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Carlos Gonzalez, M.D., Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–33]

Carlos Gonzalez, M.D., Decision and Order

On July 18, 2011, Chief Administrative Law Judge (ALJ) John J. Mulrooney, Jr., issued the attached recommended decision (also ALJ). Thereafter, the Government filed Exceptions to the ALJ's decision.[1]

Having reviewed the entire record and the Government's Exceptions, I have decided to adopt the ALJ's recommended rulings, findings of fact, conclusions of law, and recommended order except as discussed below.[2] I will therefore order that Respondent's registration be revoked and that any pending application to renew his registration be denied.

The Government's Exceptions

The Government's Exceptions fall within two categories. First, the Government takes exception to the ALJ's finding that it had not proved that Respondent violated Federal law (the Ryan Haight provisions) by issuing controlled substance prescriptions through the Internet without having conducted ''at least one in-person medical evaluation'' of the patients. Exceptions at 3; *see also* ALJ at 69–71. Second, the Government takes exception to the ALJ's declination to give weight to testimony it elicited regarding several hearsay statements which it offered to prove various material facts (including the alleged violations of the Ryan Haight provisions).

The Ryan Haight Violations

With respect to its first contention, the Government points to various controlled substance prescriptions (typically for steroids) found during an inspection of a Florida pharmacy which list Respondent as the prescriber and the patients as residents of some fourteen States outside of Florida; the prescriptions are on forms bearing the letterhead of three separate entities, which were internet sites through which a person could obtain a prescription for a controlled substance which the pharmacy filled. Exceptions at 2; GX 37. The Government contends that the prescriptions by themselves constitute substantial evidence to support a finding that Respondent violated the CSA, which following the passage of the Ryan Haight Act, prohibits the distribution or dispensing of ''a controlled substance by means of the Internet without a valid prescription,'' and requires that such a prescription be ''issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least one in-person medical evaluation of the patient.'' 21 U.S.C. 829(e).

This is so, the Government argues, because none of the patients who received the prescriptions in GX 37 reside in Florida, and ''it is unlikely that [Respondent] traveled all over the country to conduct physical examinations with these patients'' and ''it is also highly unlikely that these patients traveled from all over the country to see [Respondent] in Florida.'' Exceptions at 3. Based on the respective geographic locations of Respondent and the patients, the Government argues that ''it is clear that these controlled substance prescriptions were issued outside of the usual course of professional practice and lacked a legitimate medical purpose because these patients were not examined by'' him. *Id.* at 4.

Contrary to the Government's position, the prescriptions alone are insufficient to establish that Respondent failed to perform an in-person medical evaluation of the patients. Notably, the Government provided only thirty-seven prescriptions, which were issued to twenty-eight patients, over a period of nearly six months. Thus, this case bears none of the hallmarks of the assembly-line prescribing methods which DEA has frequently encountered in other internet prescribing schemes and the small number of prescriptions does not foreclose the possibility that the patients traveled to Florida to be evaluated by him.[3] *See Sun & Lake Pharmacy, Inc.,* 76 FR 24523 (2011); *William R. Lockridge,* 71 FR 77791 (2006). Moreover, in contrast to other internet cases, the Government did not introduce any evidence showing how the websites functioned (such as an undercover buy) and whether persons were able to obtain controlled substances without undergoing an in-person examination. Nor did the Government produce any other evidence which might have been probative of the issue and met the Administrative Procedure Act's standard of reliability, *see* 5 U.S.C. § 556(d), such as evidence regarding how the websites promoted their service, the lack of documentation of an in-person examination in patient records, or the lack thereof of any patient records. Thus, the prescription evidence alone does not create a permissible inference that Respondent did not physically examine the patients.

The Government further argues that the ALJ erred in holding ''that additional evidence was needed * * * to prove that'' Respondent did not physically examine the internet patients because the evidence stands unrefuted. Exceptions at 4. In support of this contention, the Government also noted that Respondent was subpoenaed and invoked his Fifth Amendment privilege and refused to testify. *Id.* at 4. Unclear is whether the Government believes that Respondent's invocation of his Fifth Amendment privilege entitles it to the adverse inference that he did not physically examine the patients.

As for its contention that Respondent's failure to refute its evidence (in any manner whatsoever) entitles it to a finding that he did not physically examine the patients, the argument ignores that the Government has the burden of proof on the issue. Because its evidence does not create even a permissible inference that Respondent did not physically examine the patients, Respondent had no obligation to refute it.

As for whether Respondent's refusal to testify entitles the Government to an adverse inference that he failed to physically examine the patients identified in GX 37, it is noted that the Government subpoenaed him to testify and obviously Respondent has knowledge of whether he did so. However, in neither its original nor its supplemental pre-hearing statement did the Government state that it intended to elicit testimony from him on this issue. *See* ALJ Exs. 5 & 6. Moreover, at the hearing, when Respondent's counsel informed the tribunal that Respondent intended to assert his Fifth Amendment privilege, the Government did not make an offer of proof. Thus, there is no basis to conclude that the Government would have questioned him about the internet prescriptions, and thus, an adverse inference cannot be drawn on the issue of whether he physically examined the patients.

[1] All citations to the ALJ's decision are to the slip opinion as originally issued on July 18, 2011.

[2] Because it is dictum, I do not adopt the first sentence of the last paragraph which begins on page 56 of the slip opinion and continues on to the following page.

[3] While there was evidence that it exceeds the bounds of professional practice to prescribe narcotics to a pain patient who had not been seen in six months without doing a new history and physical exam, no evidence was presented as to what constitutes a legitimate medical purpose for prescribing steroids and the standards of medical practice for prescribing them. Moreover, that most of the pharmacy's steroid prescriptions were mailed to the patients does not foreclose the possibility that the patients had previously been examined by Respondent.

The Government further argues that its evidence supports the conclusion that Respondent did not physically examine the patients because it also elicited the testimony of a Diversion Investigator (DI) that the prescriptions ''were 'absolutely' the result of the Internet drug-based process used by'' the pharmacy. Exceptions at 4 (citing its Post-Hearing Br. at 29). In its Exceptions, the Government acknowledges that this testimony was hearsay as it was based on the unsworn statements made by two employees of the pharmacy which filled the Internet prescriptions. Exceptions at 5.

Under DEA regulations, a party's exceptions ''shall include a statement of supporting reasons for such exceptions, together with evidence of record (*including specific and complete citations of the pages of the transcript and exhibits*) * * * relied upon.'' 21 CFR 1316.66(a) (emphasis added). The Government's citation to its post-hearing brief does not comply with this requirement, which DEA has previously applied in rejecting the exceptions filed by a respondent. *See Paul H. Volkman,* 73 FR 30630, 30640 (2008), *pet. for rev. denied* 567 F.3d 215 (6th Cir. 2009). Because the Government did not identify which specific hearsay statements it believes should be given weight, this alone provides reason to reject the exception.[4]

The ALJ's Declination to Give Weight to Various Other Hearsay Statements

In addition to the hearsay testimony related above, the Government also takes exception to the ALJ's failure to give weight to hearsay statements made by several other persons. More specifically, these statements included: (1) Those made by four patients of the pain clinic where Respondent practiced, which were related by a Task Force Officer (TFO) who interviewed them; (2) the statements made to the TFO by the co-owners of the clinic; and (3) the statements made by a former employee who had been fired by the pain clinic which were related by the DI.

As for the first category of statements, the Government cites more than 100 pages of transcript and argues that the patients' statements, which were unsworn, were supported by the patient files; however, the Government does not identify the specific statements it believes should have been ''given substantial weight.'' Exceptions at 6. Here again, the Government has not complied with the Agency's regulation and properly presented the exception for review. Beyond that, the Government's contention that the Agency should give weight to these unsworn statements because ''there would be nothing to gain through cross-examination of these * * * clinic patients because [Respondent], in his absence left the clinic operation and the issuing of controlled substances prescriptions to the [clinic] staff and therefore [has] no idea as to what occurred with these patients,'' Exceptions at 6–7, ignores that one of the fundamental purposes of cross-examination is to show that witnesses lack credibility or an accurate recollection of the event. *See McCormick on Evidence* § 19, at 47 (3d ed. 1984) (''For two centuries, common law judges and lawyers have regarded the opportunity of cross-examination as an essential safeguard of the accuracy and completeness of testimony.''). The APA specifically protects this critical right in 5 U.S.C. 556(d), which states in relevant part that ''[a] party is entitled * * * to conduct such cross-examination as may be required for a full and true disclosure of the facts.''

As for the hearsay statements of the clinic's owners and the former employee, the ALJ cited extensive judicial authority discussing when hearsay statements constitute substantial evidence, including two cases which are binding precedent in the Eleventh Circuit. *See* ALJ at 37 (citing *Basco* v. *Machin,* 514 F.3d 1177, 1182 (11th Cir. 2008) and *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000)).[5] As the ALJ explained, while hearsay evidence is admissible in administrative proceedings, the weight that can be given such evidence and whether it constitutes substantial evidence ''is an entirely different matter'' and is dependent upon ''the underlying reliability and probative value of the evidence.'' *Basco,* 514 F.3d at 1182 (quoting *U.S. Pipe and Foundry Co.* v. *Webb,* 595 F.2d 264, 270 (5th Cir. 1979)). As set forth in the ALJ's decision, the Eleventh Circuit has held that four factors should be considered in assessing whether hearsay statements are sufficiently reliable. These are: (1) Whether the declarant was unbiased and had no interest in the outcome of the case; (2) whether the opposing party could have obtained the hearsay information prior to the hearing and subpoenaed the declarant for cross-examination; (3) whether the information was inconsistent on its face; and (4) whether the information has been recognized by the courts as inherently reliable. ALJ at 37 (discussing *J.A.M. Builders,* 233 F.3d at 1354).

In its Exceptions, the Government does not even acknowledge either *J.A.M. Builders* or *Basco,* let alone offer any argument that the ALJ misapplied the relevant factors. Indeed, the Government does not cite a single judicial authority that supports its position that unsworn hearsay statements can constitute substantial evidence. However, even if it had, DEA is bound by the precedential authority of a United States Court of Appeals which would have jurisdiction over a subsequent petition for review of the Agency's final decision under 21 U.S.C. 877.

The Government nonetheless argues that other evidence, which is also hearsay, corroborates the testimony at the hearing. More specifically, with respect to the TFO's testimony as to the statements made by the clinic owners in two interviews, the Government argues that audio recordings and supporting transcripts corroborate the TFO's testimony. Exceptions at 7.

This misses the point entirely because the ALJ did not decline to give weight to the TFO's testimony regarding the interviews of the clinic owners because he found the TFO to lack credibility. To the contrary, the ALJ found the TFO to be credible. ALJ at 41. However, the ALJ

[4] In his decision, the ALJ noted that ''[i]t would not be unreasonable for the Agency to interpret the [Ryan-Haight Act] in such a way that a clear and convincing demonstration on the part of the Government that a practitioner has caused controlled substances prescribed and/or dispensed under his or her [registration] to be shipped to a remote, out-of-state location from the * * * registered address would result in a burden of production on the part of the registrant to demonstrate that an in-person physical examination had been conducted.'' ALJ at 71 n.109. I conclude, however, that such a rule is not justified given that the Government has ample means available to it to prove that a registrant failed to perform a physical examination, including by introducing the physician's patient records which it has the power to obtain through either subpoena or an administrative warrant; where such process is issued and no records are provided or a warrant is issued and no records are found, the Government would be entitled to the inference that the registrant failed to perform a physical exam. In addition, the Government can call the registrant as a witness and elicit testimony on the issue, and as explained above, where the registrant invokes his Fifth Amendment privilege, the Government would be entitled to an adverse inference. Finally, the Government can either call patients as witnesses (as it has done in several cases) or obtain sworn statements from them. In the event a potential witness resides more than 500 miles from the place of the hearing, and either the Government seeks to call the witness to provide live testimony or a respondent seeks to cross-examine the witness, the ALJ has authority to move the hearing so that a subpoena can be issued to compel the attendance of the witness and the ALJ can take such testimony through telephone or videoconferencing.

[5] To make clear, the ALJ also relied on the principles set forth in these two cases in declining to give weight to the some of other hearsay evidence such as the statements of the four patients to the TFO.

declined to give weight to this portion of the TFO's testimony because he found the statements of the clinic owners to be inherently unreliable based on the high likelihood that they were motivated by the owners' instinct for ''self-preservation'' and interest in shielding themselves from criminal liability; moreover, because the statements were not sworn, they are not the type which the courts have recognized ''as inherently reliable.'' ALJ at 39. Thus, that the transcripts and audio recording corroborate the TFO's testimony does not cure the fundamental flaws with the underlying hearsay statements to which he testified.[6]

It is acknowledged that the TFO testified that the owners had stated ''that the physician assistants were in charge of seeing patients and prescribing medications, although it was possible that they to some degree communicated with the Respondent through computer equipment at times * * * for him to approve prescriptions,'' *id.,* and that this is corroborated by the testimony at the hearing of the two UCs as to how they obtained their prescriptions. Nonetheless, this does not support reliance on the statement because the third *J.A.M. Builders* factor does not ask whether the hearsay statement is inconsistent with other evidence in the case, but only whether the hearsay statement is inconsistent on its face. Moreover, even if the owners' statements are internally consistent, and the owners could have been subpoenaed, the other factors still counsel against the Agency's reliance on the statements. Thus, the ALJ properly concluded that the statements of the clinic owners could not be relied upon. *Id.*

For similar reasons, the ALJ properly declined to give any weight to a DI's testimony regarding an interview she conducted with a former clinic employee who had been fired. Here again, while there is no evidence that the employee's statement was inconsistent on its face and the employee likely could have been subpoenaed (although the Government offered no evidence as to her whereabouts, notwithstanding that it was the proponent of the evidence), the other factors strongly support the ALJ's declination to give weight to this evidence. Having been terminated, the employee could well have been biased (again, while the Government was the proponent of statement, it did not produce any evidence that she was unbiased), and in any event, her unsworn interview with the DI is not the type of hearsay statement which the courts have recognized is inherently reliable. *See* ALJ at 42.

Accordingly, I reject the Government's various Exceptions to the ALJ's Recommended Decision. However, I agree with the ALJ's findings and legal conclusions that: (1) ''Respondent's prescribing practice fell well below the applicable standard in Florida regarding the controlled substances prescribed and dispensed to the undercover agents, as well as to the patients whose charts'' were reviewed by the Government's Expert, ALJ at 69; (2) ''Respondent employed his [registration] and/or allowed/enabled others to do so in a manner where controlled substances were prescribed and dispensed for other than a legitimate medical purpose or outside the usual course of professional practice,'' *id.,* and thus allowed controlled substances to be ''provided to individuals he never met,'' *id.* at 72; and (3) Respondent's charts include ''out-and-out falsehoods'' and ''failed to provide even the most basic documentation to support his prescribing and dispensing.'' *Id.*

I therefore conclude that Respondent has committed acts which render his continued registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Because Respondent has offered no evidence to rebut this conclusion, I adopt the ALJ's recommended Order and revoke his registration and deny any pending applications.

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), I order that DEA Certificate of Registration BG8251845, issued to Carlos Gonzalez, M.D., be, and it hereby is, revoked. I further order that any pending application of Carlos Gonzalez, M.D., to renew or modify his registration, be, and it hereby is denied. This Order is effective immediately.[7]

Dated: September 29, 2011.

Michele M. Leonhart,

Administrator.

Theresa Krause, Esq., for the Government

Michael Metz, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

John J. Mulrooney, II, Chief Administrative Law Judge. On February 18, 2011, the Administrator of the Drug Enforcement Administration (DEA or Government), issued[1] an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) immediately suspending the DEA Certificates of Registration (COR), Numbers BG8251845, FG1242471, and FG2021804, of Carlos Gonzalez, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. § 824(d) (2006), based on the Administrator's assessment of an imminent danger to the public health and safety. The OSC/ISO also seeks revocation of the Respondent's registrations, pursuant to 21 U.S.C. § 823(a)(4) (2006 & Supp. III 2010), and denial of any pending applications for renewal or modification of registration, pursuant to 21 U.S.C. § 823(f), alleging that the Respondent's continued enjoyment of the privileges vested in those registrations is inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f). On March 16, 2011, the Respondent, through counsel, timely requested a hearing, which was conducted in Miami, Florida on May 17–19, 2011. The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823(f) and 824(a)(4). The Respondent is the holder of DEA practitioner registration, No. BG8251845, which expires by its terms on September 30, 2011. The Respondent surrendered two other registrations, Nos. FG1242471 and FG2021804, prior to requesting a hearing.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel,[2] and the record as a whole, I

[6] Here again, the Government did not identify which of the numerous statements made by the clinic owners it believes the ALJ should have given weight to. Exceptions at 7.

[7] For the same reasons which led me to order the Immediate Suspension of Respondent's Registration, I conclude that the public safety requires that this Order be effective immediately. 21 CFR 1316.67.

[1] The Government served the OSC/ISO upon the Respondent on February 23, 2011.

[2] The parties were afforded the opportunity to file post-hearing briefs in this matter. The Government's brief was timely filed on June 14, 2011, but no brief was filed on behalf of the Respondent. The decision to forgo filing a brief has resulted in a record that contains no position from the Respondent on the

have set forth my recommended findings of fact and conclusions of law below.

The Allegations

The OSC/ISO issued by the Government alleges that during the approximate time period of October 2009 through September 2010, the Respondent ''distributed * * * oxycodone, a Schedule II controlled substance, and alprazolam, a Schedule IV controlled substance by issuing prescriptions to several undercover law enforcement officers for other than a legitimate medical purpose or outside the usual course of professional practice.'' ALJ Ex. 1 at 2 (internal quotation marks and parentheses omitted). Furthermore, the OSC/ISO alleges that patients at the Respondent's practice were able to procure similarly illegitimate prescriptions in a similarly illegitimate manner as the undercover officers. *Id.*

Interactions with two undercover officers are alleged in the OSC/ISO. The first undercover officer (UC1),[3] allegedly obtained prescriptions for various controlled pain medications issued from the Respondent's registration despite the Respondent's absence from the office and notwithstanding the fact that he never personally examined him. *Id.* The OSC/ISO also alleges that ''a nurse practitioner who was represented as being a doctor'' examined UC1 cursorily in the Respondent's stead, despite UC1's admission to the nurse practitioner that he had illicitly acquired controlled substances from a friend. *Id.*

The OSC/ISO also alleges that upon a subsequent visit, UC1 obtained prescriptions for, and distributions of, controlled pain medications without the Respondent conducting a physical examination, reaching a diagnosis, or providing a justification for the increase in dosage units and in the face of the UC's admission that he illegally obtained controlled substances from another person prior to the visit. Furthermore, the OSC/ISO charges that on two or more subsequent occasions, controlled substance pain prescriptions emanated from the Respondent's COR to UC1, even though UC1 was not personally examined by anyone and during a time wherein the Respondent was purportedly absent from the office. *Id.*

Regarding the second undercover officer (UC2),[4] the OSC/ISO alleges that while the Respondent was out of the office, UC2, after a cursory examination performed by a physician's assistant, was prescribed controlled pain medications through the Respondent's COR. *Id.* According to the Government, UC2 was issued the prescriptions even in the face of his admission to the physician's assistant that he had illegally obtained controlled substances from his girlfriend. *Id.*

The OSC/ISO also alleges that from February 2009 through December 2009, the Respondent allegedly procured 238,000 dosage units of oxycodone, and from January 2010 through June 2010, he allegedly obtained through purchase 259,000 dosage units of oxycodone at his registered location in Lake Park, Florida.[5] *Id.* at 3.

