Since the date of service of the Show Cause Order, more than thirty days have passed and neither Respondent, nor anyone purporting to represent him, has requested a hearing. I therefore find that Respondent has waived his right to a hearing and issue this Decision and Final Order based on the record submitted by the Government. 21 CFR 1301.43. I make the following findings.

Findings

Respondent holds DEA Certificate of Registration BJ6361036, which was last renewed on January 1, 2008. The registration does not expire until December 31, 2010.

On March 24, 2009, the MBC adopted a Default Decision and Order in a case brought against a Respondent's State medical license. *In re Nicholas Joseph Jerrard, M.D.,* No. 10–2006–179554, Decision at 1 (Med. Bd. Cal. 2009). According to the decision, in November 2006, the MBC received a report from the Oregon Board of Medical Examiners (Oregon Board) which indicated that Respondent "had failed a pre-employment drug screen by testing positive for nordiazepam and temazepam and had failed to provide proof of a valid prescription for the medication." *In re Jerrard,* Default Decision and Order at 5. After an investigation, the Oregon Board allowed Respondent to withdraw his application to reactivate his medical license and closed the matter with no action taken. *Id.*

On June 10, 2008, an Investigator from the MBC interviewed Respondent. During the interview, Respondent admitted that "he had used methamphetamines approximately every two months since 2005." *Id.* at 6.

The MBC further found that following the pre-employment drug screen which he failed, Respondent was evaluated at the Betty Ford Center. *Id.* The Center recommended that he undergo six months of inpatient treatment. *Id.* Because of financial reasons and his fear of losing two jobs, Respondent did not follow through with the recommendation. *Id.*

However, around January 2008, he underwent some ten weeks of treatment at Rancho L'Abri, another inpatient facility. *Id.* After his discharge, Respondent found out that he had been fired from both his jobs and experienced a relapsed. *Id.* Thereafter, he was readmitted to Rancho L'Abri for one month and discharged to a 90-day outpatient program. *Id.* Respondent, nevertheless, participated in the program for only one day, indicating that he did not "feel comfortable there." *Id.* Subsequently, he joined another outpatient treatment program from which he graduated in September 2008. *Id.*

The MBC further concluded that Respondent had "[s]elf-administered controlled substances" in violation of California Business and Professions Code section 2239(a), and that he "[e]ngaged in conduct which breaches the rules or ethical code of the medical profession, or conduct which is unbecoming to a member in good standing of the medical profession, and which demonstrates an unfitness to practice medicine" in violation of California Business and Professional Code section 2234. *Id.* at 7. The MBC then revoked Respondent's license to practice medicine effective April 23, 2009. Decision at 1.

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) (defining the term "practitioner" as a person "licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to distribute, dispense * * * [or] administer * * * a controlled substance"); *id.* § 823(f) ("The Attorney General shall register practitioners * * * to dispense * * * controlled substances * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.").

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 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"). Because Respondent is no longer licensed to practice medicine and therefore cannot dispense controlled substances in California, the State in which he is registered with DEA, under the CSA, he is no longer entitled to hold his registration. Accordingly, his registration 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, BJ6361036, issued to Nicholas J. Jerrard, M.D., be, and it hereby is, revoked. I further order that any pending application of Nicholas J. Jerrard, 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.

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performed an Internet search for Respondent's "possible practice locations" but was "unable to locate any pertinent information."

As regards the sufficiency of service of the Order to Show Cause, I conclude that notwithstanding that Respondent was not personally served, the Government has met the requirements of the Due Process Clause. As to notice, due process is satisfied when "[t]he means employed [are] such as one desirous of actually informing the absentee might reasonably adopt to accomplish." *Mullane* v. *Central Hanover Bank & Trust Co.,* 339 U.S. 306, 315 (1950). More recently, the Supreme Court has held that "[d]ue process does not require that a property owner receive actual notice before the government may take his property." *Jones* v. *Flowers,* 547 U.S. 220, 226 (citing *Dusenbery* v. *United States,* 543 U.S. 161, 170 (2002)). Furthermore, due process does not require "heroic efforts," *Dusenbery,* 534 U.S. at 170, but rather only that "the government * * * provide 'notice reasonably calculated, under all the circumstances to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.'" 547 U.S. at 226 (quoting *Mullane,* 339 U.S. at 314). I accordingly find that the DI's efforts to serve the Order on Respondent satisfied due process notwithstanding the Government's inability to effectuate personal service as the DI's efforts were "reasonably calculated, under all the circumstances, to apprise [Respondent] of the pendency of the action." *Mullane,* 339 U.S. at 314.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–8]

Tony T. Bui, M.D.; Revocation of Registration

On September 15, 2008, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Tony T. Bui, M.D. (Respondent), of Bedford, Texas. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BB8997857, which authorizes him to dispense controlled substances as a practitioner, and the denial of any pending applications to renew or modify his registration, on the ground that his "continued registration is inconsistent

with the public interest." ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

More specifically, the Show Cause Order alleged that Respondent has "a history of cocaine abuse" and that on, or about, December 13, 2007, the Texas Medical Board ordered Respondent to provide a urine sample. *Id.* The Order alleged that the sample "tested positive for cocaine metabolites" and that "[a] retest of the same sample reconfirmed" this result. *Id.*

The Show Cause Order also alleged that Respondent has failed to keep his registered address current with the Agency as required by 21 CFR 1301.51. *Id.* Next, the Show Cause Order alleged that Respondent was "dispensing narcotic drugs for narcotic treatment without the necessary authorization." *Id.* at 2 (citing 21 U.S.C. 823(g) and 21 CFR 101.13). Finally, the Show Cause Order alleged that Respondent had "written prescriptions for Jintropin, a human growth hormone, which the Food and Drug Administration has not approved for use in the United States." *Id.*

Respondent's request for a hearing was not received by Agency until October 29, 2008, and was thus beyond the thirty-day period for requesting a hearing. *See* 21 CFR 1301.43(a). Respondent's counsel explained that he had sent the request on October 14, but that one of his staff had typed an incomplete address on the envelope which was used for mailing the request, and that as a result, the mailing was returned. ALJ Ex. 11, at 1. Respondent's counsel promptly refiled the hearing request. ALJ Ex. 2. Finding that the Government had not objected to Respondent's hearing request, and reasoning that "the law seeks to avoid a result where a blameless party suffers because of the errors or neglect of his attorney," the ALJ concluded that Respondent had shown "good cause" for his untimely filing. ALJ Ex.12, at 1–2; *see also* 21 CFR 1301.43(d).

Following pre-hearing procedures, the ALJ conducted a hearing in Dallas, Texas on August 4–5, 2009. At the hearing, both parties elicited testimony and submitted various documents for the record. Thereafter, both parties filed briefs containing their proposed findings of fact, conclusions of law, and arguments.

On September 16, 2009, the ALJ issued his recommended decision (hereinafter, also ALJ). Therein, the ALJ concluded that the Government had proved that "Respondent ha[d] committed acts that are inconsistent with the public interest." ALJ at 37. The ALJ further concluded that "Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that" his registration should be continued. *Id.*

With respect to factor one—the recommendation of the state licensing board—the ALJ noted that "Respondent has had a somewhat storied history with the Texas Medical Board" and that "[t]here has been a repeated pattern of the Board meting out sanctions that are followed by additional misconduct," but that the Board "has authorized the Respondent to continue to practice medicine." *Id.* at 23–34. However, based on the extensive precedent which holds that the Agency has an "independent responsibility to determine whether a registration is in the public interest," and that possessing "a state license is a necessary, but not a sufficient condition for registration," the ALJ concluded that while Respondent is currently authorized to practice medicine in Texas, this factor "does not weigh for or against a determination as to whether [the] continuation of [his registration] is consistent with the public interest." *Id.* at 24.

The ALJ then turned to factor three—Respondent's conviction record for offenses relating to the manufacture, distribution and dispensing of controlled substances. While noting that Respondent had been indicted and received a deferred adjudication under Texas law for the felony offense of possession of a controlled substance, the ALJ, after noting the confused state of agency precedent, concluded that his offense did not implicate this factor because it was not an offense which "relat[es] to the manufacturing, distribution, or dispensing of controlled substances." *Id.* at 25. Thus, the ALJ held that "this factor does not weigh against * * * Respondent." *Id.* at 26.

Next, the ALJ considered together factors two (Respondent's experience in dispensing controlled substances), four (compliance with applicable laws related to controlled substances) and five (such other conduct which may threaten public health and safety). With respect to Respondent's prescribing practices, the ALJ concluded that the Government had not proven that Respondent violated Federal law by prescribing narcotic controlled substances for maintenance or detoxification purposes. *Id.* at 29.

With respect to Respondent's prescribing of human growth hormone including Jintropin, a substance which has not been approved by the Food and Drug Administration for any medical indication, the ALJ acknowledged that "human growth hormone is not a controlled substance with the meaning of the" Controlled Substances Act and that "Respondent's issuance of a prescription for the substance for purposes other than FDA-approved uses does not fall squarely within the purview of the criminal statute." *Id.* at 30. The ALJ reasoned, however, that "because he issued prescriptions for human growth hormone for unauthorized uses and for Jintropin for any use, he violated federal law by issuing prescriptions outside the usual course of professional practice." *Id.* (citing 21 CFR 1306.04(a)). The ALJ also concluded that this conduct was relevant under factor five, reasoning that "[i]t would be difficult to conceive of a scenario that hits closer to the mark of a dangerous prescribing practice than the prescribing of substances for purposes that have not been approved by the FDA and the prescribing of a substance not approved for any purpose by the FDA." *Id.* at 31.

