporosis it has nothing to do with you[,] it just has to do if the State ever comes in to monitor my charts that I have a reason for prescribing you testosterone and Deca." 16 Id. at 18. After discussing

osteoporosis, Respondent advised the UC that "at some point down the road you should get your liver enzymes checked[,] not now because you know you haven't been on anything." Id. Respondent then advised the UC how often he should get his liver enzymes tested, how to cycle on and off of the testosterone, and how to come off of it without losing his strength gains. Id. at 19-20. Respondent added: "we're looking to get you to the upper limits of normal[,] not Lyle Alzado[']s brain tumor." Id. at 21.

Respondent and the UC next discussed what drug he could take for joint pain. Id. at 21-23. Respondent recommended several drugs including anti-inflammatories such as Ibuprofen and Naproxen, narcotics such as Vicodin or Percocet, and Celebrex (if he had a sensitive stomach, but which cost \$240 for thirty pills). Id. at 24. The UC then noted that a Vicodin prescription cost only \$13 dollars at a local pharmacy while "everyone [is] talking about how much OxyContin is." Id.

Respondent then apparently wrote out various prescriptions as the UC asked if there was "[a]ny particular place you want me to give these to?" Id. at 25. Respondent recommended Comcare, the same pharmacy he had referred to earlier as compounding Deca Durabolin, and indicated that they had three offices. Id. at 25-26. Respondent further noted that "most of the pharmacists" at Comcare knew him, and added: "they're nice guys so you won't have a problem." Id. at 27.17

Later, the UC asked whether he could refer "a couple close friends." Id. at 34. Respondent initially responded that he

the UC to trust him so that he would admit that he had HIV. Tr. 515. The ALJ did not find Respondent's story persuasive. See ALJ at 17. Nor do I given that the comment was not some offhand remark but a prelude to Respondent's further explanation that he was going to write down the osteoporosis diagnosis in the UC's chart so that if "the State ever comes in to monitor my charts \* I have a reason for prescribing you testosterone and Deca." GX 10, at 18. Moreover, while the comment may have been flippant and stupid, in that it was made to an undercover officer who was wearing a wire, it is nonetheless probative of Respondent's intent.

 $^{17}$  Following a discussion of the counterfeiting of prescription drugs and the implementation of a drug tracking system to protect consumers, Respondent started discussing the ordering of drugs from Canada. GX 10, at 32. Respondent stated that he did not "know how that works," and "that's why I ask whoever comes [in] how did you get the stuff you're getting before without a prescription." Id. Respondent then noted that a patient "had a doctor who was pulling a little scam." *Id.* at 33. After the UC interjected: "Oh, I don't know where it's coming from," Respondent stated: "He [the doctor] was treating you and giving it to you without ever actually meeting you or examining you." Id. Respondent then added: "Which is not really appropriate[.] I'm sure he lost his license in the process." Id.

<sup>&</sup>lt;sup>15</sup> On June 20, 2005, the Florida Department of Health ordered the emergency suspension of Powermedica's state pharmacy permit following a joint investigation by the Food and Drug Administration and the Broward County Sheriff's Office. Powermedica eventually surrendered its state permit and DEA registration. See Wonderyears, Inc., 74 FR 457458 (2008).

<sup>&</sup>lt;sup>16</sup> In his testimony, Respondent asserted that his comment that he was "using this diagnosis [of osteoporosis] to cover my ass" was just a flippant and stupid comment which he made to try to get

didn't "normally" take on such persons, and while he would "do this" for the CI, "this is not my thing." *Id.* Respondent stated that he knew "a lot about steroids cause [he] did them in college" and had "learned the hard way how to do them." Id. at 34–35. Respondent then added that the CI "has a deficiency where he doesn't make enough \* \* \* of a certain hormone" and thus had a "medical reasons for doing it." *Id.* at 35. After the UC stated, "That's why I asked you," Respondent replied: "That's not a problem but it's not my thing to do this." *Id.* Respondent then said that he would be willing to prescribe to the UC's friends if they were HIV positive because "three quarters of men with HIV disease are low in testosterone" and there is research showing that "normal or elevated testosterone levels actually help the immune system." Id. at 36. Respondent added that while he was willing to help HIV patients, "for guys who are just looking for body building and stuff like that I don't usually do." Id. at 36.