Subsequent prehearing and supplemental prehearing statements alleged additional facts, including (but not limited to) recordkeeping deficiencies and the illegal prescribing of controlled substances over the Internet in violation of the Ryan Haight Act.[6] ALJ Ex. 6 at 6.

The Stipulations of Fact

The parties, through their respective counsel, have entered into stipulations regarding the following matters:

Stipulation A: The Respondent is registered with the DEA as a practitioner in Schedules II through V under DEA registration number BG8251845 at 7108 Fairway Drive, Suite #120, Palm Beach Gardens, Florida 33418. Respondent's DEA registration number BG8251845 expires by its terms on September 30, 2011.

Stipulation B: On February 23, 2011 the Respondent was personally served with an Order to Show Cause and Immediate Suspension of Registration and was simultaneously arrested on state drug-related felony charges. The state criminal trial is pending.

Stipulation C: Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii) (2010).

Stipulation D: OxyContin is a brand of oxycodone, a Schedule II narcotic controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii) (2010).

Stipulation E: Roxicodone is a brand of oxycodone, a Schedule II narcotic controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii) (2010).

Stipulation F: Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1) (2010).

Stipulation G: Xanax is a brand of alprazolam, a Schedule IV controlled substance pursuant to 21 C.F.R. 1308.14(c)(1) (2010).

Stipulation H: Vicodin is a brand of hydrocodone combination product, a Schedule III narcotic controlled substance pursuant to 21 C.F.R. § 1308.13(e)(1)(iv) (2010).

Stipulation I: Soma is a brand of carisoprodol which is a non-controlled muscle relaxant.

The Evidence

At the hearing, the Government presented the testimony of several witnesses on the issue of the Respondent's medical practice, recordkeeping, and controlled substance prescribing practices. The testimony received during the Government's case-in-chief revealed that three undercover (UC) law enforcement officers infiltrated the North Palm Pain Management Clinic (NPPM) where the Respondent was employed and were able to obtain controlled substances issued under his COR. The Government also presented the testimony of an expert witness who reviewed the files maintained by NPPM on two of the UC officers as well as four charts maintained on other patients of the clinic who voluntarily consented to speak with law enforcement and to have their files examined.

UC Patient Rix

Task Force Officer (TFO) William Schwartz, a sixteen-year veteran of the Sheriff's Office in Broward County, Florida, testified that he has served as a detective for thirteen years,[7] been a designated DEA TFO since 2009, and has participated in thousands of drug diversion investigations.[8] Tr. 592–93, 752. Schwartz made multiple undercover visits to the North Palm Pain Management Clinic (NPPM) under the assumed name Bill Rix (UC Patient Rix). Schwartz wore a wire, the UC

weight that should be accorded the evidence admitted during the proceedings, beyond the arguments made at the hearing in connection with objections. Neither party filed any exceptions or proposed corrections to the transcript, notwithstanding being afforded the opportunity to do so.

[3] Evidence received at the hearing establishes that UC1, as referred to in the OSC/ISO, refers to Task Force Officer (TFO) William Schwartz. TFO Schwartz employed the fictitious name ''Bill Rix'' during his undercover office visits.

[4] Evidence received at the hearing establishes that UC2, as referred to in the OSC/ISO, refers to Special Agent (SA) Jack Lunsford. SA Lunsford assumed the fictitious name ''David Hays'' during his undercover visits.

[5] COR No. FG1242471 is the corresponding registration with this address.

[6] On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), Pub. L. No. 110–425, 122 Stat. 4820 (2008), which became effective on April 13, 2009 and is codified at 21 U.S.C. § 829(e).

[7] Tr. 656.

[8] TFO Schwartz also testified that he completed the DEA Diversion Investigators Course in 2002 and the Federal Bureau of Investigation (FBI) School in 2007. Tr. 751–52.

visits were recorded, and the recordings and transcripts were received into evidence.

TFO Schwartz testified that he made his first UC visit to NPPM as UC Patient Rix on October 21, 2009 (October 21st visit).[9] Upon arrival, Rix encountered an armed security guard and Donna Palemire, one of two non-physician owners of NPPM. Tr. 598–99. In response to an inquiry from UC Patient Rix, Palemire assured him that a one-and-a-half-year-old MRI report would be sufficient to be admitted to the practice for treatment,[10] asked him to make efforts to locate past pharmacy profile documentation, and referred him to her husband, non-physician NPPM co-owner Anthony Laterza, to discuss ''rejuvenation'' therapy. Tr. 599–600.

The wire transcript and audio recording received in evidence regarding the October 21st visit are consistent with Schwartz's recollection. *See* Gov't Ex. 13. Like Schwartz's testimony, the transcript reflects that in seeking admittance to the clinic as a new pain management patient, UC Patient Rix encountered Palemire, and that she instructed Rix that he needed to furnish an MRI report as a condition precedent to begin treatment. *Id.* at 4. Although UC Patient Rix asserted that he already had a year-and-a-half-old MRI somewhere in his possession, Ms. Palemire advised that the dated MRI would be fine ''for now'' but that he would need to procure a recent one. *Id.* Palemire referred UC Patient Rix to an imagining place for another MRI, and told him to ask for ''Rose.'' *Id.* at 6; *see* Gov't Ex. 40 at 1 (MRI referral). Additionally, Palemire recommended that UC Patient Rix bring in a pharmacy profile and copies of prescriptions that he had received in the past. Gov't Ex. 13 at 7. When UC Patient Rix told Palemire that he did not want the doctor to be put off by his history of having taken 80 mg oxycodone, Palemire reassured UC Patient Rix that the doctor would not be alarmed on that account. *Id.* Palemire explained, ''He * * * I mean she [sic] doesn't have a problem with [o]xycodone, but with [m]ethadone she does. But, if you come on [m]ethadone, she'll probably give it to you, but then kind of wean you off.'' *Id.* UC Patient Rix stated that he was seeking the 30 mg dose, which inspired Palemire to issue a warning that while the Respondent is ''cool'' and ''awesome,'' that Rix should not get himself caught in a lie because the doctor ''doesn't like it.''[11] *Id.* at 7–8. The referral to Laterza for rejuvenation therapy in the form of human growth hormone (HGH)[12] and testosterone is also confirmed by the transcript. *See id.* at 5, 10–11.

TFO Schwartz testified that he again presented to NPPM as Rix two days later on October 23, 2009 (October 23rd visit).[13] Tr. 603. According to Schwartz, Ms. Palemire explained some NPPM paperwork procedures, accepted the fictitious lumbar/thoracic MRI and pharmacy profile he offered as UC Patient Rix, and instructed him to wait for the Respondent's assistant. Tr. 605. According to Schwartz, while waiting to be seen by the assistant, Laterza coached him through the preparation of some paperwork, and advised him to indicate as many health issues as he could. Tr. 605–08. Specifically, the wire transcript indicates that Laterza advised Rix ''to have as many complaints as possible.'' Gov't Ex. 14 at 18.

It was at this point that UC Patient Rix encountered a female identified by Laterza as ''Dr. Betsy.'' Tr. 608. Schwartz later ascertained that ''Dr. Betsy''[14] is not really a doctor at all, but a nurse practitioner named Betsy Sanchez. *See* Tr. 777. Sanchez asked Rix if he had ''[a]ny medical history,'' Gov't Ex. 14 at 62, checked his heart rate and respiration, and applied pressure with her fingers below his navel, Tr. 609–10; Gov't Ex. 14 at 62–63. Nurse Sanchez told Rix that it would not be necessary for him to remove his shirt for the examination. Gov't Ex. 14 at 62. Laterza then left Rix alone with Nurse Sanchez, explaining that his rejuvenation portion of the visit was complete, and that Sanchez was going to ''triage [him] for [his] pain.'' *Id.* at 63.

Sanchez asked UC Patient Rix some questions about his reasons for seeking pain management. Intentionally omitting any reference to ''pain,'' Tr. 790, Rix told her that he was a stunt man, that he experienced some ''stiffness,'' and that as he's getting older he does not ''recover'' as quickly from workouts as he did when he was young, Gov't Ex. 14 at 65; Tr. 618. Rix also told Sanchez that his previous pain clinic had closed up suddenly, rendering his prior charts unavailable.[15] Gov't Ex. 14 at 65, 68. In response to questioning from Sanchez, Rix indicated that his pain was zero out of ten with pain medications, and four or five without. *Id.* at 67; Tr. 784. In this interview with Sanchez, as in the paperwork he filled out, Rix asserted that his discomfort was focused on his neck. Tr. 613; Gov't Ex. 14 at 69. Thus, inasmuch as the fictitious MRI[16] he provided related only to the lumbar/thoracic regions of his back, no objective evidence related to any neck malady was ever presented by this patient. The forms Rix completed also represented his pain levels between zero and a maximum of three and restricted the complaints to his neck.[17] Tr. 613; Gov't Ex. 4 at 5–6. Notwithstanding Rix's written and oral complaints centered on his neck, and his lumbar/thoracic MRI, neither his neck nor his back were examined by Sanchez, Laterza, or anyone else during the visit. Tr. 620–22.

In another, intentionally-engineered anomaly,[18] UC Patient Rix provided Sanchez with a physician name that conflicted with the information he provided on the fictitious pharmacy printout to see if it would generate a reaction from her. Tr. 619, 788–89; Gov't Ex. 14 at 70. It did not. *Id.* Sanchez told Rix that she would review his case ''with the doctor,'' and would ''find out[] when he's coming.'' Gov't Ex. 14 at 70, 72. In the waiting room, Palemire told Rix that the Respondent was in surgery and that Sanchez would ''call [the Respondent], review the chart over

[9] An audio recording and a corresponding transcript were received into evidence. Gov't Ex. 13; Tr. 596.

[10] According to Schwartz, Palemire told UC Patient Rix that she could refer him to an MRI facility if his efforts to locate his 18-month-old MRI proved fruitless. Tr. 600; *See* Gov't Ex. 40 at 1 (MRI referral).

[11] Confusingly, this transcript reflects that Palemire used the terms ''he'' and ''she'' interchangeably.

[12] HGH is not a controlled substance, and under current Agency precedent, a consideration of its handling by the Respondent is irrelevant to the public interest determination that must be made in these proceedings. *See Tony T. Bui, M.D.,* 75 Fed. Reg. 49979, 49988 (2010) (''Because it is not a controlled substance, Respondent's prescribings of [HGH] could not have violated the CSA's prescription requirement.''). Testosterone, by contrast, is an anabolic steroid and a Schedule III controlled substance. 21 C.F.R. § 1308.13(f)(1); *see* 21 U.S.C. § 802 (41)(A); 21 C.F.R. § 1300.01.

[13] A transcript of the wire recording of the visit was received into evidence. Gov't Ex. 14; Tr. 604.

[14] An examination of the wire transcript reveals that Laterza and Palemire go to considerable lengths to refer to Nurse Sanchez as ''Dr. Betsy,'' *see* Gov't Ex. 14, and Nurse Sanchez never corrects anyone in UC Patient Rix's presence or intimates to Rix that she is not a physician, Tr. 823. There is no indication in the record, however, that this was done at the direction of the Respondent. Further, during Sanchez's interaction with UC Patient Rix, she tells him that she is ''gonna review this with the doctor.'' Gov't Ex. 14 at 70; Tr. 796.

[15] Rix, as part of his undercover ruse, described his prior pain clinic to Sanchez as ''the kind of place where you had fifty (50) people in the waiting room, five (5) doctors, and whoever the doctor was available [sic] was who you went to see.'' Gov't Ex. 14 at 71. In fact, Rix told Sanchez that he was ''kinda glad they're closed.'' *Id.* By his description, UC Patient Rix unsubtly painted a picture of a pill mill. This description yielded no additional inquiry or corresponding chart note from Nurse Sanchez.

[16] Gov't Ex. 4 at 30.

[17] A copy of the NPPM patient chart prepared and maintained on UC Patient Rix was obtained by a signed release form and was received into evidence. Gov't Ex. 4; Tr. 613–15.

[18] *See* Tr. 762–63.

the phone and then * * * [Rix would be] good to go.'' *Id.* at 72. During his post-exam wait, Laterza counseled him that when he meets the Respondent (an event that ultimately did not occur during this UC visit), that he should ''[l]ook, talk, walk like you're in pain [and that] I want to see absolute suffering in you.'' *Id.* at 74.

Approximately an hour and a half later, Sanchez informed UC Patient Rix that the Respondent had approved prescriptions for controlled substances, but in lesser amounts than Rix's (fictitious) pharmacy report had indicated he had been receiving in past. *Id.* at 100; Tr. 622–23. Schwartz testified that he watched as Sanchez printed out controlled substance prescription scripts (as well as a script for physical therapy with no recommended or identified source for that modality) [19] that bore the Respondent's printed name. Tr. 624–25. Schwartz also testified that he saw Sanchez write something on or near the prescription scripts, but was unable to tell if she was signing them. *Id.* at 625. Schwartz testified that shortly after receiving the signed scripts (a remarkable development in light of the Respondent's absence from the room where the documents were printed and handed to Rix), he handed them to Palemire, who stepped into a dispensing area, filled the prescriptions, and handed the controlled substances over. Tr. 626–27, 715–16, 723–24; [20] *see* Gov't Ex. 38 at 1(a), 2(a); Gov't Ex. 39 at 4, 6–7. Schwartz left NPPM that day with the dispensed controlled substances and never encountered the Respondent, who he was told, was performing surgery. Gov't Ex. 14 at 71, 99. TFO Schwartz testified that during those visits to NPPM where he did not encounter the Respondent, the layout of the clinic and the open doors (except for the restroom door) gave him confidence that if the Respondent had been on premises, Schwartz would have seen him. Tr. 775–77.

Schwartz returned to NPPM as UC Patient Rix to pick up a lab requisition form on November 2, 2009.[21] There was also a visit where Schwartz introduced another undercover officer to Laterza as part of the operation, and some telephone exchanges related to the logistics of picking up medications. Tr. 638–43; Gov't Ex. 18.

UC Patient Rix finally got to meet the Respondent during the course of his fifth UC visit to NPPM, which occurred on November 21, 2009 (November 21st visit).[22] The November 21st visit started with Laterza opening and explaining the hormone therapy medications and enthanate (a Schedule III controlled substance testosterone medication) that were shipped to Rix in care of NPPM. Tr. 644–46. Laterza agreed to keep the delivered medications refrigerated while Rix was seen by the Respondent. Tr. 644–45.

After a short wait, the Respondent called UC Patient Rix into an examination room. Tr. 646–47. Schwartz testified that the Respondent had the Rix patient chart as the two men entered the examination room. *Id.* at 647. UC Patient Rix explained to the Respondent that he had been seen by ''Dr. Betsy'' and Laterza during his prior visit to NPPM, and that he received controlled pain medications from the former and controlled testosterone from the latter. *Id.* at 647–48. Furthermore, Rix informed the Respondent that ''Dr. Betsy'' had provided him with pain medication at a reduced level from what he had been prescribed by his former pain clinic. *Id.* Rix asked the Respondent about obtaining additional medication for breakthrough pain, acknowledged that he had run out of the pain medication that had been previously issued to him by ''Dr. Betsy'' at his last visit to NPPM, and confessed that he had procured more pain medicine ''from some people.'' *Id.* at 647; Gov't Ex. 19 at 19. Rix also mentioned to the Respondent that his last pain clinic was frequented by ''shady people'' and closed after a Molotov cocktail was thrown through a clinic window. Gov't Ex. 19 at 19. Additionally, UC Patient Rix inquired as to whether the Respondent (his pain management physician) thought that two years was enough for him to train to compete in a triathlon. Tr. 648; Gov't Ex. 19 at 22.

The Respondent, who had the Rix patient chart in hand, absorbed Rix's representation that he had received controlled substances from Laterza and ''Dr. Betsy'' without comment or discernible reaction. Tr. 647–48. Likewise, he did not question Rix about which ''people'' supplemented his controlled substance pain medications when he ran out, why he had previously frequented an unsavory pain clinic, or even why he needed pain medication at all if he felt fit enough to commence a truncated triathlete training regimen. Tr. 647–49. To the contrary, the Respondent's reaction to the input he received from Rix was to issue a script (that was filled by NPPM) increasing his Roxicodone dosage by one additional pill a day from the level set the previous month by Nurse Sanchez, with the reassurance that he generally commences prescribing medication for breakthrough pain at the third visit. Tr. 649, 718, 725; Gov't Ex. 19 at 20; Gov't Ex. 4 at 24; Gov't Ex. 38 at 4(a); *compare* Gov't Ex. 4 at 24 (script for #150 Roxicodone 30 mg issued November 21, 2009), *with* Gov't Ex. 4 at 27 (script for #120 Roxicodone 30 mg issued October 23, 2009). During this November 21st visit, UC Patient Rix was not asked to fill out any additional questionnaires or other paperwork,[23] he was not examined (or even touched) by the Respondent or anyone else at NPPM, no vital signs were taken, and he was never asked about side effects or pain issues. Tr. 649–50. There was no discussion about Rix's fictitious MRI and its facial inconsistencies with his paperwork (neck versus back), and no treatment plan, goals for treatment, risks and benefits, or alternative treatments found their way into the discussion. Tr. 651. In fact, according to Schwartz, during the entire brief encounter, the Respondent was writing in the Rix patient chart or typing on the computer, and only even made eye contact with Rix ''for a few seconds at most.'' Tr. 649. The November 21st UC visit clearly established that the Respondent knew, or should have known (in the unlikely event that he did not already know), that UC Patient Rix was receiving controlled substances at NPPM issued on scripts over his printed name.