Next, the ALJ considered the evidence pertaining to Respondent's use of cocaine and alcohol. The ALJ noted that within two months of his entering into an agreed order with the Texas Medical Board, which required him to undergo treatment and urinalysis, Respondent used cocaine and then "fabricated a tale about innocent ingestion" and "procured a false letter from a former girlfriend admitting to a soft-drink adulteration that never occurred." *Id.* at 32. Moreover, even after the Texas Board restored his license (following a suspension), Respondent failed to check in for testing and then tested positive for alcohol, a result he claimed was caused by his use of an antiperspirant. *Id.* The ALJ further noted that while the Texas Board gave him "yet another chance," Respondent subsequently tested positive for cocaine. *Id.* The ALJ further found that "Respondent has met every objective indication of his continued substance abuse issues with denials and fabrications." *Id.* at 32–33.

Noting the "settled Agency precedent that a registrant's continuing substance abuse and/or unsuccessful rehabilitation efforts are contrary to the public safety and militate against entrusting such a person with the responsibilities attendant upon a registration," the ALJ concluded that because "Respondent is not being currently monitored for substance abuse, there is no way to accurately gauge whether he has subsequently taken definitive, successful steps to overcome his substance abuse issues * * * [and] [t]he evidence regarding the continued episodes of cocaine use weighs in favor of revocation." *Id.* at 33.

The ALJ also observed that Respondent had changed his practice

address at least four different times without updating his registered location. *Id.* at 34 (citing 21 CFR 1301.12(a) & (b)(3)). While noting that "the nature of his practice at each practice address was not demonstrated with crystal clarity at the hearing," the ALJ concluded that the record showed that Respondent had administered testosterone injections to at least one person at an unregistered address. *Id.* at 34. Moreover, the ALJ noted that Respondent was apparently no longer practicing at the address listed on his renewal application and thus his renewal application could be denied on this basis alone. *Id.* at 35. The ALJ also did not find persuasive Respondent's explanation that he had failed to update his addresses because "he had difficulty remembering to fulfill this obligation." *Id.* at 36. The ALJ thus concluded that factors two, four, and five "weigh strongly in favor of revocation" of Respondent's registration. *Id.*

The ALJ thus held that "Respondent has committed acts that are inconsistent with the public interest." *Id.* at 37. Moreover, the ALJ found that "Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that" he can be entrusted with a registration. *Id.* The ALJ thus recommended that Respondent's registration be revoked and any pending applications be denied. *Id.*

Thereafter, Respondent filed exceptions to the ALJ's recommended decision. More specifically, Respondent excepted to the ALJ's finding that he had ingested cocaine in the days before his positive urine test, contending that the ALJ had disregarded several significant inconsistencies in the testimony of the Government's expert regarding the sensitivity of hair testing. Resp. Exceptions at 1–3. Respondent also maintained that an Agency Investigator had violated his right to procedural due process when she told Respondent that he could not prescribe controlled substances until further notice from the Agency. *Id.* at 3–4. Finally, Respondent excepted to the ALJ's recommendation that his registration be revoked, contending that he provided "sufficient mitigating evidence" to support his being granted "a restricted registration." *Id.* at 5.[1]

On October 13, 2009, the record was forwarded to me for Final Agency Action. Having considered the entire record, I hereby issue this Decision and Final Order. I agree with the ALJ that the Government has not proved that Respondent prescribed methadone for maintenance or detoxification purposes in violation of 21 U.S.C. 823(g), and that substantial evidence supports the conclusion that Respondent ingested cocaine in December 2007. I reject the ALJ's conclusion that Respondent's prescribing of human growth hormone (including Jintropin) violated 21 CFR 1306.04(a), and further hold that the allegation is beyond the Agency's authority to adjudicate under 21 U.S.C. 823(f). I also reject the ALJ's finding that Respondent violated Federal law by administering controlled substances at a non-registered location. However, I agree with the ALJ that Respondent has failed to accept responsibility with respect to his ingestion of cocaine in December 2007. Accordingly, I make the following findings.

Findings of Fact

Respondent is a doctor of medicine with training in physical medicine and rehabilitation who currently practices geriatric medicine in Dallas, Texas. Tr. 261 & 265; GX 3, at 1. Respondent has been licensed by the Texas Medical Board since May 10, 1997. GX 3, at 1.

Respondent previously held DEA Certificate of Registration, BB5278141, which authorized him to dispense controlled substances as a practitioner. GX 11, at 5. However, as discussed more fully below, on November 7, 2003, the Texas Medical Board suspended Respondent's medical license for a period of six months, GX 4, at 3–4; and on January 15, 2004, Respondent surrendered this registration. GX 11, at 2.

On October 28, 2004, after the State restored Respondent's medical license, Respondent obtained a new practitioner's registration, BB8997857, for the location of 4300 MacArthur Ave., Suite 265, Dallas, Texas. *Id.* at 2. On July 24, 2007, Respondent applied to both renew and modify the registration by changing his registered location to 1901 Central Drive, Suite 805, Bedford, Texas. *Id.* While Respondent was issued a new certificate for the Bedford address, the Agency did not renew his registration. GX 1. On January 8, 2009, Respondent submitted a new request to modify his registration by changing the address to 2735 Villa Creek Drive, Suite 110C, Dallas, Texas. GX 11, at 2.

The State Investigations

On April 16, 2002, Respondent was stopped by a police officer for driving with a defective brake light. GX 2. During the stop, the officer determined that Respondent's driver's license was suspended and arrested him. *Id.* While being processed at the jail, Respondent was found to have in his possession a small quantity of cocaine. GX 3, at 2. Respondent also "admitted to a history of recreational cocaine abuse." *Id.*

Respondent was subsequently indicted for the offense of possession of a controlled substance, in the amount of less than one gram, a felony under Texas law. *Id.* On November 27, 2002, the state court placed Respondent on deferred adjudication. *Id.*

Thereafter, on August 15, 2003, Respondent entered into an Agreed Order with the Texas Medical Board. *Id.* at 1. The order noted that on October 8, 2002, Respondent met with the Physician's Health and Rehabilitation Committee of Medical City Hospital, Dallas, and entered into a recovery contract, the terms of which included "an evaluation by an addictionologist and treatment, if recommended[;] abstention from drugs and alcohol; limitation of [his] prescribing authority; and random urine testing through the Texas Medical Association." *Id.* at 2.

The Board imposed various terms and conditions for a period of five years. As relevant here, the terms included that: (1) Respondent abstain from consuming "alcohol, dangerous drugs, or controlled substances in any form unless prescribed by another physician to [him] for a legitimate and documented therapeutic purpose"; (2) Respondent submit to random testing for alcohol or drug use "either through a urine, blood, or hair specimen, at the request of" the Board, "without prior notice," and at his own expense; (3) either a positive test result or his refusal to submit to a test would constitute a violation of the order and subject his license to an immediate suspension without a hearing; (4) Respondent submit to a psychiatric evaluation, and if recommended, undergo psychiatric care and treatment; (5) Respondent participate in either a program of Narcotics Anonymous or a substantially similar program; and (6) Respondent "participate in the activities of a county or state medical society committee on physician health and rehabilitation, including participation in weekly meetings, if any"; and (7) Respondent pay an administrative penalty of $5,000 within sixty days of the order. *Id.* at 4–8.

Pursuant to the Agreed Order, on October 14, 2003, Respondent provided a specimen, which "tested positive for cocaine." GX 4, at 2. On November 7, 2003, the Board found that Respondent had "failed to abstain from the consumption of dangerous drugs or

[1] Respondent also excepted to the ALJ's finding that the Diversion Investigator who investigated him was not biased. *Id.* at 3.

controlled substances" and had violated the Agreed Order. *Id.* Moreover, during a show cause proceeding before the Texas Board, Respondent admitted that he had not paid the administrative penalty. *Id.*

During the state proceeding, Respondent asserted that his positive test result was caused by his ex-girlfriend's having spiked a soft drink without his knowledge. *Id.* In support of his claim, Respondent submitted a "hand-written statement," which he claimed was from his ex-girlfriend.[2] *Id.* The Board apparently did not buy his story as it determined that he had violated the Agreed Order and suspended his state license "for a minimum period of six months" while continuing in effect the terms of the Agreed Order. *Id.* at 3. The suspension remained in effect until October 8, 2004, when the Board terminated it upon finding that Respondent was in compliance with the terms of the Agreed Order. GX 5, at 2–3.

On August 3, 2005, the Board filed a Complaint against Respondent based on violations of the Texas Medical Practice Act. GX 6, at 1. Therein, the Board alleged that on February 8, 2005, Respondent consumed alcohol and thereby violated the Agreed Order, and that he also failed to report this incident as required by the Agreed Order. *Id.* at 2. The Board further alleged that on March 2, 2005, Respondent failed to call in to determine whether he was required to submit a sample for drug testing, and that the next day, Respondent provided a sample, which tested positive for EtG (Ethyl Glucoronide), a marker for alcohol use. *Id.*

On February 3, 2006, the Board and Respondent entered into a Mediated Agreed Order. GX 7, at 1. Therein, the Board found that "Respondent did report an unintentional ingestion of alcohol," but that "the report was late." *Id.* at 2. The Board further found that Respondent "tested negative for alcohol." *Id.* While the Board also found that "Respondent was late for a call-in * * * he submitted a sample two days later that was negative." *Id.* Finally, the Board found that Respondent's "compliance officer reports he is currently in compliance with his Order." *Id.* The Board reprimanded Respondent and imposed a $5,000 administrative penalty on him. *Id.* at 3.