The record shows that during the visit, Respondent wrote Bill Rix five prescriptions, including three for controlled substances. Specifically, Respondent wrote for: 100 tablets of Vicodin ES, with three refills; <sup>18</sup> 5 cc's of nandrolone decanoate, with three refills; and 10 cc's of testosterone cipionate, with three refills. GX 6. Respondent also wrote Rix a prescription for 30 syringes with five refills and one for ibuprofen. GX 6; Stipulated Facts, ALJ at 5.

As the ALJ noted, "[t]he assessment

notes in [the UC's] medical chart were incomplete, and did not include the specific prescriptions the Respondent issued to [the UC]." ALJ at 14; see also GX 8, at 5 (sheet for listing prescriptions for both legend and over-the-counter drugs which is blank). More specifically, while the form Respondent used to indicate the patient's complaint, history, physical exam, assessment and treatment plan, indicates that he diagnosed Rix with "osteoporosis"; consistent with the transcript of the visit, there are no findings to support the diagnosis. Likewise, there are no findings to support a diagnosis of joint pain or low testosterone and neither condition is documented in the "assessment" section of the form.

The ALJ also noted that Respondent did not ask "for a copy of the results of any of [the UC's] prior blood tests or order[] new blood tests prior to prescribing testosterone." ALJ at 15. And, as the transcript of the visit make clear, at no point did the UC indicate that he had a history of shoulder and vertebral fractures, and Respondent did not question the UC regarding the purported condition. See id. at 18–19.

In his testimony, Respondent nonetheless maintained that he did a full physical exam on the UC (except for checking his prostate), Tr. 570, and that he had actually "found signs of lipodystrophy" even though there is no such documentation in UC's chart. Id. at 580. In his testimony, Respondent stated that the form was incomplete because his nurse came in to the exam room and said "that a patient was about to leave if I didn't get in there right away." Id. However, he intended to write down "history of osteoporosis second to hypogonadism [low testosterone]" at the "little pound sign [which] is [his] indication for a diagnosis." Id.

Respondent may well have intended to write this down. However, given that: (1) The transcript of the visit clearly shows that Respondent told the UC that he was writing down osteoporosis simply to "cover my ass" in the event the State inspected his records; (2) he never questioned the UC about any of the purported fractures; (3) he had been told by the UC that when he was last tested he had high testosterone levels; and (4) he had been told by the UC that he had previously obtained steroids illegally, writing down the additional information would not make the diagnosis any less fraudulent.

Regarding his "diagnosis" of the UC, Respondent testified that "[i]n [his] mind, Bill Rix had osteoporosis." Id. at 597. Thus, "in [his] mind, that was not a false diagnosis." Id. at 593. On crossexamination, Respondent admitted, however, that he would not "find out whether this [sic] testosterone prescriptions that [he] issued were medically valid" until three months later, after the UC underwent a blood test. Id. at 604. Moreover, the ALJ specifically found incredible Respondent's testimony that he genuinely believed that the UC had osteoporosis, noting his statement during the UC's April 24 visit. ALJ at 19 (quoting GX 10, at 17-18) ("Just to cover my ass I'm going to put down you got a history of osteoporosis. \* \* \* [W]hen I write osteoporosis it has nothing to do with you[.] [I]t just has to do if the State ever comes in to monitor my charts that I have a reason for prescribing you

testosterone and \* \* \* [Deca].") I agree with the ALJ's credibility determination.

Finally, in his testimony, Respondent stated that "[i]n [his] mind, everything [the UC] said was legitimate because I had already the knowledge that he was HIV and he did show signs of it." Tr. 503. Furthermore, he was "trying to develop a rapport with this man. I was trying to get him to trust me \* \* \* to get him to eventually admit to me that he knew he was HIV positive." *Id.* at 505. Respondent maintained that he had lied to the UC about having used steroids in college because he "wanted to develop a rapport that 'Hey, he's a cool guy.' [The UC] was telling me he used steroids in the past, I wanted him to think I was a sympathetic ear." Id. at

The ALJ did not address whether she found this testimony credible. However, I note that this testimony flows from Respondent's claim, which I find is not credible, that the CI had told him in a telephone call prior to the UC's visit that the UC was HIV positive. Moreover, at no point did Respondent order a blood test to verify the UC's purported condition. Finally, while Respondent testified that he believed that the UC had been infected with HIV since 2002, id. at 562, Respondent did not discuss with the UC what doctors he had previously seen and offered no evidence that he had attempted to obtain the UC's medical records. In short, he did nothing to verify whether the UC was HIV positive. Thus, I find this testimony disingenuous.

#### Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration 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 render 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 making the public interest determination, the CSA requires 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.

<sup>&</sup>lt;sup>18</sup> The ALJ reasoned that because "the record contains no expert medical testimony or any other evidence which demonstrates that the Respondent's treatment of [the UC] in this area was not for a legitimate medical reason or outside the course of professional practice," the preponderance of the evidence did not indicate that this prescription was invalid. ALJ at 22. For reasons explained in the discussion section of this decision, I conclude otherwise.

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

These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors, and I may give each factor the weight I deem appropriate in determining whether to revoke an existing registration. *Id.* Moreover, I am "not required to make findings as to all the factors." *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173–74 (DC Cir. 2005).

The Government bears the burden of proof. 21 CFR 1316.56. However, where the Government makes out a *prima facie* case that a registrant's continued registration is inconsistent with the public interest, the burden shifts to the registrant to demonstrate why he can be entrusted with a registration.

Having considered all of the factors, I acknowledge that the record contains no evidence that the State of Florida has taken action against Respondent's medical license (factor one) or that Respondent has been convicted of an offense related to controlled substances (factor three).19 However, with respect to Respondent's experience in dispensing controlled substances (factor two) and his record of compliance with applicable Federal and state laws (factor four), the record establishes that Respondent violated the CSA's prescription requirement, see 21 CFR 1306.04(a), and Federal law when he prescribed anabolic steroids and narcotics to the UC in that he acted outside of the usual course of professional practice and/or lacked a legitimate medical purpose. See 21 U.S.C. 841; 21 CFR 1306.04(a). The record also demonstrates that Respondent violated the prescription requirement and Federal law on numerous occasions by prescribing Subutex to the CI for detoxification purposes when he was not qualified to treat and manage opiate-dependent patients. 21 U.S.C. 823(g); 21 CFR 1306.04(c). Finally, I agree with the ALJ that Respondent has failed to rebut the Government's prima facie case. Accordingly, Respondent's registration will be revoked and his pending application to renew his registration will be denied.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws.

Under a longstanding DEA regulation, a prescription for a controlled substance is not "effective" unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). This regulation further provides that "an order purporting to be a prescription issued not in the usual course of professional treatment \* \* \* is not a prescription within the meaning and intent of [21 U.S.C. 829] and \* \* \* the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." Id. See also 21 U.S.C. 802(10) (defining the term "dispense" as meaning "to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance") (emphasis added).

As the Supreme Court recently explained, "the prescription requirement \* \* \* ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)). Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act "in the usual course of  $^{*}$   $^{*}$  professional practice" and to issue a prescription for a "legitimate medical purpose." Laurence T. McKinney, 73 FR 43260, 43265 n.22 (2008); see also Moore, 423 U.S. at 142-43 (noting that evidence established that physician "exceeded the bounds of 'professional practice,'" when "he gave inadequate physical examinations or none at all," "ignored the results of the tests he did make," and "took no precautions against \* \* \* misuse and diversion"). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. See Kamir Garces-Meijas. 72 FR 54931, 54935 (2007); United Prescription Services, Inc., 72 FR 50397, 50407-08 (2007).

Under the standards adopted by the Florida Board of Osteopathic Medicine, to evaluate a patient: [a] complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Fla. Admin Code Ann. r. 64B15—14.005(3)(a). The Board's standard further states that "[t]he osteopathic physician should discuss the risks and benefits of the use of controlled substances with the patient." *Id.* para. (3)(c). Moreover, as relevant here, an

ostheopathic physician is required to keep accurate and complete records to include, but not be limited to:

- 1. The medical history and physical examination;
- 2. Diagnostic, therapeutic, and laboratory results;
  - 3. Evaluations and consultations;
  - 4. Treatment objectives;
  - 5. Discussion of risks and benefits;
  - 6. Treatments; [and]
- 7. Medications (including date, type, dosage, and quantity prescribed)[.] *Id.* para (3)(f).