Schwartz returned to NPPM on December 18, 2009 (December 18th UC visit) [24] and was seen by Nurse Sanchez. Tr. 661. UC Patient Rix told Sanchez that he had been hospitalized with the flu, lost weight, was working out, and only had three out of ten pain, but would like some breakthrough medication based on the Respondent's previous encouragement that breakthrough pain medication prescribing could commence at the third visit. Tr. 661; Gov't Ex. 24 at 8–11. When questioned on the issue of pain level, UC Patient Rix told Sanchez that ''[i]t's not that it gets so bad, it's just that

[19] Tr. 627.

[20] While later in his testimony TFO Schwartz misidentified pictures depicting a bottle of 2 mg alprazolam tablets as dispensed to him on December 21, 2009, the photographs clearly show a dispense date of October 23, 2009. *Compare* Tr. 724, *with* Gov't Ex. 38 at 2(a).

[21] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 15; Tr. 631.

[22] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 19; Tr. 644.

[23] Schwartz testified that as UC Patient Rix, he was never asked to fill out another form after the October 23rd visit. Tr. 649.

[24] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 24; Tr. 660.

I run out.'' Gov't Ex. 24 at 10. Rix even asked if the three of ten number pain assessment he provided was appropriate. *Id.;* Tr. 662. Sanchez demurred on Rix's request for breakthrough pain medication, emphasizing to Rix that the Respondent had just increased his dosage. Tr. 661–62, 800; Gov't Ex. 24 at 11. Again, this UC visit, like the visit before it, did not include any type of physical exam, treatment plan, objectives and goals discussion, medication risks and benefits discussion, alternative pain treatment modalities, or follow up on the previous script that recommended a physical therapy consult. Tr. 663–64. At Sanchez's command, the examination room printer yielded the same compliment of prescription scripts for controlled substances that had been produced by the Respondent on the previous visit. Tr. 665; *see* Tr. 719–20, 724, 727–28, 800–01; Gov't Ex. 38 at 2(a), 11(a), 12(a), 13(a); Gov't Ex. 39 at 22, 26. Sanchez wrote something on the prescription scripts, and the visit ended with controlled substance prescriptions being authorized and dispensed, and without the Respondent making an appearance.[25] Tr. 665.

The next NPPM visit by UC Patient Rix occurred on January 11, 2010.[26] Tr. 666. Upon UC Patient Rix's arrival at NPPM, Palemire told him that the Respondent was not in the office because his wife was in the hospital giving birth, but that because Rix was ''an established patient,'' he would not need to see the Respondent to get his controlled substance prescriptions. Tr. 671; Gov't Ex. 26 at 6. At Palemire's direction, Rix left the clinic and telephoned back on two occasions to query when he could return. Tr. 668; Gov't Ex. 25. On the second call, Palemire told Rix that he could come in. Gov't Ex. 25 at 3; Tr. 668. Palemire handed Rix two controlled substance prescription scripts and dispensed the medications. Tr. 671–72, 728–29; Gov't Ex. 26 at 15; *see* Gov't Ex. 4 at 18; Gov't Ex. 38 at 13(a), 14(a).

Schwartz did not return to NPPM for six months. On July 22, 2010, UC Patient Rix visited NPPM and told Palemire he has been away in California starring in films.[27] Tr. 679. After a brief conversation, Palemire handed UC Patient Rix three controlled substance prescriptions. Tr. 680. Although Rix conversed with an individual named ''Ted'' regarding rejuvenation therapy, he never met with any medical professional during this UC visit. Tr. 681. He was not asked anything further about his extended absence from the practice or what treatments and/or medications he received during the hiatus. No one asked if he had been taking medication during that time, or if not, how well (or poorly) he was able to manage his activities of daily living without the benefit of controlled substance medications.

The testimony presented by TFO Schwartz was sufficiently detailed, consistent, and plausible to be found fully credible. Schwartz's demeanor appeared forthright and candid, and although his recollection of the relevant events was excellent, he demonstrated a consistent readiness to not acknowledge elements of the case where he was in any way unsure (*e.g.,* whether Nurse Sanchez was affixing a signature to prescription scripts in his presence).

A patient chart maintained by the Respondent's practice on UC Patient Rix was received into evidence. Gov't Ex. 4. The chart contained what the evidence established to be a compliment of forms and documents that are generally common to other patient charts from the Respondent's practice that were also admitted into evidence. These forms are collected, completed, and/or executed by the patient during initial intake procedures. *See* Tr. 617. These intake documents include: (1) A patient sign-in sheet; (2) a patient information form (Patient Intake Form); (3) a consent to treat and guarantee of payment form; (4) a Brief Pain Inventory (Pain Inventory); (5) a Patient Medication Management Agreement (Pain Med Contract); (6) a Contract for Long-Term Use of Opioid Analgesic (Opioid Contract); (7) an advisal to patients regarding possible criminal consequences under state law associated with acts of drug-diversion-related activity and consent for the Respondent's practice to cooperate in law enforcement efforts associated with diversion; (8) an advisal to patients regarding possible consequences of lost medication; (9) a HIPAA [28] notice to patients; and (10) a driver's license photocopy. Gov't Ex. 4 at 2–14, 34, 36; Tr. 615–17. Additionally, the chart contained forms that were completed by the Respondent and/or personnel at the practice, such as a Patient Reassessment Opioid Analgesic 4–A's+ Chart Note (Chart Note), as well as progress note pages (Progress Note Form), imaging reports, and copies of prescription scripts. Gov't Ex. 4 at 15–33, 35; *see* Tr. 17–18, 21.

In the Patient Intake Form, UC Patient Rix listed his occupation as an actor, described the purpose of the visit simply as ''pain,'' and he wrote that he heard of the Respondent's practice through a ''friend/word of mouth.'' *Id.* at 3. Rix responded on the form that he was not involved in an auto accident. *Id.* Under a section labeled ''MEDICAL HISTORY: (CHECK ALL THAT APPLY),'' concerning a legion of listed medical ailments, conditions, diseases, and symptoms, Rix declined to identify a single malady, and responded that he had no allergies. *Id.*

The Pain Inventory consists largely of questions prompting the Respondent to rate his pain and how it interferes with daily activities and quality of life on a ten-scale (with zero representing no pain and ten amounting to ''pain as bad as you can imagine''). *Id.* at 5–6. UC Patient Rix affirmatively indicated therein that he experienced pain on the same day different from ''everyday'' pain, and signaled that he experienced neck pain by circling the corresponding anatomical representation on a diagram. *Id.* Underneath the diagram, Rix expressed that his pain in the last twenty-four hours had been constant, to wit: he rated his pain at its least, worst, average, and at present all as a three. *Id.* Also within the last twenty-four hours, Rix marked that he had experienced no pain relief (zero percent) from pain treatments or medications, despite reporting in an adjacent area that he was receiving oxycodone 30 mg, oxycodone 15 mg, and Xanax for his discomfort. *Id.* The next array of seven questions inquired into the level of interference that the patient's pain caused with routine functions. *Id.* The scale employed also ranges from zero (does not interfere) to ten (completely interferes). *Id.* To these metrics, UC Patient Rix variably fixed his pain between one and three on a ten scale, and in another portion of the form, characterized his pain as ''aching'' that has lasted more than a month. *Id.* at 6. Regarding the kinds of things that improve his pain or make it worse, Rix wrote in respectively ''medication'' and ''no medication.'' *Id.* At another part of the form, Rix declined to circle any of a large number of symptoms. *Id.*

The fictitious reports supplied to NPPM by Schwartz are in the Rix chart.

[25] Schwartz testified that he did not know if any of the scripts issued to him during any of his visits to NPPM were pre-signed. Tr. 812.

[26] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 26; Tr. 670. An audio recording and transcript of a phone call to NPPM by UC Patient Rix wherein he attempted to negotiate an earlier refill visit date was also introduced into evidence. Gov't Ex. 28; Tr. 676. Rix convinced Palemire to advance the visit from January 16th to the 11th. *Id.*

[27] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 31; Tr. 678.

[28] Health Insurance Portability and Accountability Act of 1996.

The fictitious MRI report reflects some multilevel mild thoracic and lumbar spondylosis, that there is no evidence of cord injury, and that there was no evidence of fracture history. *Id.* at 31. The fictitious pharmacy history indicates five prescriptions for controlled substances filled on two occasions during non-consecutive months and prescribed by two different doctors.[29] Gov't Ex. 4 at 33. A handwritten note across the bottom of the report reads ''South FL Pain,'' ''Moved to Pain Manager,'' ''Broward Co.'' *Id.*

During the October 23rd examination, Nurse Sanchez prepared a Chart Note. Gov't Ex. 4 at 28–29. Under a section denoted ''Current Analgesic Regimen,'' Sanchez wrote oxycodone 30 mg #210, oxycodone 15 mg #90, and Xanax 2 mg #30, with a note in the left margin signifying that they were all last filled in September 2009 (the month before this visit). *Id.* Under a section styled ''Analgesia (average/best/worst pain intensity; % pain relief),'' is found ''best 0/10'' and ''worst 4/10.'' An ''Activities of Daily Living (functional status/relationships/mood)'' section does not list any activities of daily living, but does contain the phrase ''stunt man.'' *Id.* Zeros are entered in sections entitled ''Adverse Events (type/severity),'' and ''Aberrant Drug-Related Behaviors (type/severity).'' *Id.* ''MRI 5/08 -> mild spondylosis'' are inscribed under ''Monitoring Tests/Reports (urine screen/pill counts/other).'' *Id.* at 29. UC Patient Rix's physical and psychological assessment does not contain any diagnoses, but does state that Rix is ''pleasant.'' *Id.* Sanchez's notes related to the physical examination are not entirely legible, but do include a notation that UC Patient Rix is 38 years old, is in no apparent distress, and has clear lungs. *Id.* Below the physical examination findings is a front and back body sketch, with X's drawn upon the neck and lower back of the posterior depiction. *Id.* Further below the sketches is a section entitled ''Action Plan (continue/adjust/discontinue therapy),'' wherein the controlled substances that were ultimately prescribed to Rix that day (''Roxi 30 mg #120'' and ''Xanax 2 mg #30'') are indicated. *Id.* In a space designed for the medical professional to enter additional comments, Sanchez wrote the word ''obtain.'' *Id.*

The Government presented testimony and a written report from Mark A. Rubenstein, M.D., FAAPMR, FAAEM. Tr. 24–25; Gov't Ex. 11. Dr. Rubenstein, a Florida-licensed physician and academic, whose qualifications include a board certification in Physical Medicine and Rehabilitation with a subspecialty certificate in Pain Medicine, as well as extensive experience serving as a medical expert to multiple entities in varied litigation forums,[30] was offered and accepted as an expert in the area of pain management. Tr. 21, 129; *see* Gov't Ex. 10. Rubenstein testified that he was compensated at a rate of $750.00 per hour for his testimony, $500.00 per hour for his preparation time, and that there was no cap fixed on the compensation arrangement. Tr. 118.

Dr. Rubenstein's report and testimony set forth his professional evaluation of six patient charts seized from the Respondent's practice, including the chart maintained on UC Patient Rix. Tr. 27. As a preliminary matter, it is worthy of note that the format of Dr. Rubenstein's report was confusing and singularly unhelpful. While a critical objective of securing expert assistance is to aid the trier of fact in analyzing and processing material that can benefit from expertise beyond the ken of the ordinary citizen, Dr. Rubenstein's report is disorganized, unfocused, and written in a manner that bespeaks a free association narration of documents and other items provided to him by the Government in no particular order. A principal reason for the difficulty in utilizing the report undoubtedly comes from the manner of its genesis. Rubenstein testified that over time he has developed a relationship with the Florida State Attorney's Office wherein he would review files and provide whatever opinions he felt the documents warranted, with scarce guidance regarding a specific mandate. Tr. 28–29. Moreover, Rubenstein was asked to review a mass of paper wherein patient charts that were eventually properly admitted into evidence are interspersed with DEA investigative reports and other documents that were not. Tr. 35; Gov't Ex. 12. The exhibit that contained the documents reviewed by Dr. Rubenstein was admitted into evidence in these proceedings as a single exhibit (Expert Review Package), Tr. 28–29, for the singular purpose to enable a review over whether particular facets of his opinions regarding the UC operations were informed by properly admitted evidence, Tr. 34–35. In reviewing Rubenstein's report, it was often difficult to determine whether he was relying upon information procured from a patient chart, a UC visit recording, a DEA investigatory report, or even a conversation with an agent[31] that was not an admitted part of the record in this case, and expert opinions were drafted in a manner that made it challenging to ascertain whether a single patient, several patients, or overall trends were the object of the opinion. The absence of focus that defines the pages that were submitted by the Government as the purported report of an expert severely detracted from the benefit that Dr. Rubenstein's expertise could have yielded. The disjointed nature of the report was certainly not ameliorated by Dr. Rubenstein's almost perpetual need to refer to it during his testimony.

An example of the difficulty in the manner in which Dr. Rubenstein's analysis was procured, evaluated, and presented was his observations and conclusions on the UC Patient Rix chart regarding what he perceived to be a 50-second physical exam during the October 23rd UC visit that was limited to a pupil examination. Gov't Ex. 11 at 1. Nowhere in the admitted exhibits or testimony (beyond the Expert Review Package) is the October 23rd UC visit limited to this time period and scope. Thus, this opinion cannot be used here to determine whether the Respondent's controlled substance prescribing practices were unsatisfactory.

On the UC Patient Rix chart, Rubenstein's report and his testimony criticized the practice at NPPM for introducing Nurse Sanchez as ''Dr. Betsy.'' Tr. 30. Rubenstein found this to be misleading. *Id.* As discussed elsewhere in this recommended decision, the record is not sufficiently developed on this point to ascertain the extent (if any) that this feature should impact the decision as to whether the revocation of the Respondent's COR is in the public interest. While true, as discussed above, that Rix did indicate to the Respondent that he had been previously seen and was issued controlled substances by ''Dr. Betsy,'' and was not corrected on the issue of her title, it is not clear that this was a matter that reflected controlled substance prescribing at or below the standard recognized in Florida. Stated differently, it is not Sanchez's moniker among NPPM patients that is as important here as whether the Respondent was permitting her to make controlled substance prescription decisions under his COR number. Dr. Rubenstein was unambiguous on his expert opinion that the prevailing medical standard in Florida requires

[29] This is yet another none-too-subtle reference to possible doctor shopping and a potential red flag of possible diversion that received no discernible heightened scrutiny during the visit or in the patient chart.

[30] Tr. 129.

[31] *See* Tr. 37.

that a physician must actually meet a patient prior to prescribing controlled substances, and must be physically present at a facility where controlled substances are being prescribed. Tr. 36–43. This is so, according to Dr. Rubenstein, even where medical professional ''extenders'' such as nurse practitioners or physician's assistants are utilized to take vital signs and/or conduct portions of physical examinations. Tr. 41–42.

According to Schwartz's credible testimony, he made ten visits to NPPM and received controlled substances on five of those. He met with Nurse Sanchez (not the Respondent) for the first time during the (2nd) October 23rd UC visit and got controlled substances; he met with the Respondent (for the first and only time) on the (5th) November 21st UC visit and got controlled substances; he met again with Nurse Sanchez on the (6th) December 18th UC visit and got controlled substances; he met only with Palemire on the (7th) January 11th visit and got controlled substances; and on the (10th) July 28th visit, Rix met with a non-medical office staffer named ''Ted'' and once again got controlled substances. Thus, Dr. Rubenstein's professional opinion that the controlled substance prescribing realized under the Respondent's COR was done without the Respondent present and fell below the Florida medical standards is clearly factually supported in the current record, and as discussed, *infra,* stands unrebutted. It is likewise clear that (at least) as of Rix's fifth visit where he met the Respondent for the first and last time, the Respondent knew that Rix was a patient who was procuring controlled substances under his COR by meeting with Nurse Sanchez and Mr. Laterza. The only reasonable factual inferences that can be drawn are that either the Respondent was aware that Nurse Sanchez was prescribing under his COR, or that on the fifth visit he learned about that situation and voluntarily endured it for the subsequent visits. Accordingly, the Respondent knew or should have known that Nurse Sanchez and others at NPPM were authorizing controlled substance prescriptions under his COR. In light of the fact that no surprise was expressed by the Respondent to UC Patient Rix when the latter explained to the former that he had seen ''Dr. Betsy'' and Laterza for his prior visit and received controlled substances (in the unlikely event that these statements from Rix presented an unexpected anomaly or concern to the Respondent), a glance at the Rix patient chart that the Respondent had in his hand would have provided absolute clarity.

In his testimony, Rubenstein characterized the physical exam performed on Rix as ''suboptimal.'' Tr. 36. In particular, Rubenstein noted that although ''the patient complained of neck and back stiffness * * * the neck and back were never palpated or even examined and * * * no detailed neurologic or musculoskeletal examination was performed.'' *Id.* Similarly, Rubenstein's report noted that ''no neurologic or musculoskeletal examination [was] performed,'' and that ''no objective abnormality [was] ever identified during the limited, brief and suboptimal physical examination.'' Gov't Ex. 11 at 2. The brevity and scarce content of the physical examination were credibly detailed by TFO Schwartz, thereby equipping this unrebutted expert opinion with a sufficient factual evidentiary basis in the record for reliance.

Rubenstein's report also observed that although the chart reflected a prescription for physical therapy, ''there was no recommendation to a specific therapist, a diagnosis, a type of physical therapy, frequency, duration, goals, etc.'' *Id.* In his report, Dr. Rubenstein concluded that the treatment observed during the October 23rd Rix office visit

> Does not represent even minimal standards to justify controlled substances, and there would be no basis to prescribe highly addictive medications such as oxycodone 30 mg in large quantities as well as Xanax 2 mg based on the history provided or the physical examination performed [and that] [t]his represents a deviation from the standard of care.

Id.

Dr. Rubenstein also opined that having UC Patient Rix execute a pain contract, medical management agreement, and an advisal regarding safeguarding opioids at the outset of treatment, before a determination could be made by a physician that opiates were even appropriate, is a practice that falls below the standard of care in Florida. Tr. 43–46; Gov't Ex. 4 at 7–11.