On December 13, 2007, Respondent was subjected to a random urine drug screen. The specimen, which was analyzed using an initial test and confirmed through the Gas Chromatography and Mass Spectrometry methods, was positive for cocaine metabolites at the level of 627 ng./ml., an amount more than four times the 150 ng./ml. level which confirms a positive test result. GX 8, at 2 & 4. The result was confirmed by a retest of Respondent's specimen, which was conducted by a second laboratory. *Id.* at 5.

On December 19, before the retest of his urine sample was completed, Respondent submitted a hair specimen, which represented three to four months of growth, for screening by another laboratory. RX 2, at 1. Respondent's specimen tested negative for prohibited substances including cocaine and its metabolites. *Id.* On January 10, 2008, Respondent submitted an additional hair specimen for screening. RX 3, at 1. This specimen also tested negative for cocaine and its metabolites. *Id.*

To address these conflicting test results, the Government called Dr. Angela Springfield as an expert witness. Tr. 22. Dr. Springfield holds a PhD in Pharmacology and Toxicology, has served as Chief Toxicologist for Tarrant County, Texas for more than twenty-five years, and was an Assistant Professor at the University of North Texas Health Science Center. GX 12. Dr. Springfield is a member of the Society of Forensic Toxicology and of the American Academy of Forensic Sciences, and holds a diploma from the latter organization. *Id.* at 2; Tr. 22. Dr. Springfield was qualified as an expert in toxicology.

Dr. Springfield testified that urine drug screening uses an "enzyme mechanism" which looks for various "classes of drugs" such as cocaine by causing a "reaction above a given cut off point." *Id.* at 24. The sample is then tested using the gas chromatography-mass spectrometry method, "which identifies the component in the urine, and then quantitates the * * * amount of drug that may be present in the sample." *Id.* Dr. Springfield further testified that urine drugs tests are "very reliable" and will detect cocaine usage within 36 to 48 hours of ingestion. *Id.* at 25.

Dr. Springfield testified that hair testing uses a similar process in which the specimen is ground up into a powder or other form and subjected to a preliminary test and, if a positive result is returned, is then tested using gas chromatography-mass spectrometry. *Id.* at 27–29. Dr. Springfield stated that hair testing is also "very reliable" and that the drug binds itself to melanin in the hair and will stay there until it has been cut. *Id.* at 28–29. However, because the drug enters the hair in the bulb, it "takes four or five days before the hair" containing the drug "extrude[s] from the scalp." *Id.* at 30.

With respect to the first urine drug screen, Dr. Springfield testified that the report indicated that a "Quantitative Result" of Cocaine Metabolite in the amount of 627 ng./ml. When asked by the ALJ if that was the result of the "GC-mass spec test?," Dr. Springfield answered: "I'm assuming that is a mass spec test. They have GC here." Tr. 33. Apparently, this was a reference to a notation on the lab report: "Test confirmed by GC." GX 8, at 4. Dr. Springfield then explained: "A GC and a GC-mass spec are two different instruments. I would have thought they would put GC-mass spec on there." Tr. 34. Dr. Springfield testified that she assumed that the reference to GC on page 4 of the lab report was to "GC-mass spec" based on the first page of the report which indicated Respondent's positive test result for cocaine metabolites and that the quantitative levels for a positive result under both the initial test (300 ng./ml.) and the GC/MS Confirmation (150 ng./ml.). *Id.* at 35. Dr. Springfield testified, however, that based on this report, this particular [urine] sample contained the presence of benzoylecgonine and by inference, cocaine. *Id.* at 38.

Dr. Springfield further testified that the second report confirmed the findings of the first test. *Id.* at 40. While there is no indication on the report form as to what procedures were followed in conducting the test, GX 8, at 5; and no evidence was adduced showing what procedure the lab follows for a retest, Respondent did not challenge the adequacy of the procedures used in conducting the retest.

In any event, Dr. Springfield testified that there was no way to tell whether the cocaine was ingested by snorting it or drinking it. *Id.* at 41. She further testified that if a person "took small doses, [he] might not be aware if [he was] in a party situation. If [he] were having a good time, [he] might not notice whether [he is] ingesting that or not." *Id.* at 42.

Dr. Springfield then testified that the negative hair test results could support either of two conclusions. *Id.* First, that Respondent did not use drugs. *Id.* at 44. Second, that the drug used was "outside of the limitations of the hair." *Id.* at 45. With respect to the first sample, Dr.

[2] At the instant hearing, Respondent admitted repeatedly that he had lied to the Board about this incident. Tr. 311–12. Explaining his conduct, Respondent testified that he was in denial, and that when "you're up against a wall * * * you're going to lie. You're going to try to pull the wool over people's eyes." *Id.* at 312. He insisted, however, that he is not on cocaine. *Id.* at 315.

Springfield explained that "there's a possibility that hair had not been extruded" from Respondent's scalp between the time of ingestion and the taking of the sample. *Id.* at 46.

As for the second sample, Dr. Springfield testified that the other possibility is that "the amount of the drug that was used was small enough to not be detected" by the testing process. *Id.* at 45. Dr. Springfield further testified that while the 600 nanograms of metabolite which were detected in the urine screen were above the cut-off, this number does not indicate "that somebody is a binge user." *Id.* Continuing, Dr. Springfield added that "it may well be that the dose was not high enough to sequester in sufficient amount to be detected in this second process." *Id.*

However, Dr. Springfield acknowledged "that sufficient time had elapsed" for ingested drug to be present in the hair which was tested in the second sample and that she "would have expected to have seen benzoylecgonine [cocaine metabolite] in that sample." *Id.* at 46. Dr. Springfield explained that there might well have been drug present but that the drug was below the cutoff level and was not reported as a positive test. *Id.* She thus concluded that Respondent's negative hair tests neither confirmed nor refuted the urine test. *Id.* at 47.

On cross-examination, Dr. Springfield testified that she could not say whether or not 627 nanograms per milliliter is a lot of cocaine because it would depend on how soon the sample was taken after ingestion. *Id.* at 53. However, she reiterated that this level could "very well * * * be under the detection limits" and that hair testing is not "sensitive enough to see low doses of cocaine" and probably would not pick up either "[a] small one-time use or a two-time use of a small amount." *Id.* at 61. Dr. Springfield also stated that this is widely accepted in the scientific community. *Id.* at 53–54. Respondent did not refute this testimony.

On cross-examination, Respondent questioned Dr. Springfield about research she had performed which involved hair testing on Peruvian mummies to determine the presence of cocaine. *Id.* at 72. In her testimony, Dr. Springfield explained that the testing had found the presence of cocaine metabolites in the mummies after many years. More specifically, Dr. Springfield stated that while the Peruvians "were chronic users [of] cocaine," the "levels were low" and were "not in the 600 nanogram range." *Id.* at 72–74.

In his Exceptions, Respondent contends that Dr. Springfield's testimony regarding the level of cocaine metabolites found in the mummies contradicted her earlier testimony that the level of 600 nanograms in urine would be under the detection limits of the hair test. Exceptions at 2–3. Respondent, however, produced no evidence that the ingestion of an amount of cocaine would result in the presence of cocaine metabolites in hair at similar levels as would be found in urine. Notably, hair testing results are typically expressed in *picograms* per milligram, a unit which is one one-thousandth of a nanogram. As Respondent's hair test results indicate, a positive test for benzoylecgonine would be triggered by a level of 300 picograms per milligram, a level which is one two-thousandth of 600 nanograms. *See* RX 2–3. This suggests that the absolute amounts of cocaine metabolites that are found in hair are three orders of magnitude lower than the amounts which are found in urine. It thus also suggests that there was no inconsistency in Dr. Springfield's testimony.

I thus conclude that Respondent's hair test results do not refute the results of the December 13, 2007 urine sample. I therefore find that sometime shortly before December 13, Respondent ingested cocaine.

Following his positive test for cocaine, Respondent, who had apparently been summoned to appear before the Texas Medical Board, obtained three letters to support his continued licensure. The first of these (dated February 1, 2008) was from J. Douglas Crowder, M.D., a general and forensic psychiatrist who has treated him since July 22, 2005. RX 9. Therein, Dr. Crowder stated that he has treated Respondent eleven times and had "never noted any evidence of substances abuse, intoxication or withdrawal on mental status examination." *Id.* Dr. Crowder further noted that Respondent "has always seem dedicated to his recovery program and quite focused on setting his life aright again after having used cocaine in the past." *Id.* While acknowledging that he could not "know whether [Respondent] has been honest with me or returned to cocaine use," Dr. Crowder wrote that "my clinical impression is that he has been honest and straightforward with me, having freely admitted his past problems." *Id.* Dr. Crowder admitted that he was speaking from a "limited perspective" but then claimed that "all the data available to me indicate that [his] trace positive result in December was a false positive result rather than due to renewed cocaine use." *Id.* Dr. Crowder further stated that "I would consider him fully rehabilitated." *Id.* Of note, however, nowhere in his letter did Dr. Crowder indicate that he had examined Respondent following his positive test.