As found above, during the UC's April 24 visit, Respondent issued him a prescription for 100 tablets of Vicodin ES, with three refills, a schedule III controlled substance which contains hydrocodone. ALJ at 5 (stipulated facts). While the prescription was purportedly issued to address the UC's joint pain, Respondent did not physically examine the UC. Moreover, although the UC made an oblique reference to pain in his knees while performing squats, Respondent did not further question the UC as to the nature and intensity of the pain or the pain's effect on the UC's physical and psychological function. Furthermore, Respondent did not discuss the risks and benefits of using controlled substances. Finally, Respondent did not document any past or current treatments for the purported pain and did not document the presence of a medical condition for which the use of controlled substances was indicated. Therefore, in accordance with the standards of the Florida Board, I conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the Vicodin prescription (with three refills) to the UC and violated Federal law. See 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a).

I further conclude that Respondent violated both state and Federal law when he prescribed to the UC two anabolic steroids, which are schedule III

<sup>&</sup>lt;sup>19</sup>This Agency has long held that a State's failure to take action against a practitioner's authority to dispense controlled substances is not dispositive in determining whether the continuation of a registration would be consistent with the public interest. See Mortimer B. Levin, 55 FR 8209, 8210 (1990). Likewise, the absence of a criminal conviction is not dispositive of the public interest inquiry. See, e.g., Edmund Chein, 72 FR 6580, 6593 n.22 (2007).

controlled substances: 15 cc's of nandralone decanoate (with three refills), and 10 cc's of testosterone cipionate (also with three refills). Under Florida law, "prescribing \* \* \* testosterone or its analogs \* \* \* for the purpose of muscle building or to enhance athletic performance" is unlawful.<sup>20</sup> See Fla. Stat. Ann. § 458.331(1)(ee). As found above, during the April 24 visit, the UC was clearly seeking the anabolic steroid prescriptions for muscle building purposes, which is not a legitimate medical purpose under Florida law (and therefore Federal law as well).

Moreover, the transcript of the visit further establishes that Respondent clearly knew that the UC was seeking the steroids for this purpose. Specifically, the UC did not complain of any problem other than that he was aging and losing strength; related that he had obtained steroids through a pharmacy, which arranged for doctors, who never saw patients, to write the prescriptions lawfully required to dispense the steroids; that he had gone to the pharmacy one day only to find that it had been raided by the police; and that when he had last undergone a blood test, his testosterone levels were high.

Respondent's statements during the undercover visit further support the conclusion that he knew the UC was seeking the steroids for other than a legitimate medical purpose. As found above, Respondent stated that "just to cover my ass," he was going to "put down" in the UC's chart that he had "a history of osteoporosis," and that "when I write osteoporosis it has nothing to do with you[,] it just has to do if the State ever comes in to monitor my charts that I have a reason for prescribing you testosterone and Deca." GX 10, at 17–18. Thus, it is clear that Respondent knew that he lacked a legitimate medical purpose for prescribing steroids to the UC.21

Respondent therefore violated the prescription requirement of Federal law when he wrote the UC prescriptions for nandralone and testosterone. I further

hold that Respondent's issuance of the Vicodin and anabolic steroid prescriptions to the UC each provide an independent and adequate basis to satisfy the Government's prima facie case that Respondent's continued registration is inconsistent with the public interest.

Respondent also repeatedly violated Federal law by prescribing Subutex to the CI. According to the record, Respondent had initially referred the CI to a psychiatrist who specialized in detoxification of opiate-dependent patients and from whom the CI received prescriptions of Subutex for this purpose. When, however, the CI complained that the detox specialist charged too much and insisted on seeing him every month, Respondent agreed to write Subutex prescriptions for the CI and wrote him numerous prescriptions (as well as authorized refills) over the course of nearly three and a half years. Respondent did not dispute that the Subutex prescriptions were written for this purpose.

Under Federal law, a physician who dispenses (which includes prescribing) narcotic drugs in schedules III through V to a person for maintenance or detoxification treatment need not necessarily obtain a separate registration for this purpose. However, the physician must satisfy extensive conditions to prescribe these drugs for these purposes. See 21 U.S.C. 823(g)(2)(A) & (B). These conditions include that the practitioner must, "before the initial dispensing of narcotic drugs in schedule III, IV or V" for these purposes, notify the Secretary of the Department of Health and Human Services (HHS) of his intent "to begin dispensing the drugs \* \* \* for such purpose." Id. § 823(g)(2)(B). And as part of the notification, the physician must make three certifications.