The Rix patient chart also contains progress notes [32] pertaining to Rix's (5th) November 21 UC visit, the first and only time the Respondent was in the same room with UC Patient Rix. Gov't Ex. 4. Rix was seen only by the Respondent, and the handwritten progress notes are signed with the letter ''g.'' *Id.* at 26. The progress notes reflect marks on the form denoting inquiries regarding medication side effects (constipation, loss of appetite, and insomnia checked off), social history (single and living with spouse oxymoronically checked off), daily substance intake (half pack of cigarettes and no alcohol checked off), and physical examination (reflects examination of head, ears, eyes, nose, throat, and abdomen, and that Rix was pleasant and appeared in pain). *Id.* at 25. The form also indicates negative psychological history findings for eight mental health symptoms and ''rarely'' designated for three others. *Id.* at 26. Additionally, the form indicates that Rix had been ''counseled on risks/benefits of [the prescribed medications and] will take exactly as prescribed,'' that ''fish oil/omega 3 was recommended [in a dosage of] 3–6 grams per day,'' that alcohol and soda avoidance was urged ''@ length [sic],'' that Rix was ''strongly advised'' to stop smoking, and responded negatively when asked whether he has used recreational drugs while taking pain medication. *Id.* Schwartz's credible testimony and the transcript of the wire he wore show that none of those areas were the subject of any discussion or examination during the brief encounter. Gov't Ex. 4 at 25–26; Gov't Ex. 18 at 17–22; Tr. 647–53. Thus, to the extent that the progress notes reflect these events, questions, and examination results, they are plainly fabricated.

Under the section labeled ''plan,'' six controlled and non-controlled substances are preprinted in predetermined strengths. The list contains Roxi 30 mg, Roxi 15 mg, Valium 10 mg, Xanax (with a blank next to the strength), Mobic 7.5 mg (non-controlled), and Soma (non-controlled with a blank next to the strength). *Id.* Next to each drug is a corresponding area with a blank field and the words ''continued as prescribed'' next to it. *Id.* Handwritten by the Respondent is a check next to Roxi 30 mg and an ''up'' arrow with the number 150 next to ''continued as prescribed.'' *Id.* Also marked is Xanax for 2 mg. *Id.*

In evaluating this November 21st UC visit, Dr. Rubenstein's report notes that although no physical examination was conducted on Rix during this visit, the office visit form has no patient name and falsely reflects that an examination of the patient's head and other enumerated body parts and organs occurred. Gov't Ex. 11 at 3. Hence, based on the credible testimony of TFO Schwartz and the corroborating transcript received into evidence, these chart notes are plainly untrue.

The UC Patient Rix patient chart contains a progress note prepared in

[32] Although the patient name on this page is left blank, there is adequate, unchallenged record evidence to support a finding that this page was contained in the Rix patient chart provided to TFO Thomas by NPPM. *See* Gov't Ex. 4 at 1.

connection with Schwartz's (6th) December 18th UC visit. Gov't Ex. 4 at 22–23. Consistent with Schwartz's credible testimony that his procurement of controlled substances on this occasion was preceded by contact with Nurse Betsy Sanchez and not the Respondent, the progress notes are signed with the letter ''B.'' *Id.* at 23. Suffice it to say that the progress notes prepared by Nurse Sanchez during this UC visit are as distant from the reality of what happened as were the Respondent's recorded recollections of the November 21st visit. In short, the observations set forth in these chart notes are as phony as those concocted by the Respondent regarding the November 21st UC visit.

Dr. Rubenstein's report on the December 18th UC visit notes that this visit also resulted in the issuance of controlled substance prescriptions issued under the Respondent's COR although he was nowhere in sight, and that this visit included neither a physical examination nor even the taking of vital signs. Gov't Ex. 11 at 3. These are factual predicates that find support in the record in Schwartz's credible testimony. Tr. 660–65. The absence of any examination and vital readings did not result in the absence of values regarding those aspects from appearing in the progress notes, which Rubenstein characterizes as ''fraud in the examination scenario.'' Gov't Ex. 11 at 3. Rubenstein also found it remarkable that UC Patient Rix told them his pain was ''not bad'' so long as he has his medication and that Rix asked for advice about what number to volunteer on the pain scale and whether a three would be too low. *Id.* Although Patient Rix informed the practice that he had been in the hospital for a week, lost ten pounds, and had been unable to keep food down, conditions that could have precluded his ability to finish the medication that had been prescribed on the prior visit, Nurse Sanchez presented him with prescriptions for #150 Roxicodone 30 mg and #30 Xanax 2 mg, both of which were dispensed by Ms. Palemire. *Id.* at 3–4.

The Rix patient chart contains a progress note prepared in connection with the (7th) January 11 UC visit by UC Patient Rix. Gov't Ex. 4 at 19–20. Although, according to the credible testimony of TFO Schwartz, UC Patient Rix was issued controlled substances after consultation with only Palemire (and no medical professional), Tr. 681, the progress note reflects recorded observations, history, advice, and counseling reminiscent of previous (equally false) versions prepared in connection with other visits by the Respondent and Nurse Sanchez. The form is signed with the letter ''g.'' Gov't Ex. 4 at 20.

The progress note documentation maintained in the chart in connection with the (8th) July 22nd UC visit was unnamed, incomplete, and unsigned. Gov't Ex. 4 at 16–17. Like the UC visit that preceded it by six months, the credible testimony of TFO Schwartz established that he encountered no medical professional during that visit, no history of any kind was taken, and no examination took place—the false entries on the form to the contrary notwithstanding. Tr. 681. The progress note bore no reference to the fact that Rix had not been to the practice in six months. Gov't Ex. 4 at 16–17.

Regarding this final UC visit to NPPM by Rix as a pain patient[33] and the lengthy hiatus that preceded it, Dr. Rubenstein testified that after such a long absence from the practice, that a detailed history and inquiry must precede a determination by the physician that controlled substances are an appropriate course, and that the documentation in the chart did not support such steps. Tr. 48–54. Not only did Schwartz's credible testimony and the chart note support the absence of such a probing inquiry, Schwartz's testimony establishes that the decision to prescribe controlled substance pain medication on the Respondent's COR was made by, or with input from only, Palemire, who is not a medical professional. Rubenstein opined that ''based on the records presented * * * there was no basis to prescribe oxycodone or Xanax based on the history provided or the physical examination performed.'' Tr. 50. Dr. Rubenstein elaborated that this was of particular importance in a case such as Rix presented, where the two medications have potentially dangerous interactions that can result in respiratory depression, and that a determination as to whether a patient has been off opioids for that period of time (and by virtue of that abstinence would be treated as opioid naïve) must be made by a qualified practitioner. Tr. 51–54.

Addressing the controlled substance prescribing regarding UC Patient Rix, Dr. Rubenstein testified that the amount of controlled substances prescribed was inconsistent with the relatively low levels of pain complaints. Tr. 55. According to Rubenstein, the conflict between the complaints in the neck and the MRI addressing the back made it unclear as to what body part was even being treated for pain. Tr. 56. Moreover, Rubenstein was troubled by the absence of any indication that in the face of stated back and neck complaints, no neurologic or musculoskeletal exam had been performed and that there was no evidence that UC Patient Rix's back and neck had been palpated. Tr. 56–57. Dr. Rubenstein testified that after reviewing the patient chart prepared on UC Patient Rix, it was his opinion that the care rendered to Rix at NPPM did not meet the standard of care required in pain management for the following reasons:

> There was not an adequate physician/patient relationship. The medications were excessive given the lack of appropriate history or physical examination, the lack of identified pain generators and the lack of patient complaints or objective abnormality that would have correlated to the requirement or consideration of said medications. The medications were excessive in dose and frequency given the underlying problem and there were issues with who performed the evaluation of the patient.

Tr. 59.

UC Patient Hays

Retired Special Agent (SA) Jack Lunsford testified that prior to his retirement, he had served over twenty-two years as a DEA special agent. Tr. 136. Lunsford testified that he made two UC visits to the Respondent's practice, on June 29, 2010 and July 27, 2010, respectively, under the assumed name David Hays (UC Patient Hays), and that (like TFO Schwartz's visits as Rix) both visits were recorded through the use of a bodywire and transcribed. Tr. 137, 139, 176.

SA Lunsford testified that at his initial visit to NPPM, which occurred on June 29, 2010,[34] he was greeted by an armed security guard who told him that the Respondent was not in and that he did not know whether the Respondent would return. *Id.* SA Lunsford testified that he lined up at the reception counter. Tr. 138–40. The attendant at the reception counter likewise informed UC Patient Hays that the Respondent was not available, but stated that a ''Dr. Derrick'' could see him instead.[35] Tr. 140. He was then instructed to produce his MRI report and driver's license and was asked to sign a log and fill out paperwork while he waited for his examination. Tr. 140–41.

A copy of the patient chart maintained by the Respondent's office on UC Patient Hays reveals the same

[33] TFO Schwartz returned two more subsequent times, on July 23rd and July 28th, to order and pick up anabolic steroids.

[34] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 30; Tr. 176.

[35] Derrick Davis is a physician's assistant who was employed by NPPM. Tr. 893.

compliment of standard forms present in the other patient charts received into evidence [36] and has chart entries reflecting his initial June 29th UC visit. Gov't Ex. 8. On the Patient Intake Form, UC Patient Hays indicated that he was referred to the practice by his ''friend Mark,'' and that the purpose of his visit was ''to see about medication.'' *Id.* at 2. The Pain Inventory reflects a range of pain from only 1–3 on a 10 scale, that he has endured this discomfort for ''more than a month,'' that he treats his pain with rest, hot showers, and over-the-counter Advil and Motrin, and that remedies have provided him with 30% relief (from his 1–3 out of 10 pain). *Id.* at 4–5. Diagonal lines were drawn on a Pain Med Contract that was provided to Hays, thereby alerting the patient that it is not necessary to provide either his ''[g]oals for taking opioid medications'' or ''[m]edication and proposed duration of use.'' [37] *Id.* at 6. Similar lines were pre-drawn on the provided Opioid Contract through areas designated for the patient to list ''[t]he reasons [he] has pain,'' and the specific opioid medications and doses prescribed. *Id.* at 10. Lunsford testified that these diagonal marks were not made by him. Tr. 143.

A review of the transcript prepared in connection with the June 29th UC visit,[38] to which SA Lunsford's testimony largely parallels, reveals that UC Patient Hays never interacted with the Respondent, but was seen by a physician's assistant (PA) who identified himself as ''Derrick.'' [39] Gov't Ex. 30 at 9. When, in response to an inquiry from the PA, Hays informed that he ''had not really injured'' his back, the PA told him that he was mistaken and that his back was injured, and pointed to his MRI report. *Id.;* Tr. 164. The lumbar MRI report found within the UC Patient Hays chart reflects ''[s]mall disc protrusions at L4–5 and L5–S1 with bulging of the annulus [with] [n]o nerve root effacement * * * identified at either level'' and ''[r]ecommend[s] correlation with the clinical symptoms and neurologic exam to assess the significance of the * * * findings.'' Gov't Ex. 30 at 15.

UC Patient Hays told the PA that he was a pressure washer by occupation and that his employment, as well as the mechanic work he performs on his motorcycles, results in his lifting heavy items. Gov't Ex. 30 at 10. While Hays initially told the PA that he had never been in a motor vehicle accident, *id.,* he later admitted to rear-ending a car in a motor vehicle. *Id.* at 17.[40] Regarding medication, consistent with his responses on the Pain Inventory, Hays told the PA that he has been treating his back discomfort with ''Advil and Motrin sometimes.'' *Id.* at 11; *see* Tr. 163. When asked pointedly whether he had tried other medications ''whether you got it off the street or [from] a friend,'' UC Patient Hays conceded that his girlfriend has given him oxycodone in both 30 and 15 mg strength, as well as Xanax, but that this was causing a problem because his girlfriend actually had a legitimate need for her prescribed pain medication and Hays, by his own admission, only had ''you know, a few * * * I guess relatively minor health issues.'' *Id.* at 11–12; *see* Tr. 150, 153. As the discussion between patient and PA progressed, Hays made it clear that taking his girlfriend's medication has caused some relationship disharmony because she is happy ''[w]ell, because she's medicated [and] I haven't been so much.'' *Id.* Hays told the PA that his girlfriend ''wants us to get kind of on a even bases [sic].'' Gov't Ex. 30 at 12. An almost surreal exchange followed wherein the PA (none too discreetly) re-framed the patient's issue as based really in terms of the need for back pain relief, to which the patient finally replied ''You know, [I] haven't really thought about it that way but you may be right,'' and the PA ultimately announced ''Okay. Well, let's see what we could do to make you happier and make you guys really connect, okay?'' *Id.* at 12–14; *see* Tr. 150. The PA conducted a discussion with the patient regarding potential medication side effects and risks of addiction. Gov't Ex. 30 at 15–16, 24; *see* Tr. 151, 165. A discussion on pain level followed, wherein UC Patient Hays repeatedly confessed that his earthly existence has been virtually unknown to feeling or even observing genuine pain, and is finally coaxed into agreeing that without medication, his pain level is about a three out of ten. Gov't Ex. 30 at 17–18; *see* Tr. 151. When pressed on the issue of pain, UC Patient Hays explained to the PA that ''my back doesn't feel all that bad,'' that ''I mean * * * I've drove [sic] over here, I've been sitting around, I walked freely,'' that ''[w]hen I take Advil it works pretty good [and that when] I'm taking that other stuff * * * everything's just, you know * * * [k]inda flat.'' Gov't Ex. 30 at 18; *see* Tr. 151. The PA utters an audible sigh when Hays insists ''[w]ell, my back is really nothing to be worried about.''

The PA, in an obvious testament to his (albeit arguably misguided) perseverance, conducted a physical examination where he took the patient's blood pressure and had him conduct multiple postural pushing and twisting maneuvers, none of which caused the patient to issue any manner of complaint. Gov't Ex. 30 at 23–24; *see* Tr. 150–51. Interestingly, the chart notes in the file that correspond to this UC visit reflect numerous (+) signs that correspond to illegible words, notwithstanding the absence of any complaint by the patient as captured within the transcript. Gov't Ex. 8 at 28. The PA informed UC Patient Hays that he intended to ''talk to the doctor,''[41] and shortly thereafter, the NPPM office staff provided the patient with an appointment card and prescription scripts for #150 Roxicodone 30 mg, #30 Xanax 2 mg, as well as Naprosyn (not a controlled substance), and a prescription script where the word ''consultation'' appears next to the area designated ''drug name,'' and ''see ortho and physical therapy'' appears in the area designated for pharmacy label instructions. *Id.* at 26; *see* Tr. 154. SA Lunsford testified that he recalled the prescriptions being signed with ''some form of initials,'' either something resembling a ''C'' and ''G,'' or just a lone ''G.'' Tr. 154; *see* Gov't Ex. 40 at 25–26, 28–29. According to SA Lunsford's testimony, the issuing physician's name on the script belonged to the Respondent. *Id.* However, no testimony was elicited from Lunsford as to

[36] An exception being the addition in UC Patient Hays' medical file of a copy of a DEA regulation (21 C.F.R. § 1306.13) detailing the permissible conditions for the partial filling of a prescription for a Schedule II substance. Gov't Ex. 8 at 13.

[37] SA Lunsford testified that while he was not certain when the diagonal lines appeared in the chart, they were not added by him. Tr. 143.

[38] While the foundation laid for the introduction of the transcript was certainly not a model for clarity, the document was received into evidence after SA Lunsford testified that it might contain some inconsistencies that did not rise to the level of significant, such as him saying ''Whoa'' but it appearing as ''Wow'' in the transcript. Tr. 169–76. Whatever typos he thought the transcript may possess, SA Lunsford still felt that on balance it was fair and accurate as to what transpired on June 29, 2010. Tr. 171, 175. Moreover, although the tenor of Lunsford's testimony during the authentication evolution gave the impression that the transcript contained typographical errors, the substance of SA Lunsford's recollection of events as expressed through his credible testimony was substantially the same as the version depicted in the transcript.

[39] Although the office staff told UC Patient Hays that he was going to see ''Dr. Derrick,'' the physician's assistant made it clear at the outset of his interaction with Hays that he was a ''practitioner assistant.'' Gov't Ex. 30 at 9; Tr. 149.

[40] As discussed, *infra,* the chart note prepared by the PA in connection with this visit reflects that Hays told him that he had been in a motor vehicle accident; however, UC Patient Hays denied experiencing a motor vehicle accident on his intake form. *Compare* Gov't Ex. 8 at 27, *with* Gov't Ex. 8 at 2.

[41] Gov't Ex. 30 at 26; Tr. 153.

whether he was familiar with, or could identify, the Respondent's signature.[42]

In the evaluation of this UC visit that is set forth in his report, Dr. Rubenstein notes that UC Patient Hays received controlled substance prescriptions on the June 29th UC visit, even though he received only a ''brief exam in terms of cardiac and respirator auscultation'' by a physician's assistant, performed postural maneuver tests ''with full strength and flexibility,'' and was never seen by the Respondent. Gov't Ex. 11 at 5. The report notes that Patient Hays told the physician's assistant that over-the-counter Advil[43] ''works pretty good'' and that his back ''doesn't feel all that bad [and] is really nothing to be worried about.'' *Id.* Rubenstein also found it remarkable that when Patient Hays stated that his back was ''not really injured,'' that the physician's assistant pointed to the patient chart and told him that it was. *Id.* Interestingly, the MRI report that he had provided to NPPM as Patient Hays was actually a report done on SA Lunsford's back. Tr. 143–44, 217, 226. Thus, the diagnosis of a small disc protrusion reflected in the patient chart is actually a diagnosis for Patient Hays that is supported by objective medical evidence. Tr. 217–18.

SA Lunsford's second and final foray into the Respondent's practice as UC Patient Hays occurred on July 27, 2010.[44] Tr. 176. SA Lunsford testified to entering the clinic premises and having brief interactions with a uniformed security guard as well as a receptionist. He presented his Patient Hays driver's license, signed a sign-in sheet (the single paperwork evolution associated with the visit on his part), and paid an office visit fee. Tr. 176–77, 179–80. SA Lunsford then seated himself in the waiting area until called back to the reception counter about an hour later. Tr. 177–78. As revealed in the transcript and Lunsford's testimony, the interaction involved nothing more than a visit at the reception desk that took as much time as needed by the staff person to say, ''There you go,'' and Hays to reply, ''Thank you very much.'' Gov't Ex. 33 at 3. Hays thanked the staff person for wishing him ''a wonderful afternoon'' and the transaction, *id.,* which yielded an identical battery of prescription scripts as the first UC visit, was completed[45]—but for the paperwork. The chart entry reflects a somewhat more elaborate account that (falsely) details UC Patient Hays' denial of side effects and street drug use, his pain and the appearance of his pain, as well as Hays' abnormal posture (spelled ''postue'' in the form), all recorded without an examination of any kind. Gov't Ex. 8 at 24–25. According to Lunsford, he came and left the clinic, and received his controlled substance prescriptions, without suffering the inconvenience that might be caused by interaction with medical personnel of any variety. Tr. 177–78, 246. Lunsford testified that while he was in the waiting room awaiting the issuance of his prescriptions, he saw the Respondent enter the clinic and cross the threshold into the hormone treatment area. Tr. 178–79.