The second letter (dated February 11, 2008) which Respondent produced was from Rahn K. Bailey, M.D., a board certified psychiatrist, and was addressed to the Texas Board of Medical Examiners. RX 10. Therein, Dr. Bailey stated that he had been seeing Respondent since February 7, 2007, and had done a psychiatric evaluation of him on February 11, 2008. *Id.* According to Dr. Bailey, Respondent's "mental status is within normal limits," "there is no current impairment," and his "[c]ocaine dependence [is] in remission." *Id.* Dr. Bailey further stated that he planned to release Respondent from his care. *Id.* However, Dr. Bailey's letter contains no indication that he was aware that Respondent had failed a drug test just two months earlier. *See id.*

Finally, Respondent produced a letter from Vella V. Chancellor, M.D., the Chair of the Physician's Recovery Committee of the Dallas County Medical Society. RX 11. Dr. Chancellor wrote that Respondent "has been actively seeing our committee since April 2005" and that "[s]ince that time he has complied with every aspect of our committee's goals." *Id.* Dr. Chancellor also stated that in the committee's opinion, Respondent "takes his recovery very seriously and he remains committed to maintaining both his recovery and a healthy medical practice for his patients." *Id.*

On August 15, 2008, the conditions imposed by the August 15, 2003 Agreed Order expired. RX 4. By letter dated August 18, 2008, the Texas Medical Board notified Respondent that "all restrictions and conditions imposed by the Agreed Orders are removed by the expiration of the terms of the Order" and that Respondent's license status was changed to "CL—Board Order Cleared." *Id.*

In his testimony, Respondent testified that when he was notified by the Board of his positive test result, his "jaw dropped to the floor." Tr. 282. Recognizing that the test result "was a death sentence" professionally, Respondent underwent both the hair tests and a polygraph (the latter is not, however, in evidence). *Id.* at 282–83, 313. He further testified that he had "taken almost 400 urine tests" during the period in which he was subject to the Agreed Order and had gone to hundreds of meetings and the Twelve Step Program. *Id.* at 281. He also testified that at the time of the positive test, he was "only eight months away" from completing the Agreed Order, and it would not "make sense for somebody to

relapse" at that point. *Id.* at 283. He then maintained that just as there is "no such thing as one potato chip * * * [t]here's no such thing as one beer, one line," the latter presumably being a reference to cocaine. *Id.*

Later, in response to the ALJ's question as to why his testimony should be believed when he had previously lied to the State Board and submitted a false letter, Respondent acknowledged that he had lied to the Board. *Id.* at 314. Continuing his testimony, he stated:

> Today, I mean, we're talking about not a letter from my ex-girlfriend. We're talking about a letter from specialists that work with the Medical Board, two of them, and a whole panel of physicians.
>
> Are you telling me that I pulled the wool over their eyes and faked them out? Are you telling me that I somehow faked out two hair tests and passed a polygraph test? I must be damned good. I'm that good? And, no. I'm not that good. I'm just being honest. * * * I know what I did, and I'll admit to it. I know what I didn't do, and I'm going to fight for my right.

Id. at 314–15.

The Federal Investigation

Allegations Pertaining to HGH

In June 2006, a U.S. Postal Inspector intercepted a package containing human growth hormone (HGH) which was addressed to R.G., a resident of Fort Worth, Texas, and which had been mailed from an address in Vancouver, Canada. GX 10; Tr. 137. The Postal Inspector contacted R.G., who stated that Respondent was his doctor and that he had obtained a prescription for HGH from him. *Id.* at 137–38.

At the hearing, R.G. testified that sometime in either later 2003 or early 2004, he had heard Respondent discuss testosterone treatment on a radio program. *Id.* at 103–04. Because of his age (45) and the fact that his workouts were not "going well," R.G. thought that he possibly had a low testosterone count and went to see Respondent. *Id.* at 104–05. At R.G.'s first visit, he completed a questionnaire and Respondent performed a physical exam on him and ordered a blood test. *Id.* at 105–06; 125. According to R.G., the blood test showed that he "did have low testosterone." *Id.* at 106. Respondent reviewed the physical exam findings and various treatment options with R.G. *Id.*

After obtaining the blood test results, Respondent put R.G. on testosterone and HGH. *Id.* at 107–08. According to R.G.'s memory, Respondent recommended HGH basically as an "anti-aging" treatment. *Id.* at 108. The record established that Respondent issued R.G. three prescriptions for HGH (on April 23, August 30 and October 7, 2005), the latter one being for Jintropin,[3] and one prescription for testosterone cypionate (on May 10, 2005). *See* GX 9. R.G. also testified as to obtaining additional prescriptions. Tr. 127. However, R.G. testified that Respondent performed blood tests "every six months," and that each time the tests were done, he had a testosterone deficiency. *Id.*

On some date which is not clearly established in the record, R.G. expressed his concern about the cost of the HGH and Respondent provided him with the name of a Web site which could fill his prescriptions and which was located in Vancouver, Canada. GX 9, at 5; Tr. 116–17. R.G. acknowledged that he had ordered HGH from the Web site including the package which was intercepted by the Postal Inspector. *Id.* at 119, 121. R.G. also testified that he had to take the testosterone to Respondent, who was then practicing at the Spa 02, to have it administered. *Id.* at 114. This happened either once a month or every two weeks at most. *Id.* However, as noted above, the record contains but a single testosterone prescription. Nor did the Government introduce R.G.'s patient file to show the duration of Respondent's administration of testosterone to him.

According to an FDA Special Agent, human growth hormone is approved for "short stature for children, AIDS-wasting patients, short bowel syndrome in adults, and there's several other that are pertaining to children's growth." *Id.* at 89–90. More precisely, Genotropin has been approved for: (1) "[l]ong-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone"; (2) "[l]ong-term treatment of pediatric patients who have growth failure due to Prader-Willi syndrome"; (3) "[l]ong-term treatment of growth failure in children born small for gestational age * * * who fail to manifest catch-up growth by age 2"; and (4) "[l]ong-term replacement therapy in adults with growth hormone deficiency * * * of either childhood—or adult onset etiology." *Physicians' Desk Reference* 2738–39 (59th ed. 2005). *See also United States ex rel. Rost* v. *Pfizer, Inc.,* 507 F.3d 720, 723 (1st Cir. 2007).

As noted above, the Government did not introduce into evidence R.G.'s patient file. Nor did it call any expert witness to testify as to whether Respondent had a legitimate medical purpose and acted within the usual course of professional practice in prescribing testosterone to R.G.

As for his prescribing of human growth hormone, Respondent maintained that, while the drug is not approved for anti-aging, it "is approved for adult growth hormone deficiency syndrome," and that his diagnoses of this condition in his patients were "based on a combination of factors" including "clinical symptoms and examination and blood work." Tr. 332. He also testified that R.G.'s blood work and clinical manifestations supported a diagnosis of "somatopause, which is adult growth hormone deficiency syndrome." *Id.* at 337. Here again, to the extent Respondent's prescribing of human growth hormone is even within the authority of this Agency to adjudicate, the Government did not call a medical expert to refute his testimony.

The Government also introduced a document showing additional prescriptions written by Respondent for Genotropin and testosterone cypionate for several other patients and which were dispensed by a Las Vegas, Nevada pharmacy. *See* GX 16. According to a Diversion Investigator, she contacted the five patients whose names were not redacted in the exhibit and "some of them" said that they had received HGH for anti-aging purposes, but she could not recall which ones. Tr. 201–02. Moreover, the Government did not produce any evidence that the prescriptions for testosterone were unlawful. Finally, when asked with respect to these five patients, whether there is anything "illegal * * * about these drugs," the DI testified that "there [was] nothing illegal about" Respondent's prescribing them "[i]f he has a doctor-patient relationship with these patients" and that she had verified that he did. *Id.* at 245. *See also id.* at 164 (testimony of another DI that she could not testify as to the legality of Respondent's prescribing of Somatropin, another HGH product).

[3] The parties stipulated that Jintropin is a form of HGH, which has not been approved by the FDA for use in the United States. ALJ Ex. 8, at 2. According to an FDA Special Agent, Jintropin is manufactured in China. Tr. 90. According to the DI, during an interview Respondent stated that he had prescribed Jintropin because "it was cheaper." *Id.* at 153. The DI further testified that Respondent "was unaware" that Jintropin "was not DEA approved." *Id.* DEA does not, however, approve drug products. The DI also testified that she did not know whether Respondent knew that Jintropin was made in China. *Id.*

In his testimony, Respondent stated that he did not know that Jintropin was not FDA approved and "apologized for that." *Id.* at 316. Respondent explained that it was his understanding that "Jintropin was a generic type of HGH." *Id.* Respondent then testified: "I understand ignorance is not an excuse, but that's the truth." *Id.* He maintained, however, that "[t]he only reason I prescribed the Jintropin in a few circumstances * * * was because it was less expensive." *Id.* at 317. Respondent then stated that he was no longer practicing anti-aging medicine, and had stopped doing so in "early 2007." *Id.* at 319 & 326–27.

On some date not established by the record, the Texas Medical Board ("Board") also commenced an investigation into Respondent's prescribing of Jintropin. *See* RX 7. On February 9, 2009, Respondent entered into an Agreed Order with the Board. *See* RX 12, at 9. Therein, the Board found that "respondent prescribed Jinotropin, a non-FDA-approved human growth hormone * * * to a single patient without verifying the substance was FDA approved." *Id.* at 2. The Board did not, however, find that Respondent's prescribing of HGH for anti-aging purposes was a violation of the Texas Medical Practice Act and the Board's rules. *See id.* at 1–3.

The Board ordered that Respondent "take and pass" the "Medical Jurisprudence Examination" which is administered by the Board, and that his failure to do so within one year of the order would subject his state license to an immediate suspension without a hearing. *Id.* at 3. The Board also ordered that Respondent "successfully complete 10 hours of Continuing Medical Education * * * in the area of ethics," and that his practice be monitored by a physician approved by the Board's Compliance Division, who is to review selected medical and billing records. *Id.* at 4. The Board further ordered that Respondent "pay an administrative penalty in the amount of $4000." *Id.* at 5.