More specifically, the practitioner must certify that: (1) He "is a qualifying physician"; (2) he "has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services"; and (3) "[t]he total number of patient of the practitioner at any one time will not exceed the applicable number."22 Id. With respect to the first requirement, a physician must hold (in addition to a state license) either board certification in addiction, addiction medicine, or addiction psychiatry; or have completed "not less than eight hours of training" in the "treatment and management of opiatedependent patients" provided by

various professional organizations,<sup>23</sup> or have other training or experience as either the Secretary of HHS or a State medical board has determined "demonstrate[s] the ability of the physician to treat and manage opiate-dependent patients." *Id.* § 823(g)(2)(G).

Although Respondent holds a valid state license, he did not meet any of the conditions necessary to demonstrate that he is qualified as a physician to treat and manage opiate-dependent patients such as the CI. Nor did he satisfy any of the statute's other requirements for dispensing narcotics drugs for the purpose of maintenance or detoxification treatment.

While Respondent asserted that he did not know when these requirements went into effect and was unsure as to whether "the course" was required at the time he wrote the prescriptions, they have been in effect since the year 2000.24 See Drug Addiction Treatment Act of 2000, Public Law 106-310, § 3502, 114 Stat. 1222, 1225 (2000). As for his contention that no pharmacist ever told him he needed a special registration to prescribe narcotics for this purpose, Respondent is responsible for knowing the law. Cf. Patrick W. Stodola, M.D., 74 FR 20727 20734 (2009) (quoting Hageseth v. Superior Court, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007) ("[T]he proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons \* \* \* who are licensed health care providers.").

These are serious violations of Federal law. Congress made this clear in the Drug Addiction Treatment Act, where it specifically provided that if a practitioner, "in violation of the conditions specified in subparagraph[] B \* \* \* dispenses narcotic drugs in schedule III, IV, or V \* \* \* for maintenance treatment or detoxification treatment, the Attorney General may, for

<sup>&</sup>lt;sup>20</sup> It is acknowledged that for the purpose of this provision, "the term 'muscle building' does not include the treatment of injured muscle." Fla. Stat. Ann. § 458.331(ee).

<sup>&</sup>lt;sup>21</sup> To similar effect, upon being asked by the UC whether he would accept referrals of "a couple [of] close friends," Respondent answered that while he was willing to prescribe steroids to the UC as a favor to Jimmy (the CI), "this is not my thing" and that I "know a lot about steroids cause I did them in college." GX 10, at 34. He then added that Jimmy (unlike the UC) "actually has a deficiency where he doesn't make enough of a certain hormone so \* \* \* he has medical reasons for doing" steroids. *Id.* at 35. Respondent then told the UC that "it's not my thing to do this." *Id.* 

<sup>&</sup>lt;sup>22</sup> Initially, a practitioner may only treat thirty patients. 21 U.S.C. 823(g)(2)(B)(iii).

<sup>&</sup>lt;sup>23</sup> The organizations include "the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Associations, the American Ostheopathic Association, and the American Psychiatric Association." <sup>21</sup> U.S.C. 823(g)(2)(G)(IV).

<sup>&</sup>lt;sup>24</sup> Since 1974, Federal law has required that a practitioner obtain a separate registration and meet various standards imposed by the Secretary to dispense narcotic drugs for maintenance or detoxification treatment. See Narcotic Treatment Act of 1974, Public Law 93–281, 88 Stat. 137–38 (1974). While a practitioner who seeks to dispense schedule III through V controlled substances for maintenance or detoxification treatment may obtain a waiver of the registration requirement, as explained above, he must still meet various requirements including having either board-certification or suitable experience and/or training in treating and managing opiate-dependent patients.

purposes of [21 U.S.C. 824(a)(4)], consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest." 21 U.S.C. 823(g)(2)(E)(i). Accordingly, I further hold that Respondent's prescribing of Subutex to the CI for detoxification purposes provides an additional and independent basis to support the Government's *prima facie* case.

#### Sanction

Under Agency precedent, where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present[] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'" Medicine Shoppe-Jonesborough, 73 FR 363, 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); 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).