Regrettably, the only observations in Dr. Rubenstein's report relative to UC Patient Hays' second UC visit relate to the nature of the controlled substances dispensed and the fact that no patient name was written on the progress note page. Gov't Ex. 11 at 5. However, in his testimony, Rubenstein offered his conclusion that under the prevailing standards in Florida, the controlled-substance prescribing that was undertaken with respect to Hays was not justified by the information presented to the prescriber. When asked what was missing from the chart that should have been there to support the prescribing evidenced in the case of UC Patient Hays, Dr. Rubenstein responded this way:

> An adequate history and complete physical examination, with any other objective testing to formulate an appropriate treatment plan, which may or may not include medication. In this case, [SA Lunsford] was specifically downgrading his complaints of pain * * * telling the physician's assistant that his back was ''nothing to be worried about.'' Yet high doses of medications were being recommended that were not warranted based on the patient's history. So to justify prescriptions of the agents and any opioid agent at an initial visit, I would want an appropriate history or physical examination that would indicate that there is acute or chronic pain with an objective correlation that would justify such agents, and even so, the amounts and doses of medication would be excessive for an initial visit of the patient.

Tr. 65–66. Dr. Rubenstein opined that the medical care offered to UC Patient Hays (which, in this case was controlled substance prescribing and dispensing) fell below the established standards for medical care in Florida. Tr. 76–77.

Viewed in a vacuum, the controlled substance prescribing conducted at NPPM under the authority of the Respondent's COR was effected by persons other than the Respondent. The evidence presents no serious dispute on that issue. However, the direct, credible evidence from TFO Schwartz that the Respondent was directly informed that UC Patient Rix was previously seen by, and received controlled substances from, Laterza and ''Dr. Betsy,'' with an in-hand patient chart confirming that scenario, casts the NPPM staff interactions with UC Patient Hays in a different light. Under the circumstances presented here, it is reasonable, based on the evidence of record, to conclude that the Respondent was well aware (or should have been) that these and other controlled-substance prescribing actions like these were being taken by various NPPM staff persons under his COR. This is particularly true here, where the Respondent, although called as a witness by the Government at the hearing, asserted the Fifth Amendment and declined to testify. Although the Respondent was an employee of NPPM, he was the master of his COR. His status as an NPPM employee in no way diminished his responsibility to safeguard the authority associated with his COR.

UC Patient Barbaro

SA Joseph Annerino, an agent with two and a half years of experience with DEA, and with a decade of prior experience as a Chicago police officer, testified that he made two UC visits to the Respondent's practice using the name Joe Barbaro (UC Patient Barbaro), that he never met the Respondent or any other physician there, and yet received Testosterone Cypionate[46] under the authority of the Respondent's COR. Tr. 261–62, 287, 311. SA Annerino testified that UC Patient Rix introduced him to Mr. Laterza at NPPM to effectuate the sale of anabolic steroids. Tr. 263.

SA Annerino testified that shortly after being introduced to Mr. Laterza at the first visit on November 16, 2009,[47] Laterza provided quite a bit of information in response to questions he posed about testosterone and HGH, as well as explaining the benefits of hormone replacement therapy (HRT). Tr. 262, 264. The transcript of the first of the UC visits reflects a lengthy conversation with Laterza about

[42] The Government sought to elicit testimony regarding conversations between patients that were overheard by Lunsford as he sat in the waiting area, but inasmuch as there was no link between the Respondent and any of these purported conversations, the testimony was excluded as irrelevant. Tr. 158–63.

[43] Actually, the transcript of this interaction with the physician's assistant reflects that UC Patient Hays told him he had been treating his back with ''Advil and Motrin.'' Gov't Ex. 30 at 11.

[44] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 33; Tr. 182.

[45] Gov't Ex. 8 at 23; Tr. 177–78.

[46] A Schedule III controlled substance.

[47] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 17; 268.

purported benefits of testosterone and HGH treatment and an examination conducted by Nurse Sanchez, who, like in the case of UC Patient Rix, was introduced and answered to the moniker ''Dr. Betsy.'' Gov't Ex. 17 at 40–42; Tr. 273–74. As testified by SA Annerino, Laterza instructed him to complete a personal history form, upon which he declined to put down any physical ailments. Tr. 264–65. As a result, Laterza spent much of his time coaching UC Patient Barbaro on the most advantageous answers to questions asked in the patient information form, even to the point that Laterza personally changed answers provided by UC Patient Barbaro from ''no'' to ''yes.'' Gov't Ex. 17 at 17–19, 36–39; Tr. 265–66, 268–69. At one point, Laterza admonished him that ''if you say no to everything, then the doctor is not going to know what he's treating.'' Gov't Ex. 17 at 37; Tr. 268. SA Annerino testified that an examination was conducted by Nurse Sanchez. Tr. 273; Gov't Ex. 17 at 41. However, SA Annerino testified that none of his discussions with Nurse Sanchez bore upon the subject of testosterone. Tr. 274.

Laterza arranged for UC Patient Barbaro to have his blood drawn at a lab and left a phone message for him four days later wherein he attempted to arrange for a time to ''go over'' Barbaro's ''labs'' with him. Tr. 274, 278, 282; Gov't Ex. 20 at 3. Four days after the phone message, on November 24, 2009, UC Patient Barbaro telephoned Laterza, and the latter explained the blood analysis results to the former in great detail, ultimately advising that ''basically, you are going to need some testosterone'' due to ''deficiencies'' that Laterza identified in the results. Gov't Ex. 21 at 4; Tr. 282–84. On December 9, 2009, UC Patient Barbaro presented himself to the Respondent's practice [48] (following a voicemail from Laterza on November 30, 2009 to pick up his Testosterone Cypionate from the clinic, Tr. 284), and upon little more than stating his (fictitious) name and providing cash, was presented by Ms. Palemire with a box containing a vial of Testosterone Cypionate and a syringe, Tr. 287–88; Gov't Exs. 22–23. While vial of the controlled testosterone reflects that it was prescribed pursuant to the Respondent's COR, Tr. 304, 331–32; Gov't Ex. 38, at 7–A, Laterza made no representations to SA Annerino that he ever consulted with the Respondent about UC Patient Barbaro's treatment, that the Respondent had actual knowledge of his treatment, or that the Respondent personally prescribed the controlled substances or authorized Laterza to issue the prescriptions,[49] Tr. 284, 325–27, 332. Annerino testified that although he obtained controlled steroids issued under the Respondent's COR, the only medical professional he interacted with at NPPM was Nurse Sanchez, and that the first time he ever laid eyes on the Respondent was at the hearing. Tr. 311, 316.

Although Dr. Rubenstein did not review any patient chart associated with the Annerino's UC visits as Barbaro, his testimony was unequivocal that the issuance of controlled substance prescriptions without meeting a patient falls below the Florida prescribing standards. Tr. 36–43. If the evidence of record stood, thus, with no evidence of a direct connection between Laterza and the Respondent, there would be little to recommend wrongdoing on the part of the Respondent based on the testimony of SA Annerino. However, the Respondent's November 21st UC visit and interaction with UC Patient Rix, wherein the former was advised by the latter that he was receiving anabolic steroids through exchanges with Laterza, provides ample support for the proposition that the Respondent knew or should have known that Laterza was consulting and prescribing controlled steroids armed with the Respondent's COR. This is particularly so on this record wherein the Respondent asserted his Fifth Amendment right against self-incrimination and declined to testify although called as a witness by the Government.

Patient Chart Reviews

At the request of the Government, Dr. Rubenstein reviewed charts maintained on four of the Respondent's patients, prepared written comments in his report, and testified at the hearing about his conclusions. Each patient executed a written authorization for the release of their respective chart.

Chart Review: Patient SL[50]

Patient SL's chart reflects that he is a 35-year-old male patient who was treated by the Respondent from April to September of 2010. Gov't Ex. 5. On his Pain Inventory, which he completed and submitted on intake, SL signaled that he was experiencing pain in the 4–8 out of 10 range in his lower back, right knee, and left shoulder, that he had been experiencing the pain for ''over a month,'' and that his treatment with oxycodone 30 mg and Percocet 5 mg, coupled with Xanax for sleep issues, has afforded him relief at a level between 70–100%. *Id.* at 32. Further, the Pain Inventory reflects that while his discomfort is exacerbated by running, excessive walking, and prolonged sitting, that medicine, rest, and therapy provide relief. *Id.* at 33.

The SL patient chart maintained by NPPM contains, *inter alia,* multiple prescriptions authorized under the Respondent's COR for Roxicodone (30 mg) and Xanax (2 mg). *Id.* at 4–5, 11, 14, 23, 27. Dr. Rubenstein's report notes that a sign-in sheet included in the chart contains obviously discrepant dates, that the patient informed the practice that he had been referred ''by a friend,'' that no neurologic or musculoskeletal examinations were ever performed on him at the Respondent's practice, and that he traveled from a remote location to be treated by the Respondent without any obvious explanation for the commute present in the documentation. Gov't Ex. 11 at 15–16. Although at the hearing Dr. Rubenstein testified that there was no apparent reason this patient traveled a distance that Rubenstein guestimated to be about thirty to forty minutes[51] to be treated at NPPM, there was insufficient development of this issue to have the testimony bear on any issue that must be decided here. If thirty to forty minutes was a long distance, there was no evidence presented as to what a reasonable distance might be, or why the distance was or should be gauged in determining whether revoking the Respondent's COR is in the public interest.

Dr. Rubenstein testified that the SL patient file demonstrated what he characterized as a ''deficit in the standard of care.'' Tr. 81. Specifically, Rubenstein noted that the file lacked sufficient documentation to substantiate the need for the controlled substances prescribed, that there were no records from prior physicians, and that no indications that alternative treatments beyond the controlled substances prescribed were ever discussed with the patient. *Id.* at 80–81. Dr. Rubenstein summarized his conclusions in his report as follows:

[48] An audio recording and corresponding transcript were received in evidence. Gov't Ex. 23; Tr. 294.

[49] SA Annerino testified that although a search warrant was executed at the Respondent's practice pursuant to the ''round-up'' for Operation Pill Nation, he was not a part of that evolution and therefore lacks any knowledge as to whether a patient file corresponding to UC Patient Barbaro was ever identified, sought, or recovered. Tr. 272. Dr. Rubenstein's report did not contain an analysis of UC Patient Barbaro's encounters with the Respondent.

[50] Pursuant to a Protective Order issued in this case on May 2, 2011, initials have been substituted for the names of patients. ALJ Ex. 15.

[51] Tr. 82.

The records of [SL] are suboptimal. They clearly do not document the rationale or need for high doses of Roxicodone. At no point was a physical exam ever documented which would have warranted the use of these agents. There was no examination of the right knee or left shoulder consistent with the MRIs. There was absolutely no documentation in the file which would have warranted or substantiated the need for these medications. No other alternatives for treatment of these problems were reviewed. Clearly this represented simply visits to dispense medications. No other records from other providers to document the use and need of these medications [was] reviewed. In summary, this represents a deficit in the standard of care.

Id. at 16.

Chart Review: Patient CC

Patient CC's chart reveals that she was treated at NPPM from May to October of 2010, and that during that time she received multiple prescriptions for controlled substances, including (but not limited to) multiple prescriptions for Roxicodone (30 mg and 15 mg doses) and Xanax (2 mg). Gov't Ex. 6 at 5–7, 15–17, 40–41, 44–45, 48–49, 52–54. She initially presented to NPPM as an obese, 31-year-old patient with complaints of back and ankle pain that she rated between three and seven on a ten-scale. *Id.* at 20–23. The chart contains MRI reports for the ankle as well as the lumbar and thoracic areas of CC's back from 2007. *Id.* at 32–34. The back MRI reports describe anomalies that are consistently characterized as ''mild.'' *Id.* at 32, 34. The ankle MRI report includes references to an incomplete fracture, a partial tendon tear, as well as a ligament tear. *Id.* at 33. Dr. Rubenstein testified that the 2007 MRI reports could be relied upon in evaluating patient treatment, but were not current enough to justify the prescribing of pain medication. Tr. 88.

Although CC's chart shows that the controlled substance medication dosages were changed and titrated, there was no justification for the adjustments documented in the record as opined by Dr. Rubenstein. Tr. 90–91. Moreover, Rubenstein noted that CC was prescribed OxyContin in an 80 mg dose, which is a dosage indicated for opioid-dependent patients, absent a diagnosis of cancer or other terminal illness. Tr. 91–93. The chart has no indication that CC was diagnosed as having opioid dependence, a malignancy, or other terminal disease. Dr. Rubenstein testified that in his view, based on his review of the chart:

There is no basis for any of [the prescribed] medications based on lack of any neurologic or musculoskeletal exam abnormality. I * * * reviewed the imaging studies [and] noted that there were large quantities of multiple highly addictive medications prescribed without any objective abnormality other than [an] MRI from 2007 that had shown some mild abnormalities but no, in my opinion, nerve root displacement or spinal cord compression [and thus, a] [l]ack of objective correlation that would have been consistent with the patient's complaints that shepresented to [NPPM].

Tr. 86–87. This testimony was consistent with the conclusions set forth in Dr. Rubenstein's report. Gov't Ex. 11 at 7.

Chart Review: Patient CH

Dr. Rubenstein also reviewed the chart maintained on Patient CH, a 29-year-old female patient treated by the Respondent from August 2009 until October 2010,[52] when, according to a chart entry, she was discharged in a notice dated October 5, 2010 by a Dr. Randy Dean for ''Dr. Shopping.'' Gov't Ex. 7 at 1. An intake form completed by CH states that the purpose of her visit is pain management, and she claims having the diagnoses or symptoms of fibromyalgia, depression/anxiety, and neck/back pain in her medical history. *Id.* at 34. Patient CH wrote that she heard about the NPPM clinic from a business card. *Id.* At intake, CH reported on the Pain Inventory that she had pain in her neck, front and back shoulders, lower back, and quadriceps, and rates her pain between seven and ten. *Id.* at 36. She further represented that only medicine and rest improve her pain, whereas ''walking, playing [with] kids[,] standing, [and] riding in [a] car'' all aggravate her pain. *Id.* at 37. CH adds, ''[The pain] interferes with my life in everyway [sic]. I can't function to do everyday jobs when I'm in pain. It even interferes with my relationship [with] husband & kids.'' *Id.*

Among CH's documents provided at intake were an MRI report and two papers relating to prescribed controlled substances. *Id.* at 30–32. The MRI[53] is of the lumbar spine and reports minimal impressions. *Id.* at 30, 46 (''Very minimal degenerative changes in the low lumbar spine as described above. No fracture, no acute herniated nucleus pulposis. No significant facet arthritis.''). A prescription label of #56 alprazolam 1 mg by a Dr. Findley, dated May 20, 2009, is included, as well as a pharmacy profile from Orange Park Drugs between March 12, 2009 and July 9, 2009, which contains only either #120 oxycodone 30 mg or #90 Vicodin 10/500 mg, all prescribed by a Dr. Fowler. *Id.* at 31–32. It is noted that the alprazolam prescription is not included in the pharmacy profile, although it was prescribed within the same time period.

Regarding the progress notes and prescriptions for each visit, little changes each time. Usually few notes are taken or boxes checked. Controlled substances are consistently prescribed with explanations, notes on medication efficacy and results, activities of daily living, progress, or testing protocols consistently absent. Oft times, the progress notes are unsigned, un-named, and abjectly unintelligible. *See, e.g., id.* at 110–11.[54] At the initial visit on August 8, 2009, the unsigned chart contains a notation to drug test CH's urine at the next visit, although there is no documentation to suggest that this aspiration ever came to fruition during CH's year at the practice. *See* Gov't Ex. 7 at 81.

The chart reflects a more or less continuous stream of controlled substance prescriptions issued in the Respondent's name[55] throughout the year of treatment without follow up. Even should a notation appear to signal to follow up with the patient regarding a referral, *see id.* at 75–77 (August 2009 visit), no follow up is ever found or is evidenced anywhere in the chart during the months subsequent, *see, e.g., id.* at 72–74 (September 2009 visit), and instead the patient is supplied with prescriptions for greater amounts of controlled substances, *see id.* at 56–57, 59, 82, 92–93 (October 2009 visit with Roxicodone dosage increase). Furthermore, the chart reflects a pattern of premature visits during which controlled substances are prescribed every time without annotation to the medical record explaining why. *See, e.g., id.* at 75–77 (August 25, 2009 visit, 17 day cycle); *id.* at 56–57, 59, 82, 92–93 (October 17, 2009 visit, 22 day cycle); *id.* at 12–14 (December 7, 2009 visit, 18 day cycle).[56]

[52] A sign-in sheet included in the chart reflects that CH presented to NPPM on fifteen occasions from August 2009 through August 2010. Gov't Ex. 7 at 33.

[53] While the MRI refers to Patient CH as a ''man,'' this was apparently errata. *Id.* at 10.

[54] It would be difficult to imagine that any subsequent practitioner or reviewer would be able to discern the rationale employed to justify the medications prescribed that day or anything else that happed during that visit.

[55] CH also received controlled substances from times by a physician other than the Respondent. *See, id.* at 67 (Dr. Carlos Haro), 109 (same).

[56] For reasons not readily apparent or explained by testimony, the CH chart reflected another curious practice wherein the patient was provided split prescriptions. At CH's February 10 visit, which was conducted by Dr. Carlos Haro, two prescriptions were issued for Roxicodone 30 mg into two separate scripts, one for 50 dosage units and the other for 100 dosage units, but netting no difference of quantity from that prescribed the previous month. *Compare id.* at 67, 109, *with id.* at

Continued

Dr. Rubenstein's report noted the absence of neurologic examinations and multiple occasions where prescription scripts were issued without any indication of a corresponding office visit. Gov't Ex. 11 at 12. Dr. Rubenstein provided the following assessment of the patient file:

> Although at the initial visit an MRI study, physical therapy and EMG all [were] recommended[,] there was absolutely no reference anywhere in the records to suggest that specific referrals were given, that the patient completed these referrals, or even any documentation as to what occurred. There were no diagnostic studies listed in the file [and] [t]here was no neurologic exam ever performed. In summary, the records do not meet the standard of care to justify the prescriptions that were dispensed. There was no evidence of any objective abnormality[,] be it through diagnostic testing, physical examination, or even a detailed pain history that would warrant the medications.

Id. at 13. Similarly, when asked at the hearing if the chart reflects whether the standard of care was met for the prescribing of controlled substances in Florida, Dr. Rubenstein testified:

> The records did not meet with the standard of care to justify the prescriptions that were dispensed. There was no evidence of any objective abnormality, be it through diagnostic testing, physical examination or detailed pain history that would warrant the medication.

Tr. 96.

Chart Review: Patient PL

The patient file maintained by the Respondent on PL, a 48-year-old female patient who was seen by the Respondent from April to September 2010, at which time according to a chart entry she was discharged from the practice for ''Dr. Shopping,'' was also reviewed by Dr. Rubenstein.[57] Gov't Ex. 9 at 2.