Allegations Pertaining to Respondent's Controlled Substance Prescribing and Failure To Update His Registered Location

The Government also alleged that Respondent dispensed narcotics for narcotic treatment purposes without holding the authorization required by 21 U.S.C. 823(g) and 21 CFR 1301.13. In support of the allegation, the Government introduced into evidence several prescriptions which Respondent issued to D.M. for methadone (10 mg.), a schedule II control substance. *See* GX 11, at Tab E; *see also* 21 CFR 1308.12(c). According to a DEA Diversion Investigator, D.M. told her that before Respondent agreed to treat him, he had gone to several other doctors who wrote him prescriptions for OxyContin in "enormous amounts," and that Respondent agreed to prescribe methadone and "told him that eventually he would be able to lower his doses, because he was so addicted to the OxyContin." Tr. 188–89. However, D.M. told the DI that he had previously injured his back and suffered back pain. *Id.* at 188 & 232.

According to the DI, upon being questioned about his treatment of D.M., Respondent "told us that he weaned patients" off of narcotics. *Id.* at 251. She further testified that she understood this statement to mean that Respondent was treating drug addicts. *Id.* at 252. Respondent does not hold a registration to conduct a narcotic treatment program, and is not authorized to treat and detoxify patients with Suboxone. *Id.* at 190–91.

On cross-examination, the DI testified that when she interviewed D.M., she could not determine that he was addicted and that he had told her that Respondent was prescribing methadone to him for pain and that D.M. "felt like he was functioning." *Id.* at 232–33. The DI also testified that she subpoenaed D.M.'s records, and that she believed D.M.'s statement that the methadone was being prescribed for legitimate pain management. *Id.* at 233. The DI then admitted that she does not "have the expertise to determine" whether D.M. was a legitimate chronic pain patient. *Id.* at 254–55.

D.M. testified as a witness for Respondent. D.M. stated that he had undergone three back surgeries and that another physician had been prescribing methadone to him for pain management for several years when he met Respondent.[4] *Id.* at 490–91. While D.M. testified that Respondent did not ask him to provide his medical records, he further stated that Respondent performed a physical examination on him which included checking his blood pressure and lungs, having him touch his toes, and feeling the area where either a TENS unit or a stimulator had been placed in his back. *Id.* at 504, 506, 508. D.M. also stated that Respondent had successfully tapered his methadone dosage from 160 mg. to 60 mg. and that he was now "able to do a lot of things" that he could not do previously. *Id.* at 492–93.

Respondent likewise testified that D.M. was being treated with methadone "for chronic pain" and "not for heroin addiction." *Id.* at 343. While he acknowledged having used "the word 'wean' " in discussing his treatment of D.M., he maintained that he was not "running a methadone clinic," *id.,* that D.M. was already on methadone (160 mg.) when he first saw him, and that he had tried to find the right balance between controlling D.M.'s pain and maximizing his ability to function. *Id.* at 341.

The Government did not introduce into evidence D.M.'s medical records. Nor did it elicit any expert testimony probative of whether Respondent's prescribing to D.M. was lawful under Federal law. Based on the record as a whole, I find that Respondent issued the methadone prescriptions to treat D.M.'s chronic pain and not to provide either maintenance or detoxification treatment for him.

The Government also elicited testimony regarding Respondent's prescribing of hydrocodone, a schedule III controlled substance, to D.C., and clonazepam, a schedule IV controlled substance, to R.S. *Id.* at 194–96; *see also* GX 18. A DI asserted that both of these individuals were residents of Seidler House, a halfway house which forbids its residents from being prescribed controlled substances. Tr. 196.

While J.S., the assistant director of Seidler House, testified that it does not accept persons who are "not clean and sober," *id.* at 516, he further stated that Respondent had "never" prescribed a controlled substance to a resident. *Id.* at 524–25. J.S. also testified that D.C., who had received a single hydrocodone prescription from Respondent, "was a full-time staff member," and that he believed that the script was to treat pain caused by a staph infection which D.C. developed and for which he was hospitalized for thirty days.[5] *Id.* at 525. J.S. testified that R.S. had become an employee a month or so before he saw Respondent, and that in any event, it was standard procedure that "a staff member could not get anything from [Respondent] without the director knowing and having it locked" up and monitored to "make sure it was dispensed according to the prescription." *Id.* at 530. J.S. reiterated that to his knowledge, Respondent never violated the halfway house's policy by prescribing controlled substance to a resident. *Id.* at 530–31. According to Respondent, he prescribed the clonazepam to R.S. for anxiety, the prescription was documented in a medical record, and the drug was "put in a lock box" at Seidler House. *Id.* at 349.

Here again, there is no evidence that Respondent's controlled substance prescriptions to either D.C. or R.S. were unlawful. Finally, J.S. testified that Respondent was awarded several plaques for his service to Seidler House.

[4] D.M. worked at a halfway house for probationers where Respondent had performed community service and then volunteered.

[5] Respondent had earlier testified that he had prescribed fifteen tablets of hydrocodone to D.C. for acute back pain caused by a disk problem, which was kept in a lock box at Seidler House. Tr. 347. Respondent's testimony regarding the size of the prescription is corroborated by the actual prescription. GX 18. Respondent also stated that he had prescribed antibiotics to D.C. Tr. 347. He also testified that he discussed any controlled substance prescriptions with the owner of Seidler House. *Id.* at 348.

The Government also alleged that Respondent failed to keep his registered address current. ALJ Ex. 1, at 1. As found above, Respondent was registered at 4300 MacArthur Ave, Suite 265, Dallas, Texas from October 28, 2004, through July 24, 2007, when his registered location was changed to 1901 Central Drive, Suite 805, Bedford, Texas. GX 11, at 5. There is evidence that Respondent wrote controlled substance prescriptions while he was practicing at other addresses. *See id.* at Tab B (prescriptions using address of 1032 West Pioneer Parkway, Arlington, Texas); *id.* at Tab D (prescriptions using address 1701 Legacy Drive, Suite 100, Frisco, Texas)[6]; *id.* at Tab E (prescriptions using address of 2735 Villa Creek, Suite 110 C, Dallas, Texas). There was also testimony that Respondent administered testosterone to R.G. at the Spa O2 clinic because R.G. had difficulty injecting himself. Tr. 114. However, the evidence shows that R.G. obtained the testosterone through a prescription, which suggests that he brought it with him to the clinic, and in any event, there is no evidence that Respondent ordered controlled substances which were delivered to, and stored at, the clinic.

The evidence also established that Respondent did not own the Spa O2 clinic, but was merely associated with it. *Id.* at 94. There is, however, no evidence establishing who owned this clinic and whether the clinic was owned by a registered practitioner.

During an interview with a DI, Respondent admitted to practicing at these locations. *Id.* at 153–55. While he had no explanation for why he had not kept his practice locations current, he "apologized for not having done so." *Id.* at 155. Moreover, at the hearing, Respondent testified that while he mainly practiced at the MacArthur address, having previously lost his medical license, he was "in the process of rebuilding" his practice and "moonlighted" at "multiple places." *Id.* at 270. He further testified that he had notified the Texas authorities whenever he changed his practice location, and had "simply overlooked" the DEA registration. *Id.* at 271. Respondent then testified: "I apologize for it, and it will never happen again." *Id.*

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). Moreover, "the Attorney General may deny an application for [a practitioner's] registration if he determines that the issuance of such registration would be inconsistent with the public interest." *Id.* § 823(f). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

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

(2) The applicant's experience in dispensing * * * controlled substances.

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

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

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

Id. § 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 may give each factor the weight [I] deem [ ] appropriate in determining whether a registration should be revoked." *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 (DC Cir. 2005).

As explained below, having considered all of the factors, I adopt the ALJ's ultimate conclusion that Respondent's continued registration is inconsistent with the public interest and that his registration should be revoked. However, the only misconduct proved on this record involves Respondent's self-abuse of a controlled substance. Accordingly, while I conclude that the revocation of Respondent's registration is necessary to protect the public interest, I further order that in the event Respondent undergoes and successfully completes in-patient treatment as well as additional random drug testing, which shall be at his own expense, the Agency shall give favorable consideration to a new application after a period of one year from the effective date of this Order.[7]

Factor One—The Recommendation of the State Licensing Board

At the outset, it should be noted that the Texas Medical Board has not made a formal recommendation as to what action this Agency should take in this matter. However, DEA precedents have typically taken a broader view as to the scope of this factor. *See Edmund Chein,* 72 FR 6580, 6590 (2007).

As the record demonstrates, Respondent is no stranger to the disciplinary proceedings conducted by the Texas Medical Board. As found above, Respondent and the Board have entered into several agreed orders which have imposed extensive conditions on him. The Board, however, has allowed the 2003 Agreed Order to expire notwithstanding Respondent's failed drug test and Respondent is currently authorized to practice medicine in Texas and presumably is authorized to handle controlled substances.[8]

Although Respondent's licensure status satisfies an essential requirement for holding a registration under CSA, this Agency has repeatedly held that possessing a valid state license is not dispositive of the public interest inquiry. *See Patrick W. Stodola,* 74 FR 20727, 20730 (2009); *Robert A. Leslie,* 68 FR 15227, 15230 (2003). While the Board has allowed the 2003 Agreed Order to expire, as explained more fully below, the evidence presented in this case shows that Respondent still has a cocaine problem. Accordingly, I decline to treat the Board's action as a recommendation to continue Respondent's registration. I therefore adopt the ALJ's conclusion that this factor neither "weigh[s] for or against [the] determination" that Respondent's continued registration is consistent with the public interest. ALJ at 24.

[6] This was the address of the Spa O2 clinic. Tr. 145.