As part of this determination, this Agency also places great weight on a registrant's candor, both during an investigation and in any subsequent proceeding. See, e.g., 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."). See also Rose Mary Jacinta Lewis, M.D., 72 FR 4035, 4042 (2007) (holding that lying under oath in proceeding to downplay responsibility supports conclusion that physician "cannot be entrusted with a registration").

Here, as the ALJ found, the evidence supports the conclusions that Respondent has failed to accept responsibility for his misconduct and gave false testimony in the proceeding. ALJ at 30. More specifically, based on the transcript of the April 24 visit, which clearly shows that Respondent falsely documented that the UC had osteoporosis, the ALJ found not credible Respondent's testimony that he genuinely believed the UC had osteoporosis. I agree.

Moreover, while the ALJ expressly declined to make any findings as to whether she found credible Respondent's testimony that the CI had phoned him and related that the UC had various conditions such as HIV and a history of bone fractures (which was offered to provide some medical justification for the steroid prescriptions), as explained above, as ultimate factfinder, I have rejected his testimony as not credible for multiple reasons. In short, the entirety of the evidence convincingly demonstrates that Respondent's testimony regarding the purported phone call was patently self-serving and disingenuous.

Respondent further argues that he refused to prescribe HGH to the UC and also refused the UC's request to accept the latter's friends as "patients." As for Respondent's refusal to prescribe HGH (which is not a controlled substance), it is far from clear that the UC was seeking HGH as he noted that it's "the most expensive stuff on earth" and that it had caused an acquaintance's head to swell.<sup>26</sup> GX 10, at 11. While it is true that Respondent told the UC of other serious side effects caused by HGH, this no more mitigates his misconduct in issuing the steroid prescriptions than would an argument that one had prescribed a slightly less dangerous narcotic rather than a more dangerous one sought by a drug abuser (for example OxyContin instead of Fentanyl), when there was no legitimate medical purpose for any such prescription. Put another way, the fact that a controlled substance causes less dangerous side effects than another drug which a drug abuser may have sought does not make a prescription for a controlled substance, which lacks a legitimate medical purpose, any less illegal.

As for Respondent's declining the UC's offer to refer his friends because he "usually" did not do "guys who are just looking for bodybuilding and stuff like that," he nonetheless was willing to issue illegal prescriptions to the UC. Moreover, that Respondent did not "usually" write steroid prescriptions for

those into bodybuilding implies that, in some other instances, he did. *See* ALJ at 32.

In short, even were I to view the evidence as supporting both Respondent's contention that the UC sought HGH but he refused to prescribe it and that he declined the UC's offer to refer his friends, these circumstances are not sufficient to rebut the Government's prima facie case and demonstrate that he can be entrusted with a registration. Moreover, regarding his extensive violations of Federal law in prescribing Subutex for detoxification treatment, Respondent did not accept responsibility, but rather blamed his misconduct on the fact that no pharmacist told him that he needed a separate registration to do so.27

In conclusion, because Respondent has failed to accept responsibility for his misconduct and provided less than candid testimony in the proceeding, it is clear that his continued registration "would be inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, Respondent's registration will be revoked and his pending application to renew his registration will be denied.

#### Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BH1292642, issued to Robert F. Hunt, D.O., be, and it hereby is, revoked. I further order that Respondent's pending application to renew his registration be, and it hereby is, denied. This Order is effective immediately.

Dated: July 30, 2010.

## Michele M. Leonhart,

Deputy Administrator.

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#### **DEPARTMENT OF LABOR**

### Office of the Secretary

# Submission for OMB Review; Comment Request

August 3, 2010.

The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of

 $<sup>^{26}</sup>$  In her opinion, the ALJ found that the UC had "hinted that he would like a prescription for" HGH. ALJ at 22. This does not seem to be an accurate reading of the evidence in light of the UC's complaint that HGH is "the most expensive stuff on earth." GX 10, at 39.

<sup>&</sup>lt;sup>27</sup>I have also considered Respondent's evidence regarding his volunteer activities related to persons with HIV. While his activities are laudable, they do not negate the fact that Respondent knowingly diverted steroids and repeatedly violated Federal law in prescribing Subutex. Nor are his activities relevant in determining whether Respondent has accepted responsibility for his misconduct.