PL's sign-in sheet indicates five visits in 2010, on April 10, May 7, June 10, July 19, and August 16, but curiously the only minimally-completed progress note contained in the entire chart is dated September 17 (a date subsequent to the final sign-in date). Gov't Ex. 9 at 3–8, 23.

The intake forms indicate that PL identified herself as a manager at a storage facility, represented that the purpose of her visit was to ''receive pain medications,'' and stated that she was referred by someone with an identical name to her emergency contact person. *Id.* at 9. PL indicated complaints of anxiety, neck pain, and arthritis. *Id.* On the Pain Inventory, PL drew X's on an illustration depicting pain running all along her shoulders and arms, down her legs, and on her neck. *Id.* at 11. On a ten-scale, PL rated her pain between six and ten. *Id.* PL wrote on the form that she had been prescribed #240 oxycodone 30 mg, #120 oxycodone 15 mg, #90 Xanax, and #90 Soma sometime in the last 40 days. *Id.* To describe the variety of pain she experienced, PL circled every adjective listed on the inventory form except for ''dull.'' *Id.* at 12. Medicine, rest, and ice all purportedly improved her pain, while lifting, standing, or even writing exacerbated it. *Id.*

A cervical spine MRI report dated March 11, 2008 is found within the PL chart exhibit. *Id.* at 21–22. It identified mild impingement of the left C4 and left C5 nerve roots caused by disc herniation at C3–C4 and C4–C5, and bone marrow edema associated with the C4 and C3 areas that was opined to be a secondary result of bone contusion. *Id.* at 22.

As discussed, *supra,* scantily-completed progress notes are found within the chart for the September 17 visit, only. *Id.* at 3–4. The marks upon it indicate PL was observed to exhibit abnormal posture, appeared in pain, and had pain in her abdomen. *Id.* at 3. The word ''denies'' is written near the section inquiring about recreational drugs. *Id.* Roxicodone in the 30 mg and 15 mg varieties are checked to be continued as described, as is Xanax 2 mg and Soma 350 mg. *Id.* at 4. The word ''Naprosyn'' is also written near the treatment plan area. *Id.* The rest of the form, in pertinent part, is left blank. *See id.* at 3–4. Prescriptions in the medical file issued on September 17 are for #60 Naprosyn 500 mg, #180 Roxicodone 30 mg, #30 Rocicodone 15 mg, #60 Soma 350 mg, and to see a neurologist and primary care physician for chronic pain, to obtain lab workups including liver function tests, and for medical records of an injury. *Id.* at 6–7.

In his report, Dr. Rubenstein notes that PL's emergency contact in her paperwork is the same person that she indicated as the person who referred her to the practice to ''receive pain medications,'' that chart documentation did not support the controlled substance prescriptions issued, and that the file was bereft of any indication that a neurologic or musculoskeletal examination was ever performed. Gov't Ex. 11 at 13. Dr. Rubenstein set forth his analysis of PL's care as follows:

> The records of [PL] are also beneath the standard of care. No attempt was actually made to review previous medical records. There was no documentation as to the need for Roxicodone at the doses prescribed, *especially at the initial visit and all subsequent visits.* No neurologic exam was ever documented. There was no focal objective deficit on exam or even any specific exam that would correlate with the MRI findings in the cervical spine that would have justified the prescriptions that were provided. No other [treatment] alternatives were reviewed in the file.

Id. at 14–15 (emphasis supplied). In like manner, when asked during the hearing whether he had an expert opinion about whether the controlled substance prescribing demonstrated in the PL patient chart met the standard of care required to be exercised in Florida, Dr. Rubenstein testified that:

> The records were beneath the standard of care, that no attempt was actually made to review the previous medical records, there was no documentation as to the need for Roxicodone at the doses prescribed, *especially at the initial visit and all subsequent visits,* no neurologic exam was ever documented, there was no focal objective deficit on exam or even any specific exam that would have correlated with [the] MRI findings of the cervical spine that would have justified the prescriptions provided. There were no other alternatives that I saw in the file to medication management offered.

Tr. 98 (emphasis supplied). Although Dr. Rubenstein specifically bases at least a portion of his expert opinion regarding the PL chart review on the controlled substances prescribed at the initial visit and subsequent visits, the patient file provided by the Government and accepted into evidence reflects a chart note relative to only a single visit (September 17, 2010). Dr. Rubenstein's report reflects events that purportedly occurred during visits that correspond to dates entered into the sign-in sheet. *Compare* Gov't Ex. 9 at 8, *with* Gov't Ex. 11 at 13–14. Inasmuch as the copy of the PL patient chart that was provided by the Government does not have the information regarding these visits beyond the sign-in sheet, it is likely that the Government-provided version is incomplete, or at a minimum, at some variance with the chart reviewed by Dr. Rubenstein. While this is an admittedly disconcerting inconsistency, no conclusions will be drawn in this recommended decision regarding those portions of the chart not in evidence.

The Expert Opinion of Dr. Rubenstein

In his report Dr. Rubenstein provided a synopsis of his overall evaluation of the charts from the Respondent's

17. This method was also employed the following month by the Respondent on a visit occurring March 6, 2010, whereby he provided dual prescriptions for Roxicodone 30 mg, one for 150 tablets and another for 75 tablets, resulting in a cumulative increase of 75 dosage units. *Id.* at 112–13. No evidence was developed in the record regarding the propriety of subdividing controlled substances prescribed by issuing multiple scripts, nor was comment drawn by Dr. Rubenstein in his review about the increase of oxycodone afforded by the Respondent through this technique.

[57] This entry was signed by Dr. Randy Dean, rather than the Respondent. Gov't Ex. 9 at 2.

practice that he was asked to review. According to Dr. Rubenstein, the reviews he conducted clearly suggest that medications are being prescribed and/or dispensed from North Palm Pain Management without objective abnormalities correlating with patient pain complaints. High doses of highly addicting medications in the form of Roxicodone and Xanax are prescribed to each individual, yet not one of the patients showed any objective abnormality. In fact, no new neurologic exam was performed on any of the patients at any of the visits, and there were multiple visits when the patient was not even examined. Even more alarming is the fact that prescriptions were dispensed from the office without even physician encounters or visits, and at times there was not even a medical paraprofessional present. There were also times when patients did not complain of any significant pain, yet [were] still provided with high doses of medications and weaning was not discussed. The patient specifically did not even complain of back pain, yet was given high doses of Roxicodone. This does not appear to meet with the standard of care of pain management. Clearly, these are visits designed to supply patients with Roxicodone, Xanax, and in one patient, Soma. Although physical therapy was mentioned for at least two of the patients, there was no formal physical therapy prescription ever written or even referenced. The patients that were referred to Neurology were never given the name of a consultant to see, nor even a diagnosis to consider. Gov't Ex. 11 at 7.

Notwithstanding the disjointed organization of Dr. Rubenstein's written report, his arguably inordinate dependence on prior notes while on the witness stand, and the discrepancy noted, *supra,* between the version of Patient PL patient chart he apparently reviewed and the copy of the chart received in evidence at this hearing, his testimony was sufficiently clear, cogent, and supported by identified elements in the charts and admitted evidence to be relied upon in this recommended decision. Dr. Rubenstein highlighted consistent themes in his generally well-reasoned conclusions that lend credibility to the opinions he offered. Perhaps most significantly here, Dr. Rubenstein's expert opinion stands unrebutted.

TFO Thomas

The Government also presented the testimony of TFO Robert Thomas. TFO Thomas testified that he has been a police officer in the City of Palm Beach Gardens since 1994, that he works as a field training officer for the city, and that he has also been cross-designated by DEA as a TFO since May of 2009. Tr. 837–38. TFO Thomas served as the case agent [58] for the investigation of the Respondent, which began around September 2009. Tr. 839.

TFO Thomas testified that he personally obtained the undercover patient files for TFO Schwartz and SA Lunsford at NPPM by presenting Mr. Laterza with signed Florida Department of Health (DOH) medical release forms and identifying himself only as a police officer at Palm Beach Gardens. Tr. 841. He testified that he was also responsible for securing the patient files for Patients CH and PL by observing them exiting the clinic at different times, following them to their next destination, and then approaching them after they stopped [59] by identifying himself as a TFO for DEA inquiring whether they would voluntarily answer questions. Tr. 844–46. Accordingly to TFO Thomas, both agreed to speak to him and to execute a DOH release form so that he could retrieve their medical records from NPPM. Tr. 844–46. Similarly, TFO Thomas testified that while conducting surveillance, he spied Patient SL leave NPPM and caused an officer in a marked patrol car to conduct a traffic stop on Patient SL for extreme window tint. Tr. 842, 900. TFO Thomas's testimony continued that at the conclusion of the stop and after Patient SL was informed that he was free to leave, Thomas approached him as a TFO, and during this encounter SL agreed to answer questions and to sign a DOH release form. *Id.* TFO Thomas testified that he used the executed form to obtain a copy of SL's patient file from Mr. Laterza. *Id.* Finally, Thomas testified that Patient CC, who was cooperating with Assistant State Attorney Christy Rogers at the Palm Beach County State Attorney's Office, furnished the prosecutor's office with a signed DOH medical release form, but TFO Thomas could not recall if he personally retrieved the patient file from NPPM or if possession of the file was the result of the fruits of some other agent's endeavors of the State Attorney's Office.[60] *Id.* at 842–43. Thomas also testified that CC had some outstanding criminal matter with the State Attorney's Office, but stated that he did not know the details, effectively short-circuiting any meaningful ability to cross-examine on that issue. Tr. 881–82, 885–86.

TFO Thomas presented testimony regarding an interview in which he participated of Patient CH. Tr. 848. The conversation was purportedly recorded, but neither the recording nor a transcript derived therefrom was offered into evidence. *See id.;* 902–03. TFO Thomas testified that Patient CH told him she had been treated at NPPM for the last twelve to fifteen months, yet she was only seen by the Respondent five or six times. Tr. 848–49. According to Thomas, Patient CH stated that she received prescriptions for oxycodone without ever seeing the Respondent or any medical professional at her last six office visits. Tr. 849. Still, according to TFO Thomas's testimony, she paid a $200 office visit fee each time and sat in the waiting room for fifteen minutes to an hour for her prescriptions. *Id.* During one of these visits, it was TFO Thomas's testimony that Patient CH stated that she received prescriptions for controlled substances after she observed the Respondent leave the clinic premises. *Id.* Furthermore, TFO Thomas provided testimony that during his interview of Patient CH, she represented that she once observed the Respondent pre-sign a fresh pack of blank prescription pads opened, in her view, by Ms. Palemire. *Id.* 850. Patient CH purportedly described to Thomas that she watched as Ms. Palemire then loaded a portion of the pre-signed prescriptions into the printer used by the office for writing out the scripts. *Id.* Later in his testimony, TFO Thomas denied ever seeing pre-signed prescriptions himself. Tr. 855–56, 935.

Hearsay evidence is admissible evidence in administrative proceedings. *Richardson v. Perales,* 402 U.S. 389, 402 (1971) (signed reports prepared by licensed physicians correctly admitted at Social Security disability hearing); *Keller v. Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991) (insurance company investigative reports correctly admitted in Social Security disability hearing where sufficient indicia of reliability established); *Calhoun v. Bailar,* 626 F.2d 145, 149 (9th Cir. 1980) (hearsay affidavits correctly admitted where indicia of reliability established). However, the weight afforded such testimony and, *a fortiori,* whether that testimony can support substantial

[58] As described by TFO Thomas through his testimony, the case agent is in charge of a particular case and is primarily responsible for initiating the investigation, directing the course of the investigation, and documenting its developments. Tr. 869.

[59] TFO Thomas made contact with CH at a Burger King on North Lake Boulevard, Tr. 844, and with PL at a nearby gas station about a quarter-mile from NPPM, Tr. 845–46.

[60] TFO Thomas later clarified on cross-examination that the State Attorney's Office obtained CC's patient file prior to his being brought into her interview. Tr. 911.

evidence is an entirely different matter. As succinctly stated by the Eleventh Circuit:

> Although the rules of evidence are not strictly applied in administrative hearings, there are due process limits on the extent to which an adverse administrative determination may be based on hearsay evidence. As was held in *U.S. Pipe and Foundry Company* v. *Webb,* ''hearsay may constitute substantial evidence in administrative proceedings as long as the factors that assure the 'underlying reliability and probative value' of the evidence are present.'' 595 F.2d 264, 270 (5th Cir. 1979).

Basco v. Machin, 514 F.3d 1177, 1182 (11th Cir. 2008). Thus, the utility of hearsay evidence before an administrative tribunal is limited by its reliability and credibility. Divining the correct use of hearsay evidence requires a balancing of four factors: (1) whether the out-of-court declarant was not biased and had no interest in the outcome of the case; (2) whether the opposing party could have obtained the information contained in the hearsay before the hearing and could have subpoenaed the declarant; (3) whether the information was inconsistent on its face; and (4) whether the information has been recognized by the courts as inherently reliable. *Id.* at 1182; *J.A.M. Builders v. Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000).

Timely, well-reasoned objections were interposed by the Respondent's counsel at the time this evidence was offered. Tr. 847–48. Although the Respondent's counsel conceded that he made no attempt to subpoena any of the patients with whom TFO Thomas spoke, including Patient CH, Tr. 847, all other factors militate against consideration of the hearsay evidence elicited through Thomas pertaining to this and other interviews he conducted which were offered as evidence by the Government. Regarding possible bias, CC had an open criminal case, and no foundation was laid by the Government regarding the absence of bias from the other interviewees. The information provided could not be tested for consistency as the propositions contained in the interviews is corroborated by no other evidence of record, and there is no case law or other authority recognizing this variety of evidence as inherently reliable. Simply put, the Government, as the proponent of the evidence, did not lay a foundation sufficient to permit this tribunal to consider, with any appreciable value, the hearsay testimony of TFO Thomas regarding Patient CH or the other individuals he interviewed, absent the information being subject to the crucible of cross-examination. The Government opted to elicit the relevant information from TFO Thomas rather than to examine Patient CH directly, and did so at its own peril. Without more of a foundation, such as a way to gauge Patient CH's degree of bias or the consistency of her recollection, the reliability of the testimony as it stands on the record has not been shown to be adequate to merit gainful consideration for any purpose. Hence, this testimony, as helpful as it may have been to support the Government's investigation, cannot be used to support the enforcement action it seeks or to support any Agency finding or action that requires the benefit of substantial evidence.

Similarly, TFO Thomas testified to participating in two meetings with Mr. Laterza and Ms. Palemire occurring on October 14, 2010 [61] and October 20, 2010,[62] which were also recorded by TFO Thomas and later transcribed. Tr. 851–53, 856–57; *see* Gov't Exs. 35, 36. Specifically regarding the Respondent's controlled substance prescription writing, TFO Thomas testified that Mr. Laterza and Ms. Palemire explained that the Respondent would come in to NPPM for close to nine hours per week to pre-sign blank prescriptions so that a physician's assistant or nurse practitioner could print and issue prescriptions under his signature while he was not in the office. Tr. 854. TFO Thomas testified that he was told that the Respondent would be contacted to come back to the clinic if the clinic ran out of pre-signed scripts as its throughput could be as many as one hundred patients per day. Tr. 854. As conveyed to him by Mr. Laterza, TFO Thomas testified that the physician assistants were in charge of seeing patients and prescribing medications, although it was possible that they to some degree communicated with the Respondent through computer equipment at times, owned by the Respondent, for him to approve prescriptions.[63] Tr. 854–55, 861.

Thomas's recollection was that Laterza informed him that he was motivated to come forward about the Respondent by an ''internal investigation'' conducted by NPPM's attorney at the company's own initiative, and that this was commenced on suspicion that the Respondent was self-prescribing anabolic steroids and other medications by proxy through his father, and defrauding the clinic of thousands of dollars in the process. Tr. 853, 860–61; *see* Gov't Ex. 35 at 16.

This is again the type of hearsay evidence that, while not patently inadmissible, may not constitute substantial evidence and be afforded any weight, based upon an identical result yielded from a weighing of the *J.A.M. Builders* factors.[64] Mr. Laterza as an owner of NPPM had an obvious interest in protecting the integrity of the clinic and shielding it from liability, be it civil or criminal. Regarding possible bias, few situations would likely invoke a more heightened sense of self-preservation than when Mr. Laterza is speaking to law enforcement and reporting on potential criminal activity occurring within his own business, while specifically identifying and shifting blame to a former employee (the Respondent). Accordingly, the self-interest by which Mr. Laterza hoped law enforcement would rely and act upon his statements could not be greater, and his assertions were never put to the test of a meaningful cross-examination. Similarly, there is no corroborating information of record to test for consistency, and the information procured is clearly not of a nature that has been recognized by the courts as inherently reliable. The testimony regarding this interview can play no part in supporting a finding of substantial evidence in this case.

In an effort to generally establish the form and style in which the Respondent signed prescriptions, the Government elicited testimony from TFO Thomas that he spoke to Assistant State Attorney (ASA) Christy Rogers who spoke to Agent Bujnowski [65] who spoke to the Respondent who allegedly confirmed that he effected his signature upon a single prescription by employing a

[61] During this interview, Laterza's attorney, Myles Malman, Esq., was also present. Tr. 856.

[62] Theodore Degel, an employee at the clinic, was an additional participant to this interview. Tr. 851.

[63] TFO Thomas acknowledged that he had never seen any blank, pre-signed prescriptions with the Respondent's signature. Tr. 856.

[64] Timely, cogent, persuasive objections were interposed by the Respondent's counsel at the time this evidence was offered by the Government. Tr. 857.