[7] In his Exceptions, Respondent argues that the ALJ erred in finding that an Agency DI was not biased against him. Exceptions at 3. He also maintains that the DI violated his rights to procedural due process because she told his counsel that he "could not prescribe controlled substances until further notice from the" Agency. *Id.*

In light of my rejection of all the allegations with the exception of those pertaining to Respondent's failed drug test, there is no need to address the contention that the DI was biased against him. As for the second contention, the DI's advice was not a formal order of the Agency and does not rise to the level of a constitutionally significant deprivation of a property interest.

[8] Texas requires that a practitioner obtain a state-issued controlled substances registration. There is no evidence in the record as to the status of Respondent's registration.

Factors Two, Four, and Five—Respondent's Experience in Dispensing Controlled Substances, Record of Compliance With Laws Relating to Controlled Substances and Such Other Conduct Which May Threaten Public Health and Safety

Reasoning that "[m]any of the Respondent's controlled substance prescribing practices impact not only Factor 2 * * *, but also Factors 4 * * * and 5[,]" the ALJ combined these three factors in his analysis of the Government's case. ALJ at 28. While the ALJ correctly rejected the Government's allegation pertaining to Respondent's prescribing of methadone, he erroneously concluded that Respondent's prescribing of human growth hormone violated the CSA's prescription requirement. *See* ALJ at 30. His further conclusion that Respondent's prescribing of human growth hormone could be considered under factor five is not supported by Agency precedent, has been previously rejected—at least implicitly—by the Agency, and would require this Agency to exercise authority which the Supreme Court has made clear it does not possess.

The ALJ did, however, correctly conclude that Respondent's history of cocaine abuse should be considered under factor five. Moreover, I also concur with the ALJ's conclusion that Respondent still does not accept responsibility for his cocaine addiction.

Respondent's Prescribing Practices

As noted above, at the hearing, the Government put on evidence regarding three different aspects of Respondent's prescribing practices: (1) His prescribing of controlled substances to two persons who allegedly were residents of Seidler house; (2) his prescribing of methadone to D.M., which it alleges constituted "dispensing narcotic drugs for narcotic treatment without the" authorization required by 21 U.S.C. 823(g) and 21 CFR 1301.13; and (3) his prescribing of human growth hormone for anti-aging purposes.

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-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007).

The Government put on evidence (which included both testimony and documentary evidence) establishing that Respondent prescribed hydrocodone (totaling 15 tablets) to D.C., and clonazepam to R.S., both of whom it alleged were residents of Seidler House. Apparently, the Government found this inappropriate because Seidler House has a policy which forbids its residents from being prescribed controlled substances. Yet the Government produced no evidence that either prescription lacked a legitimate medical purpose or that Respondent acted outside of the usual course of professional practice in prescribing to these individuals. 21 CFR 1306.04(a). Thus, the Government has failed to show that Respondent violated Federal law in issuing the prescriptions.[9]

Having failed to put on any evidence relevant to whether these prescriptions violated Federal law, perhaps the Government's theory was (as notwithstanding the evidence it introduced on the issue, its brief sets forth no legal theory) that Respondent's prescribing to these persons is actionable as "other conduct which may threaten public health and safety" because Seidler House's policy forbade its residents from being prescribed controlled substances. 21 U.S.C. 823(f)(5). However, even assuming that this conduct is properly considered under this factor, I would still reject the contention because the Government failed to show that either person was a resident of Seidler House at the time Respondent prescribed to them.

The Government also put on evidence regarding Respondent's methadone prescriptions to D.M. Apparently, this evidence was the basis of the Show Cause Order's allegation that Respondent was engaging in narcotic treatment without the authorization required under 21 U.S.C. 823(g) and 21 CFR 1301.13. ALJ Ex. 1, at 2. As noted above, the ALJ properly rejected this allegation as unsupported by substantial evidence.

Under Federal law, "practitioners who dispense narcotic drugs [in schedule II] to individuals for *maintenance treatment or detoxification treatment* shall obtain annually a separate registration for that purpose." 21 U.S.C. 823(g)(1)(A) (emphasis added).[10] While this provision requires a separate registration when a practitioner seeks to dispense methadone for the purpose of providing maintenance or detoxification treatment for a patient, a practitioner may nonetheless lawfully prescribe

[9] It is noted that this conduct was not alleged in the Show Cause Order and that the Government did not disclose that it intended to pursue these allegations in either of its pre-hearing statements. *See CBS Wholesale Distributors,* 74 FR 36746, 36750 (2009). Respondent did not, however, object to this line of inquiry.

[10] To obtain this registration, a practitioner must meet three main requirements. First, the Secretary of the Department of Health and Human Services must determine that he is "qualified (under standards established by the Secretary) to engage in" either maintenance or detoxification treatment. 21 U.S.C. 823(g)(1)(A). Second, the Attorney General must determine that he "will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with [21 U.S.C. 827]) on such drugs." *Id.* § 823(g)(1)(B). Third, the Secretary must "determine[] that the applicant will comply with standards * * * respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment." *Id.* § 823(g)(1)(C).

methadone to a patient for pain management purposes under his practitioner's registration. *Id.* § 823(f).

Notwithstanding the DI's testimony that D.M. had told her that he was addicted to OxyContin, there is no expert evidence establishing that D.M. was a drug addict (as opposed to a patient who, over time, developed opioid tolerance and required greater doses). Moreover, notwithstanding that Respondent used the word "wean" to describe his treatment of D.M., even the DI testified that she believed that D.M., who had undergone three back surgeries, was a legitimate chronic pain patient.

While methadone is approved by the FDA, and has long been used, for the treatment of opioid addiction, *see* 42 CFR 8.12(h)(2), the drug is also approved for the treatment of pain. *See* FDA, *Information for Healthcare Professionals Methadone Hydrochloride* (FDA Alert Nov. 2006). Moreover, the record contains no expert evidence showing that Respondent's prescribing of methadone was inconsistent with accepted medical practice for prescribing the drug for pain management. Indeed, it would seem that reducing the daily total dosage of a narcotic which a patient needs to take to achieve adequate pain control while allowing him to function is fully consistent with accepted medical practice. The allegation is therefore not proved.

Finally, the Government put on extensive evidence regarding Respondent's prescribing of human growth hormone. Moreover, in its closing argument, the Government argued that the evidence showed that Respondent had prescribed to five patients "human growth hormone for its anti-aging effects, and of course, that is an illegal, nonapproved use." Tr. 576.

In his decision, the ALJ explained that "human growth hormone is not a controlled substance within the meaning of the CSA and is controlled by the" Anabolic Steroids Control Act. ALJ at 30. He further observed that "Respondent's issuance of a prescription for the substance for purposes other than FDA-approved uses does not fall squarely within the purview of the criminal statute."[11] *Id.* Citing the CSA's prescription requirement (21 CFR 1306.04(a)), the ALJ then explained: "However, because he issued prescriptions for human growth hormone for unauthorized uses and for Jintropin for any use, he violated federal law by issuing prescriptions outside the usual course of a professional practice." *Id.*

The ALJ's reasoning is erroneous for two reasons: First, it fails to recognize that the CSA's prescription requirement—in keeping with the limited authority the CSA grants the Attorney General, *see Gonzales* v. *Oregon,* 546 U.S. 243 (2006)—applies only to prescriptions for controlled substances. Indeed, the text of the regulation could not make this clearer. *See* 21 CFR 1306.04(a). As pertinent here, the regulation states:

> A prescription *for a controlled substance* to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing *of controlled substances* is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

21 CFR 1306.04(a) (emphasis added). *See also* 21 U.S.C. 802(6) ("The term 'controlled substance' means a drug or other substance or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter.").

Second, while criminalizing conduct is a form of control, *see Merriam-Webster's Collegiate Dictionary* 252 (10th ed. 1998), the ALJ failed to recognize that, under the CSA, the term "control" is a term of art which has been statutorily defined. *See* 21 U.S.C. 802(5) (defining "[t]he term 'control' [to] mean[] to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise").

Thus, while Congress criminalized certain conduct related to the distribution of human growth hormone in the Anabolic Steroid Control Act of 1990, most significantly, it did not include human growth hormone when it amended the CSA to include anabolic steroids as schedule III controlled substances. Anabolic Steroids Control Act of 1990, Public Law 101–647, 104 Stat. 4851–52 (1990) (codified at 21 U.S.C. 802(41)(A)). Indeed, the House Report, which accompanied the legislation, specifically noted in several places that "[h]uman growth hormone * * * is often mistakenly considered an anabolic steroid." H. Rep. No. 101–681(I), at 95 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 6472, 6499. *See also id.* at 97, *as reprinted in* 1990 U.S.C.C.A.N. at 6501 ("Human growth hormone, often mistakenly considered an anabolic steroid, is defined as 'somatrem, somatropin or an analogue of either of them.'").

Thus, contrary to the ALJ's understanding, human growth hormone was not—unlike anabolic steroids—"controlled by the ASCA." Moreover, the House Report makes clear that the ASCA's human growth hormone provision "amend[ed] * * * the Food, Drug and Cosmetic Act," and not the CSA. Because it is not a controlled substance, Respondent's prescribings of human growth hormone could not have violated the CSA's prescription requirement. The conduct is therefore not relevant in assessing either his experience in dispensing contorlled substances or his record of compliance with laws related to controlled substances.