[65] At another point in the proceedings, the Government signaled its intention to elicit information acquired by Bujnowski from DI McRae, who was apparently prepared to testify that she had obtained the information from Bujnowski through the means of a telephone call the day before the hearing. Tr. 565–69. That effort was abandoned upon the simultaneous representation that Bujnowski would be produced for the hearing. Tr. 569. Notwithstanding the Government's representation in this regard, Bujnowski was not produced. The Government indicated that a subpoena would be required to procure his testimony and was offered one on the spot, but declined and persevered in its efforts to present this information in this unfortunate manner. Tr. 828–33. During cross-examination, DI McRae even testified that Bujnowski located prescription scripts that were pre-signed by the Respondent. Tr. 587. Unfortunately, this testimony was not elicited from a witness with first-hand knowledge in a manner that could be relied upon in these proceedings.

single letter resembling a ''G'' or ''C'' that was obtained by law enforcement from a pharmacy and somehow suspected to have been pre-signed before it was issued. Tr. 861–64. In addition to speaking to ASA Rogers, TFO Thomas testified that he read a report drafted by Agent Bujnowski regarding this interaction with the Respondent. Tr. 863–64. The witness was not familiar with the details of the conversation purportedly conducted between Bujnowski and the Respondent, or even when it occurred. Tr. 862–63. The witness actually testified that he read a report (the details of which he could not remember) and spoke to someone who spoke to Bujnowski, who spoke to the Respondent. Tr. 864. This evidence was actually offered in this manner by the Government in support of its case. Even a highly-skilled cross-examiner, such as the Respondent's counsel in this case, would be at a loss to effectively engage such a vague, amorphous presentation of testimony. A timely, well-reasoned, continuing objection was interposed by the Respondent's counsel at the time this evidence was offered by the Government. Tr. 861. Like other evidence of similar ilk offered by the Government in this case, that the testimony was not patently inadmissible at administrative proceedings does not answer the question of whether it can be used to uphold an administrative enforcement action that must be supported by substantial evidence, a query that must ultimately be answered in the negative. Because of the obvious concerns regarding the reliability of this testimony and the needlessly tortured and obscure way that it was offered, even if the *J.A.M. Builders* factors weighed in favor of admission (which they most clearly do not), no weight whatsoever can be assigned to this testimony insofar as it pertains to the way the Respondent purportedly signed prescriptions at NPPM, or that the Respondent gave an admission about the manner in which he signed prescriptions while at NPPM. To consider such evidence against the Respondent on this record would violate the Administrative Procedure Act and result in a grievous miscarriage of justice. *See* 5 U.S.C. § 556(d) (''A party is entitled * * * to conduct such cross-examination as may be required for a full and true disclosure of the facts.'')

TFO Thomas also testified that a database maintained by DEA reflects that two phone calls were placed to DEA by the Respondent in September 2010, wherein he complained that although he was no longer working at NPPM, individuals associated with that clinic were still utilizing prescriptions in his name on forged scripts. Tr. 865–66, 920–22. Thomas testified that he placed two calls to the cellular phone number left by the caller, left detailed voicemails identifying himself as a DEA TFO, and received no call back. Tr. 867. In a peculiar irony, the same rationale that precludes consideration of unsubstantiated, unreliable hearsay offered against the Respondent precludes even negligible consideration of the DEA record of this phone call that purportedly emanated from the Respondent. That some DEA database contains a note entered a by an unknown DEA employee about a phone call that was purportedly lodged by the Respondent, offers little that can support or negate a finding of substantial evidence. In any event, as discussed in more detail, *infra,* the Respondent was present at the hearing and elected not to testify.

Subject to the parameters set forth above regarding weight and the permissible uses of his elicited testimony, TFO Thomas provided testimony that was sufficiently detailed, plausible, and internally consistent to be deemed credible.

DI McRae

Further testimony was elicited by the Government through DI Victoria McRae, who at the time of hearing worked at DEA as a Diversion Investigator for twenty-two years. Tr. 553. DI McRae is currently stationed at the Miami Field Division. *Id.* Although DI McRae provided some helpful foundational information regarding the admission of some DEA documentation,[66] that is where the utility of her testimony for these proceedings began and ended.

DI McRae testified that she was present when a search warrant was executed at NPPM and that she and TFO Thomas interviewed employees of the clinic as part of the investigation. Tr. 556–58. According to McRae, she and Thomas conducted an interview of former NPPM employee and pharmacy technician, Crystal Laster, on November 5, 2010 at the Palm Beach Gardens Police Department.[67] Tr. 556–58. According to DI McRae's testimony, Ms. Laster told her that she had worked at NPPM from April to July of 2010, had been fired,[68] and consequently sought in October 2010 to report illegal activity that she had observed during her employment. Tr. 558–60. McRae testified that Laster told her that she was directed by Palemire to deduct dosage units from filled prescriptions to make up for shortfalls, and that it was office practice to flush away overages. Tr. 560. Additionally, McRae testified that Laster said Palemire permitted early refills, that Laster saw the Respondent pre-sign prescriptions, and that the Respondent was not always present at the clinic when patients were being seen. Tr. 560–61, 578–79. McRae also testified that Laster told her that NPPM tolerated the practice of sponsoring.[69] Tr. 562, 585.

Notwithstanding the reality that the Respondent (like the Government)[70] could have sought process to compel Laster's appearance at the hearing, all other *J.A.M. Builders* factors weigh powerfully against admission of the testimony regarding this interview. That she was fired from her employment by NPPM and waited several months to report alleged misconduct raises the specter of bias, there was no admissible evidence upon which to test consistency, and the information was not of a type that has been recognized as inherently reliable by the courts. While the information that was purportedly obtained through Laster's interview was clearly relevant, it was not offered through a vehicle that could ever be considered to support a finding of substantial evidence and must be afforded no weight in these proceedings.

Subject to the parameters set forth above regarding weight and the permissible uses of her elicited testimony, DI McRae provided testimony that was sufficiently detailed, plausible, and internally consistent to be deemed credible.

GS Langston

The Government presented the testimony of Group Supervisor (GS) Susan Langston to support its allegation that the Respondent violated the Ryan

[66] Tr. 554–56; Gov't Exs. 1, 2.

[67] Although DI McCrae testified that the interview was recorded, for reasons not readily apparent, the Government did not seek admission of a recording or transcript of the interview. *See* Tr. 574.

[68] Ms. Laster told DI McRae that she was fired by Ms. Palemire due to a discovered shortage of twenty oxycodone tablets. Tr. 573–74.

[69] Sponsoring was explained as the process through which one person would pay the transportation, room and board, office visit, and/or medication costs for a group of patients traveling from out of state in exchange for a percentage of their controlled substance medication. Tr. 562–64.

[70] In view of the nature of the information purportedly held by Ms. Laster (pre-signed prescriptions, patients treated while the Respondent was not present, inventory regularities regarding controlled substances procured under the Respondent's COR), and the absence of any indication of her unavailability or unsuitability to process, the Government's tactical decision to present her information in this manner is striking.

Haight Act. GS Langston testified that she has been the Group Supervisor of Diversion at the DEA Fort Lauderdale Resident Office for the past two years and that she has been a DI since 1996. Tr. 509.

GS Langston testified that she came upon evidence related to this case while conducting an investigation into an unrelated matter. Specifically, Langston testified that on February 14, 2011, while conducting an on-site inspection of a retail pharmacy named American Pharmaceutical Group (American Pharmaceutical)[71] in connection with that entity's application for a second COR, she came upon prescription scripts for controlled substances that were authorized under the Respondent's name and COR number. Tr. 510–12, 539. During the course of her inspection, GS Langston spoke to Bruce Derby and Jay Olynck, who respectively served as company pharmacist/pharmacy department manager and company accountant. Tr. 513–17. According to Langston, these officials of American Pharmaceutical told her that their company had a business arrangement with three Internet companies: Key to Life Therapy, HMMG Medical, and Total Rejuvenation (contract Internet providers). Under the business arrangement, when authorized prescription orders were received by American Pharmaceutical via fax from the contract Internet providers, the prescriptions would be filled and shipped out directly to the patient/customer/ultimate consumer. The scripts authorized by the Respondent that Langston found bore the indicia of the three Internet companies involved in the arrangement.

According to Langston, the American Pharmaceutical employees told her that the contract Internet providers would match website-solicited patient/customers from various locations with physicians on contract with them. Tr. 513–14. The patient/customer would apparently request a specific controlled substance, and if, after blood work and consultation with one of their physicians on contract, the physician agreed to write the prescription, that script would be sent to American Pharmaceutical, which would then fill the prescription and ship it out. Tr. 514–15. Langston testified that during her inspection, she came upon scripts authorized under the Respondent's name and COR number that also bore the indicia of the contract Internet providers. Tr. 513–17.

Additionally, GS Langston testified that she was told that before American Pharmaceutical would fill prescriptions for a contract doctor, it required that he or she file a form certifying that a proper patient-doctor relationship was maintained with all patients for which prescriptions were transmitted. Tr. 541–44. While GS Langston looked through a file that American Pharmaceutical kept up containing these forms signed by many doctors, and based on what American Pharmaceutical told Langston there could/would/should have been one corresponding to the Respondent, Tr. 542–43, 546, GS Langston chose not to look for or take custody of a copy, and testified that she does not know whether such a form was ever executed by the Respondent, Tr. 542, 544.

The lion's share of GS Langston's testimony was devoted to detailing thirty-two prescriptions for anabolic steroids that were filled, over the Respondent's name and CORs issued to him, by American Pharmaceutical and a part of the document seizure performed by Langston.[72] *See generally* Tr. 519–33. The prescriptions were dispensed and shipped to patients located throughout the United States, over the Respondent's three registrations, for each of three contract Internet providers. *See* Tr. 519, 524, 532; Gov't Ex. 37. The documentation submitted into evidence demonstrates that between August 26, 2010 and February 11, 2011, controlled substance prescriptions were filled through American Pharmaceutical and shipped to twenty-eight clients in fourteen states outside Florida.[73]

During her testimony, GS Langston acknowledged that shipping controlled substances is not in itself a violation of the Ryan Haight Act, but urged that prescribing without establishing a valid doctor-patient relationship based upon at least one in-person examination is.[74] Tr. 544. GS Langston conceded that she did not actually know whether any of the patients who were prescribed anabolic steroids in documentation supplied by the Government were seen by the Respondent or by another physician who was in consult with the Respondent. Tr. 547–48. Furthermore, GS Langston testified that her assumption that the prescriptions were filled via the Internet process was based exclusively on her conversation with the American Pharmaceutical employees, Tr. 538, and that she neither took any steps to corroborate American Pharmaceutical's account of the business relationships involved in the Internet prescribing scheme, such as talking with personnel at the contract Internet providers, Tr. 517, nor did she verify with any of the patients the manner by which they were prescribed controlled substances, Tr. 548, as the focus of her investigation was solely on American Pharmaceutical, *id.*

The manner in which the Government's hearsay evidence on this issue was elicited presents a closer case regarding the appropriate weight to be accorded under the *J.A.M. Builders* factors. *See* 233 F.3d at 1354. While true that the Respondent arguably could have located and subpoenaed the American Pharmaceutical personnel interviewed by Langston, and that the information obtained is not the type traditionally deemed reliable by the courts, it is equally true that there is no obvious equation that suggests bias on the part of the interviewees towards the Respondent, and the scripts received into evidence that were obtained through a DEA inspection does add at least some level of corroboration to the account in view of the remote distances between the prescriber and patient/customer. However, it is not necessary to reach this issue, because, as discussed in more detail, *infra,* even if this evidence were deemed, *arguendo,* to be sufficiently reliable to support a substantial evidence finding, no evidence has been introduced from which it can properly be inferred that controlled substances were issued to the patient/customers without physical examinations. In fact, Langston conceded that American Pharmaceutical also had a walk-in aspect to its pharmacy, and that the admitted documents do not all even reflect that the controlled substances were shipped to the recipients. Tr. 536–37.

Regarding credibility, GS Langston's testimony was sufficiently detailed, plausible, and consistent to be deemed credible in these proceedings.

DI Milan

DI Marjorie Milan also testified on behalf of the Government. DI Milan testified that she is a Diversion Investigator at the Miami Field Division

[71] The notice of inspection (DEA Form 82) that was issued in connection with Langston's inspection indicates that American Pharmaceutical was located in Wilton Manors, Florida. Gov't Ex. 37 at 1.

[72] GS Langston admitted that while she seized all of American Pharmaceutical's prescription records, she did not go through all of them, and she had not gone through all of the prescriptions related to the Respondent. Tr. 511, 513, 518. GS Langston ended her investigation into American Pharmaceutical once it voluntarily surrendered its COR and ceased business, an event which was precipitated by the results of her inspection. Tr. 518.

[73] One page from the Government's exhibit does not list any controlled substances. Gov't Ex. 37 at 32.

[74] *See* 21 U.S.C. § 829(e) (2006 & Supp. III).

for just short of twelve years.[75] Tr. 435–36. DI Milan's participation of the investigation into the Respondent involved examining records seized on February 23, 2011 from NPPM by the West Palm Beach Sheriff's Office. Tr. 441. DI Milan's testimony was offered to identify records within the seized documents pertaining to the Respondent, Tr. 441–42, and to support the Government's allegation that the Respondent was noncompliant with his recordkeeping obligations as a DEA registrant.

DI Milan testified to her opinion that the controlled substance records were deficient in that they were not ''readily retrievable'' in violation of 21 C.F.R. § 1304.03–.04 (2011).[76] DI Milan explained (without benefit of specific guidance document or instruction)[77] that the term ''readily retrievable'' was the window of time that it takes DEA personnel to conduct an on-site inspection of a practitioner's premises, should DEA request at that time to review inventorying, dispensing, or any other applicable documents required to be maintained and so produced under the CSA. Tr. 442–43. To add generally to the confusion wrought by her testimony, Milan also informed that a registrant's required records may still be deemed ''readily retrievable'' if provided within a day or two of the request.[78] Tr. 443. Putting aside the relative merits of DI Milan's flexible definition of whether a registrant's records are ''readily retrievable,'' her testimony is clear on the point that the Respondent was never asked to retrieve anything. Tr. 444, 470–72. Milan's opinion that the Respondent defaulted in his responsibility to have ''readily retrievable'' records is based upon a sterile review of documents seized from NPPM at a time well after the Respondent's employment at that clinic was terminated. Tr. 473. The Respondent was terminated from his employment in September 2010, Tr. 473, but the seizure of records at NPPM did not take place until February 2011, Tr. 441. Milan testified that she was neither present during the seizure of records by the sheriff's office, nor was she aware of any inquiry made to the Respondent regarding the readily retrievable nature of what was recovered. Tr. 443–44. Indeed the records were taken pursuant to a criminal state search warrant, not an administrative inspection warrant, and the only time that DI Milan was in personal contact with the documents was while they were in custody of the sheriff's office. Tr. 443–45. No further testimony by DI Milan is on the record characterizing why or how the applicable information required to be kept was not retrievable in a ready fashion.

Aside from the merits of the celerity or accessibility of the files procured, DI Milan testified to required recordkeeping records that she noted were absent from the nine boxes of evidence held in custody by the sheriff's office. Tr. 475. DI Milan asserted that she specifically looked for inventory records or ordering records that would indicate amounts of controlled substances purchased. Tr. 475–76. This testimony (which was actually extracted from the witness on cross-examination) was insufficiently developed to ascertain anything concrete regarding whether recordkeeping was maintained in compliance with DEA regulation or whether those records, if they existed, would have been contained in the boxes seized. Moreover, while DI Milan explained why she did not need to look at every single page within the seizure to know the contents (a remarkable assertion in and of itself), she declared, ''I could pretty much distinguish what did not pertain to what I needed to look for. In other words, if it looked like it was financial records [sic], that was something that I wouldn't be looking at, because I was looking for any documentation that showed whether controlled substances had been ordered, and also what was being dispensed.'' Tr. 475–76. Even if the unreasonable proposition that records evaluated under the circumstances here could ever be assessed as ''readily retrievable'' or not was hypothetically indulged, from Milan's testimony it would be impossible to ascertain what, if any, documents were present or missing from the seized records; no one who testified has even reviewed all the seized records. Thus, the record is devoid of any evidence from which a finding of deficiency founded on lack of readily retrievable records could be based.

DI Milan also testified that she reviewed logbooks containing affixed controlled substance dispensing labels issued over the Respondent's COR, which she electronically scanned at the sheriff's office. Tr. 446–48. She then selected, without any particular process or method, one day in each month of February, March, April, May, and June in 2010 to concentrate her analysis.[79] Tr. 446–47, 481. She also scanned the executed scripts corresponding to the dispensing labels found within the records seized.[80] Tr. 451–53. The extent of the analysis conducted by DI Milan was limited to calculating the sums of dosage units dispensed by the Respondent for each of oxycodone 15 mg, oxycodone 30 mg, and alprazolam 2 mg on each of the five dates, Tr. 456–59, as well as providing less than assertive testimony coming up with a minimum and maximum prescribed dosage unit range for each of the three drug varieties cumulatively based upon the five dates.[81] Tr. 459–61. The documents providing the basis of DI Milan's testimony, included in the proposed exhibit by the Government (Government's Exhibit 43), were provisionally admitted into evidence subject to the witness providing a foundation sufficient to support why it was relevant. Tr. 448–49. While the exhibit remains in evidence, the Government provided no contextual evidence from which any relevant conclusion could rationally be based other than a statement of the tallies themselves. The total dosage units of a single type of substance prescribed on a particular day, or prescribed concurrently with other substances, without more, speaks nothing to the propriety or impropriety of the practitioner's prescribing behavior and

[75] Through DI Milan's testimony, the Government offered into evidence voluntary surrender forms signed by the Respondent for COR Numbers FG1242471 and FG2021804. While the Government noticed all three of the Respondent's CORs in its charging document, including the remaining registration of BG8251845, almost all of the misconduct alleged by the Government occurred over COR FG1242471, the registration associated with the NPPM address. Notwithstanding, misconduct, if proven, is relevant not only to the COR connected to the misconduct, but for all under the public interest factors.

[76] DI Milan was not able to testify as to which regulations required readily retrievable records, Tr. 442, and this issue likewise occupied no portion of the Government's brief.

[77] DI Milan could not identify any source for the ''readily retrievable'' records requirement. Tr. 442.

[78] On the issue of what temporal parameters define ''readily retrievable,'' Milan provided the following less-than-helpful guidance: ''Um, usually I think we give them like maybe a day or two for them to go ahead and provide the records to us so that we can review them. After that then we pretty much will, we figure if there's another avenue that we have to go through to be able to see the records.'' Tr. 443.

[79] The precise dates selected were February 19, March 5, April 1, May 28, and June 18, 2010. Tr. 450–51.

[80] DI Milan acknowledged that she had no idea who assembled the records or the significance of their organization scheme. Tr. 454.

[81] While it was proffered that DI Milan would testify as to how many patients were seen by the Respondent on each of the particular days examined by DI Milan based solely on the dispensing labels, Tr. 449, DI Milan eventually admitted that while this figure was ascertainable, she did not tally it, Tr. 460–63; *see* Tr. 487–88, 490–91. Later, DI Milan testified that her analysis did not suggest that the Respondent saw ''some exorbitant number'' of patients each day, all of to whom he prescribed controlled substances. Tr. 486, 492.

adds nothing (in the absence of contextual evidence) to the equation of whether it is in the public interest to continue the Respondent's privileges as a registrant. The same holds true for the range of tablets prescribed at any one time. In fact, DI Milan specifically testified that she was suggesting nothing proper or improper about what was prescribed or how many patients the Respondent prescribed to on any given day. Tr. 481, 492. For these reasons, Government's Exhibit 43 and the associated testimony by DI Milan sheds no appreciable light on the determination as to whether the Respondent's continued registration would be inconsistent with the public interest and has been given no weight in this recommended decision.