Factor five authorizes the Agency to consider "such other conduct which may threaten public health and safety." 21 U.S.C. 823(f)(5). The ALJ correctly recognized that this factor authorizes the Agency to consider "a somewhat broader range of conduct reaching beyond those activities typically" associated with a registrant's practices in dispensing controlled substances, ALJ at 31, and encompasses "wrongful acts relating to controlled substances committed by a registrant outside of his professional practice but which relate to controlled substances." *David E. Trawick,* 53 FR 5326, 5327 (1988). The Agency has thus long held that "all wrongful acts relating to controlled substances committed by a registrant can be taken into consideration by the Administrator when deciding whether to allow that registrant to retain the privileges granted him by a DEA Certificate of Registration." *Id.* However, our cases have established that for conduct to be actionable under factor five, there must be a substantial relationship between the conduct and the CSA's purposes of preventing drug abuse and diversion, and that the conduct may constitute a threat to public health and safety.[12]

[11] The ALJ did not clarify whether "the criminal statute" he was referring to was the CSA or 21 U.S.C. 333(e), the provision of the Food, Drug and Cosmetic Act, which criminalizes the "knowing[] distribut[ion] * * * [of] human growth hormone for any use in humans other the treatment of a disease or other recognized medical condition, where such used has been authorized by the Secretary of Health and Human Service under [21 U.S.C. 355] and pursuant to the order of a physician."

[12] In his decision, the ALJ stated that "an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety." ALJ at 31 (citing *Holloway Distributing,* 72 FR 42118, 42126 (2007)). *Holloway* involved a list I chemical distributor, and as such, a different standard applied. *See* 21 U.S.C. 823(h)(5) (directing the consideration of "such other factors as are relevant to and consistent with public health and safety"). Moreover, no case of the Agency holds that the conduct must constitute an "actual threat," a reading which is at odds with Congress' inclusion of the word "may" in the text of factor five. *See Merriam-Webster's Collegiate Dictionary* at 719 (defining "may" to mean in part: "used to indicate possibility or probability").

Reasoning that "[i]t would be difficult to conceive of a scenario that hits closer to the mark of a dangerous prescribing practice than the prescribing of substances for purpose that have not been approved by the FDA and the prescribing of a substance not approved for any purpose by the FDA," the ALJ concluded that Respondent's prescribing of human growth hormone was "relevant under factor five." ALJ at 31. The ALJ's reasoning reflects a fundamental misunderstanding of legitimate medical practice and would embark this Agency on a function it has no authority to engage in.

Most significantly, even assuming that prescribing human growth hormone for anti-aging purposes threatens public health and safety and that prescribing it for this off-label use violates Federal law, the ALJ erred in considering this conduct because he failed to identify how Respondent's prescribing of human growth hormone is related to controlled substances. While the record establishes that Respondent also prescribed testosterone to various patients who were receiving HGH, there is *no evidence* that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the testosterone prescriptions. Moreover, that Respondent may have issued the HGH prescriptions concurrent with his issuance of testosterone prescriptions does not establish a substantial relationship to controlled substances.[13]

To be sure, Agency decisions have at times discussed a practitioner's prescribing of non-controlled drugs to provide factual context. *See, e.g., Paul H. Volkman,* 73 FR 30630, 30633–34, 30636–37 (2008) (discussing physician's prescriptions for drug cocktails which included opioids and benzodiazepines (both of which are controlled) and carisoprodol (which is not controlled)); *Edmund Chein,* 72 FR 6580, 6582 (2007) (discussing physician's distribution of HGH to undercover operatives). Yet in neither of these decisions did the Agency hold that it has authority to adjudicate the medical propriety of a physician's act in prescribing a non-controlled drug.

In *Chein,* my discussion of Respondent's dispensing violations focused entirely on the physician's prescribing of controlled substances and did so notwithstanding that the evidence showed that the physician had distributed HGH to an undercover operative who sought the substance for athletic enhancement. *Compare* 72 FR at 6582, *with id.,* at 6590. To similar effect, in *Volkman,* notwithstanding the evidence that the physician had issued prescriptions for carisoprodol, my discussion of the lawfulness of his prescribing practices was based solely on his controlled substance prescriptions. *See* 73 FR at 30642–43. In short, DEA has never held that a practitioner's prescribing practices with respect to non-controlled substances provide an independent basis for concluding that the practitioner has engaged in conduct which may threaten public health and safety and has thus committed acts inconsistent with the public interest.

This is for good reason as the CSA does not grant this Agency the sweeping authority suggested by the ALJ's decision and, in particular, by his reasoning that prescribing a drug for a non-approved use constitutes "a dangerous prescribing practice." ALJ at 31. As the Supreme Court explained in *Gonzales,* the CSA and its case law "amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally[,]" an authority which remains vested in the States. 546 U.S. at 270. Moreover, to the extent the "[t]he CSA allocates decision making powers among statutory actors * * * medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary." *Id.* at 265.[14]

It is acknowledged that the medical judgment at issue here—the propriety of prescribing HGH for anti-aging purposes—may have already been decided by Congress. *See* 21 U.S.C. 333; *but see United States ex rel. Rost* v. *Pfizer, Inc.,* 507 F.3d at 723 (dictum stating that "[p]hysicians may prescribe Genotropin for non-FDA-approved indications, but the Food, Drug & Cosmetic Act * * * prohibits pharmaceutical companies from marketing drugs for such 'off-label' uses"). Yet neither the Government nor the ALJ cited any judicial authority definitively construing the statute as prohibiting a physician from prescribing HGH for anti-aging purposes. Likewise, neither the Government nor the ALJ cite any definitive construction of the Food, Drug and Cosmetic Act (FDCA) by the Secretary or her authorized delegatee holding that a physician who acts in good faith violates 21 U.S.C. 333(e) if he prescribes HGH for anti-aging purposes. In any event, what is clear is that because DEA is not charged with administering the FDCA, I have no authority to definitively interpret that statute, and/or to declare the practice of prescribing HGH for anti-aging purposes to be a violation of Federal law. Accordingly, the propriety of Respondent's prescribing of HGH is outside of the Agency's authority to adjudicate.[15]

However, DEA has long held that a practitioner's self-abuse of a controlled substance is a relevant consideration under factor five and has done so even when there is no evidence that the registrant abused his prescription writing authority. *Trawick,* 53 FR at 5326. Moreover, DEA has revoked registrations and/or denied applications for a registration even where there is no evidence that the practitioner committed acts involving unlawful distribution to others. *See, e.g., Kenneth Wayne Green, Jr.,* 59 FR 51453 (1994); *Allan L. Gant,* 59 FR 10826 (1994); *William H. Carranza,* 51 FR 2771 (1986).

As found above, in December 2007, Respondent gave a urine sample which twice tested positive for cocaine. As the ALJ noted, Respondent did not challenge either the chain of custody for his sample or the validity of the procedures used by the labs which tested his samples. Nor did he put on any evidence pertaining to the rate of false positives using the labs' testing procedures. Instead, he twice submitted hair samples. While his hair samples were negative, as the Government's expert testified, these tests neither confirm nor refute the urinalysis results. Accordingly, substantial evidence supports the conclusion that he ingested cocaine in December 2007.

In his testimony, Respondent maintained that it would not make sense for him to relapse with only eight months remaining on the Agreed Order

[13] Nor is there any expert testimony establishing what a physician must do to diagnose whether an adult patient has a human growth hormone deficiency.

[14] *See also* 546 U.S. at 268 ("Under the Government's theory, * * * the medical judgments the Attorney General could make are not limited to physician-assisted suicide. Were this argument accepted, [the Attorney General] could decide whether any particular drug may be used for any particular purpose, or indeed whether a physician who administers any controversial treatment could be deregistered.").

[15] The Government does not cite any judicial authority establishing that the issuance of a prescription for a non-FDA approved drug, which is made in a foreign country, by itself, constitutes a violation of Federal law. Nor does this case raise the question of whether a criminal conviction for either illegally distributing or importing (or conspiring to distribute or import) a non-controlled drug such as HGH can be considered under Factor Five.

and raised the Lays' defense that there is no such thing as just one line of cocaine. Respondent also contended that he had been subjected to some 400 other tests, which he implied that he had passed.

The short answer to these contentions is that none of them refute the urinalysis results.[16] Rather, what Respondent's testimony suggests is that he still has a problem with cocaine abuse which he refuses to acknowledge.

It is acknowledged that after his positive test result, Respondent procured several letters (including two from psychiatrists who treated him) which supported his continued licensure. However, none of the letters' authors testified in this proceeding. Accordingly, the basis of their opinions was not subject to cross-examination. Moreover, each of the letters from Respondent's treating psychiatrists raises issues as to the basis for their respective opinions. For example, while Dr. Crowder's letter stated that Respondent had visited him eleven times since July 22, 2005, and that "[d]uring this entire time, I have never noted any evidence of substance abuse, intoxication or withdrawal on mental status examination," RX 9, Dr. Crowder did not indicate when he had last examined Respondent. And as Dr. Crowder acknowledged in his letter: "Of course, I cannot know whether he [Respondent] has been honest with me or returned to cocaine use." *Id.* Moreover, Dr. Crowder acknowledged that he was "speaking from a limited perspective." *Id.*[17] Thus, his letter does not establish that Respondent has successfully rehabilitated himself.

Dr. Bailey's letter stated that he had performed a psychiatric evaluation of Respondent on February 11, 2008, and found that his "mental status is within normal limits" and that "there is no current impairment." RX 10. Dr. Bailey also found that Respondent's "[c]ocaine dependence [was] in remission," and he planned to release Respondent from his care. *Id.* However, there is no indication in the letter that Dr. Bailey was aware of Respondent's failed drug test from two months earlier, which would seem to be critical information for determining whether his cocaine dependence is in remission. Accordingly, while this letter is somewhat more probative of Respondent's condition, I conclude that it is not dispositive of whether he has a continuing problem with cocaine abuse.[18]

In any event, the record establishes that Respondent has illicitly used cocaine on at least three separate occasions including once in the recent past and that he has also abused alcohol in violation of the Board's order. Moreover, the record also establishes that Respondent lied to the State Board and went so far as to produce a false written statement that his positive test was the result of his ex-girlfriend's having spiked a drink. Given this record, the ALJ's skepticism of Respondent's rehabilitative efforts was entirely warranted. Furthermore, Respondent's cocaine abuse provides reason alone to conclude that he has committed acts which render his continued registration inconsistent with the public interest and which justify the revocation of his registration.[19]

"Proceedings under sections 303 and 304 of the CSA, however, are non-punitive." *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (citing *Leo R. Miller,* 53 FR 21931, 21932 (1988)). DEA has repeatedly recognized that "this proceeding 'is a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be [en]trusted with the responsibility'" that attaches with a registration. *Id.* (quoting 53 FR at 21932).

Consistent with these principles, where the only misconduct proved on the record involves self-abuse, this Agency has frequently granted a new registration to those practitioners who undergo treatment and thereafter demonstrate their continued sobriety. *See Steven M. Abbadessa,* 74 FR 10077 (2009); *Scott H. Nearing,* 70 FR 33200 (2005); *Vincent J. Scolaro,* 67 FR 42060 (2002). Therefore, while I revoke Respondent's registration, I further hold that in the event he undergoes inpatient treatment for his substance abuse problem, demonstrates his continued sobriety for a period of one year from the effective date of this Order, and does not engage in any other misconduct related to controlled substances during this period,[20] favorable consideration should be given to an application for a new registration which is submitted at the conclusion of this period. Moreover, as a condition of receiving a new registration, Respondent must agree to undergo random drug testing for a period of three years which shall begin on the date any new registration is issued to him.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a)(4), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, BB8997857, issued to Tony T. Bui, M.D., be, and it hereby is, revoked. I further order that any pending application to renew or modify the registration be, and it hereby is, denied.

[16] While Respondent may have taken 400 tests during the period of the Agreed Order, as found above, he also tested positive for cocaine in October 2003, as well as alcohol (which he was also prohibited from consuming under the Agreed Order) in March 2005, and had also failed to call in to determine whether he was required to submit a sample.

[17] Dr. Crowder also indicated that "all data available to [him] indicate that [Respondent's] trace positive result in December was a false positive." RX 9. Putting aside that the result did not appear to be a trace positive—as it was four times the minimum detection limit using the GC/MS Confirmation, *see* GX 8, at 5; Dr. Crowder did not explain exactly what data he reviewed and whether it included any of the data from the actual lab tests of Respondent's urine sample.

[18] Having reviewed the letter from Dr. Chancellor on behalf of the Physician Recovery Committee, I conclude that it does not constitute a clinical evaluation of Respondent's condition and give it no weight.

[19] There is also evidence that Respondent practiced at various locations without updating his registration to reflect that he was doing so. However, under DEA's regulation, a practitioner is not required to obtain a registration for "[a]n office used by a practitioner (who is registered at another location in the same State * * *) where controlled substances are prescribed but neither administered nor otherwise dispensed *as a regular part* of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained." 21 CFR 1301.12(b)(3) (emphasis added).

With the exception of the Spa 02 clinic, the Government produced no evidence that he did anything other than write prescriptions at these offices. Although there is evidence that Respondent administered testosterone at the Spa 02 clinic, the only evidence of this activity produced by the Government pertains to a single patient, R.G. While there was evidence to the effect that the administrations occurred either once a month or every two weeks at most, Tr. 114, the Government produced only a single testosterone prescription written by Respondent for R.G. and did not introduce his medical record. Thus, the evidence does not establish the duration of Respondent's administration of testosterone to him.

Furthermore, the evidence suggests that R.G. brought the testosterone with him to the clinic and there is no evidence that Respondent maintained supplies of any controlled substance at the clinic. The Government has therefore failed to show that Respondent administered controlled substances "as a regular part of [his] professional practice" at this office. 21 CFR 1301.12(b)(3). I therefore hold that Respondent was not required to be registered at this location.

Moreover, the Government produced no evidence to refute Respondent's testimony that while he was moonlighting at these other offices, he was mainly practicing at the MacArthur office. Thus, it is clear that he was registered within the State of Texas and was in compliance (based on this record) with the regulation. The allegation therefore fails.

[20] To make clear, Respondent (and not this Agency) is responsible for the costs of any treatment program as well as demonstrating his sobriety including drug testing both before and during the period of any new registration.

This order is effective September 15, 2010.

Dated: July 30, 2010.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–26]

Beverley P. Edwards, M.D.; Revocation of Registration

On January 21, 2010, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Beverly P. Edwards, M.D. (Respondent), of Indianapolis, Indiana. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BE8619667, and the denial of any pending applications to renew or modify her registration, on the ground that Respondent's "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)).

The Show Cause Order specifically alleged that Respondent was prescribing controlled substances over the Internet based on "online questionnaires and/or webcam consultations and without first conducting an in person physical examination" and that she lacked a "legitimate medical purpose" and acted "outside the usual course of professional practice" in issuing the prescriptions in violation of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1). *Id.* at 2. Next, the Order alleged that while Respondent is licensed to practice medicine in only the States of Indiana, California and New York, she was prescribing controlled substances to persons throughout the United States from her residence in Texas, where she is not licensed, and was engaged in the unauthorized practice of medicine in violation of the laws of Texas, as well as the various States where the patients resided. *Id.* (citations omitted). Relatedly, the Order alleged that Respondent was using her "DEA registration to prescribe controlled substances from locations outside of the State [Indiana] where [she is] registered with DEA, in violation of 21 CFR 1301.12(a) & (b)(3)." *Id.* Finally, the Show Cause Order alleged that Respondent was authorizing refills of schedule II controlled substances in violation of 21 U.S.C. 829(a). *Id.*

Based on the above, I concluded that Respondent's continued registration during the pendency of the proceeding would "constitute[] an imminent danger to the public health and safety." *Id.* I therefore invoked my authority under 21 U.S.C. 824(d) and immediately suspended Respondent's registration. *Id.* at 2–3.

On January 25, 2010, Respondent requested a hearing on the allegations and the matter was placed on the docket of the Agency's Administrative Law Judges. Thereafter, on February 2, 2010, the Government moved for summary disposition contending that on January 29, 2010, the State of Indiana had summarily suspended Respondent's state medical license effective January 28, 2010, as well as her state controlled substances registration. Mot. for Summary Disp. at 1. The Government also noted that on February 2, the State had issued an amended order which summarily suspended her state medical license, which was also effective on January 28, 2010.[1] *Id.* As support for its motion, the Government attached copies of the various state suspension orders as well as other documents. Based on Respondent's lack of authority under state law to dispense controlled substances in Indiana, the State in which she holds her DEA registration, the Government requested that the ALJ issue a decision recommending that Respondent's registration be revoked. *Id.* at 2–3.

Thereafter, the ALJ issued an Order for Respondent's Response to the Government's Motion and gave Respondent until February 10, 2010 to file a response. Subsequently, on Respondent's motion, the ALJ granted her an extension until February 22 to file her pleading.

On February 18, Respondent filed her Response. Therein, Respondent did not dispute that she "currently lacks the authority to handle controlled substances in the State of Indiana, the jurisdiction in which until February 2, 2010 she was duly licensed." Response to Gov. Mot. for Summ. Disp. at 1. Respondent argued, however, that the Government's request was "premature" because the Medical Licensing Board of Indiana had not issued a final decision and that "any attempt to seek revocation at this time is without basis and premature." *Id.*

On February 19, the ALJ issued her decision (also ALJ). Therein, the ALJ noted that the State of Indiana has suspended Respondent's medical license and that she had admitted "that she no longer has authority to handle controlled substances in Indiana." ALJ at 4. Noting that DEA does not have "authority under the Controlled Substances Act to maintain a controlled substances registration if the registrant is without state authority to handle controlled substances in the state in which she practices medicine," and that "revocation is * * * appropriate [even] when a state license has been suspended * * * with the possibility of future reinstatement," the ALJ concluded that there was no dispute over the material fact that Respondent "lacks authority to handle controlled substances in Indiana." ALJ at 5 (citations omitted). The ALJ thus held that "DEA lacks authority to continue * * * Respondent's DEA registration," granted the Government's motion, and recommended that Respondent's registration be revoked and that any pending applications be denied. *Id.* at 5–6.

While neither party would file exceptions to the ALJ's decision, on February 24, Respondent filed a motion to stay the ALJ's decision "until such time as the matter before the Medical Licensing Board of Indiana can be resolved." Motion to Stay Decision at 1. Respondent also noted that the State hearing had been set for March 25, 2010. *Id.* The Government opposed the motion.

On March 12, the ALJ denied the motion noting that Respondent had "offered no evidence suggesting that the circumstances have changed or that she currently has authority to handle controlled substances in Indiana." Order Denying Respondent's Motion to Stay Decision at 2. On March 19, the ALJ forwarded the record to me for final agency action.

Thereafter, the Government filed a motion to supplement the record. Therein, the Government noted that on March 30, 2010, the Medical Licensing Board of Indiana had issued a final order permanently revoking Respondent's medical license. Mot. to Supplement at 1. The Government attached a copy of the state order, which included extensive findings of fact and conclusions of law (many of which Respondent apparently stipulated to). *See In re Edwards,* No. 2009 MLB 0024 (Med. Lic. Bd. Ind., Mar 30, 2010) (final order). The findings established numerous instances in which Respondent, who "is only licensed to practice medicine in the States of

[1] Apparently, the amended summary suspension order was issued to extend the length of the suspension from 90 days (as provided in the initial order) "until the date of the final hearing in this matter." Compare Mot. for Summary Disp. Attachment 1, at 2, *with Attachment* 2, at 2.