SDI Wright

The Government provided the testimony of Senior Diversion Investigator (SDI) Kyle Wright, Chief of DEA's Targeting and Analysis Section. Tr. 346. SDI Wright testified that he and his staff analyze data from the Automated Records and Controlled Ordering System (ARCOS), a database maintained by DEA pursuant to its obligations under the CSA. Tr. 346–47. Through ARCOS, DEA has the capacity to track the path of all Schedule II and Schedule III narcotic drugs [82] throughout their lifecycle events in the distribution chain, from the time their raw form elements are imported or created, through manufacturing, distribution, and the dispensing to the ultimate end user, i.e. typically the patient. Tr. 347. SDI Wright explained that the data loaded into ARCOS pertains to two broad groups, those DEA registrants who must report controlled substance transactions to ARCOS (e.g., manufacturer, distributor), and those registrants on whom transactions are reported to ARCOS (e.g., pharmacy, dispensing practitioner).[83] Tr. 348. The COR number of every party participating in an event is entered in connection with each transaction. Tr. 348, 358. According to SDI Wright, the information loaded into ARCOS is used both to monitor the legitimate flow of controlled substances within the closed regulatory system, as well as to highlight numerical anomalies that could reflect the potential for diversion. Tr. 349– 52.

Through SDI Wright's testimony, the Government presented some absolute and comparative statistical information based upon data culled from ARCOS. The data related to the Respondent's COR and was relevant to the extent that it showed purchasing trends of Schedule II and Schedule III narcotics associated with the Respondent's COR. However, the information, in the form it was offered, did not provide any insight into whether the Respondent committed any activity that was consistent or inconsistent with his responsibilities as a registrant.[84] This is not to say that statistical data could not support substantial evidence to revoke a registrant's COR in all cases. There was simply insufficient contextual evidence adduced at the hearing to utilize the statistics that were offered.[85] In the absence of testimony or other evidence that could provide some context to the data, and why the numbers Wright provided demonstrated whether or to what extent the Respondent was exercising due care regarding his responsibilities as a registrant, there is no use that the impressive array of statistical information he provided can be put to.[86] Beyond doubt, there are a host of factors that could account for why the Respondent's level of controlled substance prescribing should have been lower, higher, or was just right. A non-exhaustive list of such evidence might include (but not be limited to) the nature of his practice (pain specialist versus nephrologist),[87] the geographical location (and population) of his practice, the scarcity or abundance of other practitioners practicing the same medical field in similar proximity, the number of hours per week he practiced and number of patients he treated during that time period, and even the socioeconomic status of the region. All these factors, and certainly others, could likely shed light on why ARCOS figures related to the numbers of controlled substance prescriptions that were issued and/or dispensed reflected well or poorly on whether the Respondent was adequately discharging his duties under the CSA. To the extent that reasonable expectations regarding the Respondent's practice or similarly-situated registrants could be divined, it was not presented. The Respondent's level of dispensing was not compared with other registrants with a reliable metric that could establish anything relevant about the numbers. Here, the most SDI Wright could offer is that the numbers presented could support an investigatory red flag. Tr. 384. Beyond question, DI Wright presented as a forthright, credible witness with a superior command over the subject matter of his testimony. That said, the data was presented in something of a contextual vacuum, and as such, cannot be used to reach a determination as to whether the continuation of the Respondent's COR is in the public interest.[88]

The Respondent did not testify and presented no evidence at the hearing.

Other evidence required for a disposition of this issue is set forth in the analysis portion of this decision.

[82] SDI Wright explained that while all Schedule II substances are tracked, only a subset of Schedule III controlled substances considered to be narcotic drugs are tracked. Tr. 420; *but see* 21 C.F.R. § 1304.33 (2011) (also requiring reporting on all Schedule I controlled substances, gamma hydroxybutyric acid (Schedule III), and some activities involving selected psychotropic substances in Schedules III and IV).

[83] Registrants who are ''reported on'' are also referred to as the ''retail side'' in contrast to the ''reporter side.'' Tr. 348. Some of the types of transactions that trigger a reporting requirement are importation, loss, destruction, and purchases/sales. *Id.*

[84] The first set of data presented by SDI Wright consisted of raw numbers of dosage units purchased over the Respondent's COR in 2009 and 2010, Tr. 367–86, that, on SDI Wright's admission, did not suggest anything improper or illegal but that only raised an investigatory flag based primarily on a sharp increase from one quarter to a following quarter, Tr. 382–84; Gov't Ex. 41, at 1–6. SDI Wright's attention was also drawn to data indicating that variations of oxycodone 30 mg tablets were ordered much to the exclusion of other controlled substances. Tr. 382. Additionally, SDI Wright presented tables and graphs comparing the amount of oxycodone dosage units purchased by the Respondent to countywide, statewide, and nationwide practitioner ordering averages, Tr. 386–92, 395; Gov't Ex. 41 at 8 (calendar year 2009), 12 (calendar year 2010), and comparing the Respondent to two other practitioners constituting the top three purchasers in zip code 33404, Tr. 393–97; Gov't Ex. 41, at 9–11 (calendar year 2009), 13–15 (calendar year 2010).

[85] At the hearing, the Respondent's counsel interposed timely (ultimately well-founded) objections to various aspects of DI Wright's testimony. Tr. 353, 374, 376–77, 381, 391.

[86] When Wright was asked if he knew whether the Respondent authorized the prescriptions in question, he responded in this way: ''Okay, I'm going to answer your question precisely. I know nothing about his prescribing at all, because that's not what ARCOS tracks.'' Tr. 398.

[87] Tr. 406–07.

[88] The Government's argument that these raw numbers demonstrate the impact of the Respondent's poor prescribing practices, Gov't Br. at 26, is not persuasive on this record. The numbers here reflect only volume; not high volume or low volume. If the record revealed that controlled substances were being improperly dispensed through every (or even most) prescription issued or dispensed, the number of controlled substances being released without the benefit of adequate controls would arguably be relevant to show the impact of the Respondent's laxity. Here, beyond the instances demonstrated in the record where the Respondent's prescribing practices fell below the standard described by the Government's expert, there is no sensible way to extrapolate what percentage (if any) of the balance of the issued scripts or dispensed medications were disgorged from the closed regulatory system in an improper way. Put another way, volume of total prescriptions issued does not reveal anything meaningful (or even useable) about community impact.

The Analysis

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

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
(4) Compliance with applicable State, Federal or local laws relating to controlled substances.
(5) Such other conduct which may threaten the public health and safety.

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

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *Morall v. DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs,* 53 Fed. Reg. 43945, 43947 (1988); *David E. Trawick, D.D.S.,* 53 Fed. Reg. 5326, 5327 (1988); *see also Joy's Ideas,* 70 Fed. Reg. 33195, 33197 (2005); *David H. Gillis, M.D.,* 58 Fed. Reg. 37507, 37508 (1993); *Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16422, 16424 (1989). Moreover, the Administrator is ''not required to make findings as to all of the factors * * *.'' *Hoxie v. DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173–74. The Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick v. DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *.'' *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 C.F.R. § 1301.44(e) (2011). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys v. DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 Fed. Reg. 72311, 72312 (1980). Further, ''to rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.'' *Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8236 (2010).

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23848, 23853 (2007). Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Abbadessa,* 74 Fed. Reg. at 10078; *see also Gregory D. Owens, D.D.S.,* 74 Fed. Reg. 36751, 36757 (2009).

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

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

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein v. DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz v. Glover Livestock Comm. Co.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S. Ct. 1033, 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein

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

regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. § 557(b) (2006); *River Forest Pharmacy, Inc. v. DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

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

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine in Florida. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant state licensing board or professional disciplinary authority. However, that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 Fed. Reg. 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 Fed. Reg. at 461. It is well-established Agency precedent that a ''state license is a necessary, but not a sufficient condition for registration.'' *Leslie,* 68 Fed. Reg. at 15230; *John H. Kennedy, M.D.,* 71 Fed. Reg. 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 Fed. Reg. 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6590 (2007), *aff'd, Chein v. DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S. Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General, not state officials. *Stodola,* 74 Fed. Reg. at 20375. Here, there is no evidence of record that the state licensing board has even considered the issue of a formal action against the Respondent's licensure. Thus, on these facts, that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

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

Although the standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest, evidence that a registrant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA certificate. The probative value of an absence of any evidence of criminal prosecution is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities. *See Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.,* 75 Fed. Reg. 49956, 49973 (2010) (''[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.'' (citing *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 461 (2009); *Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6593 n.22 (2007), *aff'd, Chein v. DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S. Ct. 1033 (2009))); *Ladapo O. Shyngle, M.D.,* 74 Fed. Reg. 6056, 6057 n.2 (2009). Although there is information in the record implying that the Respondent was arrested for conduct connected to that which was alleged in this case,[90] no evidence was offered or received which indicates whether law enforcement authorities are still engaged in a prosecution (or even a criminal investigation) of the Respondent, the current status of the charges that supported the arrest, or (beyond being ''drug-related'') even what the Respondent was arrested for or charged with. More to the point, an arrest is merely an untested accusation, not a conviction.

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

Factors 2, 4, and 5: The Respondent's Experience in Dispensing Controlled Substances; Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances; and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, the gravamen of the allegations in the OSC/ISO, as well as the factual concentration of much of the evidence presented, share as a principal focus the manner in which the Respondent has either prescribed and dispensed controlled substances under the authority of his COR, and/or permitted/authorized others to do so. Thus, it is analytically logical to consider public interest factors two, four, and five together. That being said, factors two, four, and five involve analysis of common and distinct considerations.

Regarding Factor 2, in requiring an examination of a registrant's experience in handling controlled substances, Congress, in mandating a consideration of this element, manifested an acknowledgement that the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances, and how long he has been in the business of doing so, are significant factors to be evaluated in reaching a determination as to whether he should be entrusted with a DEA certificate. In some cases, viewing a registrant's actions against a backdrop of how he has performed activity within the scope of the

[90] Stipulation B; Tr. 468–69.

certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

Evidence that a practitioner may have conducted a significant level of sustained activity within the scope of the registration for a sustained period is a relevant and correct consideration which must be accorded due weight. However, the Agency has taken the reasonable position that this factor can be readily outweighed by acts held to be inconsistent with the public interest. *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463. Experience which occurred prior and subsequent to proven allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against his registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are congruous with a consistent past pattern of poor behavior can enhance the Government's case.

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

In *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463, DEA policy regarding this aspect of the public interest determination was clarified to some extent. The decision in that case acknowledged the reality that even a significant and sustained history of uneventful practice under a DEA certificate can be offset by proof that a registrant has committed acts inconsistent with the public interest. *Id.; see also Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8235 (2010) (acknowledging Agency precedential rejection of the concept that conduct which is inconsistent with the public interest is rendered less so by comparing it with a Respondent's legitimate activities which occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 36 Fed. Reg. 51592, 515600 (1998) (''even though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.''). In the context of a pharmacy registrant, Agency precedent has consistently held that even a significant level of legitimate dispensing cannot offset flagrant violations. *See, e.g., Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 386 & n.56 (2008).

The Agency, in its administrative precedent (notwithstanding what might be perceived as an arguable lack of at least readily-apparent ambiguity employed by Congress in the language of the statute) [91] has further curtailed the scope of Factor 2. The Agency's current view regarding Factor 2 is that while evidence of a registrant's experience handling controlled substances may be entitled to some weight in assessing whether errant practices have been reformed, it is entitled to no weight in cases where the Government has met its *prima facie* burden and a practitioner has failed to acknowledge wrongdoing. *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. 19450 n.3 (2011); *Roni Dreszer, M.D.,* 76 Fed. Reg. 19434 n.3 (2011); *Michael J. Aruta, M.D.,* 76 Fed. Reg. 19420 n.3 (2011); *Jacobo Dreszer, M.D.,* 76 Fed. Reg. 19386–87 n.3 (2011). In this case, it is undisputed that the Respondent was issued a license to practice medicine in Florida. Since neither party to the litigation introduced any evidence regarding how the Respondent conducted himself as a registrant prior to the conduct alleged in the OSC/ISO, the quality and history of the Respondent's prior experience as a DEA registrant was simply not an issue in this case. However, as discussed, *infra,* other features of Factor 2 clearly do bear on a disposition of this case.

Regarding Factor 4, to effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, ''Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' *Gonzales v. Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 C.F.R. § 1306.04(a). Furthermore, ''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 knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.*

A registered practitioner is authorized to dispense,[92] which the CSA defines as ''to deliver a controlled substance to an ultimate user [93] * * * by, or pursuant to the lawful order of a practitioner.'' 21 U.S.C. 802(10) (2006 & Supp. III 2010); *see also Rose Mary Jacinta Lewis,* 72 Fed. Reg. 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 Fed. Reg. at 17541 (citing *Gonzales v. Oregon,* 546 U.S. 243, 274 (2006); *United States v. Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors ''peddling to patients who crave the drugs for those prohibited uses.'' *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States v. Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States v. Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

[91] See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837 (1984) for the two-step process constructed by the United States Supreme Court regarding the deference afforded to an agency in interpreting a statute it is charged to administer.

First * * * [i]f the intent of Congress is clear, that is the end of the matter; for the * * * agency[ ] must give effect to the unambiguously expressed intent of Congress. * * * [I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.''

467 U.S. at 842–43.

[92] 21 U.S.C. § 823(f).

[93] ''Ultimate user'' is defined as ''a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.'' 21 U.S.C. § 802(27).

Prescribing Under the Respondent's Registration

Beyond doubt, the Government's evidence establishes that employees at NPPM, utilizing the authority of the Respondent's COR, were playing fast and loose with controlled substance prescriptions, which were preceded by physical examinations that could be only generously described as cursory, and which were conducted in a slovenly manner by non-physicians. The activities were unquestionably the crudest form of a mass-production operation aimed at making money by providing controlled substances without regard to medical need or legal requirement. That said, the evidence also establishes that the Respondent was not the owner of NPPM, but an employee from early 2009 to September 2010. Tr. 588, 865, 892. The focus of a correct determination in this case hinges on the appropriate level of responsibility to be required of a DEA registrant under these facts.

The Agency has consistently held that a DEA registrant is strictly liable for the misconduct of any person or entity he authorizes to act under his registration. *Scott C. Bickman, M.D.,* 76 Fed. Reg. 17694, 17703 (2011); *Paul Volkman,* 73 Fed. Reg. 30630, 30644 n.42 (2008), *aff'd, Volkman v. DEA,* 567 F.3d 215, 224 (6th Cir. 2009); *Rose Mary Jacinta Lewis, M.D.,* 72 Fed. Reg. 4035, 4041 (2007). While complete omniscience on the part of a registrant is not the standard, the Agency has made it clear that it will not countenance deliberate indifference on the part of those who enjoy the privileges of a DEA COR. *See Holloway Distrib.,* 72 Fed. Reg. 42118, 42124 (2007) (a policy of ''see no evil, hear no evil'' in a List I distributor context is held to be fundamentally inconsistent with the obligations of a DEA registrant). Even in a criminal context regarding prescriptions illegitimately issued, the courts have held that a factfinder ''may consider willful blindness as a basis for knowledge.'' *United States v. Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006).

TFO Schwartz made ten visits to NPPM as UC Patient Rix, received controlled substances for his efforts during five, and obtained an unfilled prescription for controlled substances during one. Controlled pain medications and testosterone were provided to him under the Respondent's COR although he did not meet the Respondent until his fifth (November 21st) visit. *See* Tr. 646, 807. As UC Patient Rix, Schwartz had met with Laterza about obtaining testosterone and HRT, and with Nurse Sanchez about pain management, during clinic UC visits which occurred on October 21st and 23rd. Tr. 600–01, 608–12, 618–19. During the fifth (November 21st) UC visit, where he met with the Respondent for the first time, Patient Rix informed the Respondent (who had picked up the Patient Rix medical chart from the reception desk and was punching keys at a computer terminal during their entire interaction in the examination room) that he had previously met with Ms. Sanchez at this practice and received controlled substance pain medication, and that he had previously met with Laterza and received controlled substance testosterone from him. Tr. 647–49; Gov't Ex. 19 at 18. To emphasize the point, Patient Rix highlighted Ms. Sanchez's decision to provide a level of pain medication that was below the amount Rix had sought from her. Tr. 647; Gov't Ex. 19 at 18. Similarly, Rix explained to the Respondent that he was consulting with Laterza about HRT and sought advice from the Respondent about possible medication interactions, which the Respondent answered with assurances. Tr. 648; Gov't Ex. 19 at 18. Thus, there is no doubt, that based on Schwartz's credible testimony in this regard, that the Respondent knew or should have known that his COR was being used for the prescribing of controlled substances in the past, at times when he was or was not present. The Respondent's decision to blithely press on and issue prescriptions for controlled substances at an increased level to UC Patient Rix, based upon the conversation that he had with the patient and the chart he held in his hand, stands unexplained and unexplainable. Whether the Respondent knew of (or even designed) the controlled-substance shenanigans perpetrated by Laterza and Sanchez before that moment, or prescribed in spite of them and thereby ratified it thereafter, his actions fell markedly below the level of care required by one entrusted with a DEA COR. If he was so inclined, he could have, at a minimum, evaluated UC Patient Rix himself with a full and adequate physical examination. Instead, the Respondent, unfazed, increased UC Patient Rix's prescriptions for powerful and addictive controlled narcotics and endorsed their use by the patient with controlled steroids. Even a brief examination of the patient chart that the Respondent held in his hand would have allowed him to evaluate the discrepancies between the neck complaints expressed at the visit with the back complaints addressed in the MRI report provided. Further, the chart notes are replete with examinations and observations that can accurately be described as based in fantasy. It is clear that the Respondent prescribed dangerous and controlled substances to UC Patient Rix for reasons that lacked a legitimate medical purpose and were outside the course of professional practice in violation of 21 C.F.R. § 1306.04(a).

The Respondent's decision to prescribe controlled substances under the circumstances present at the (5th) November 21st UC visit without corrective action or even cursory inquiry, standing alone, is conduct sufficient to sustain the Government's burden to establish that the Respondent has committed acts inconsistent with the public interest. However, the Respondent's demeanor and inaction upon the direct communication by UC Patient Rix about how prescribing was being handled at NPPM under his COR stands as powerful and unrebutted evidence that the Respondent knew what was going on and ignored it—or worse. Thus, the evidence demonstrates that the Respondent either intentionally violated 21 C.F.R. § 1306.04(a) through the agency of NPPM functionaries when controlled drug prescriptions were issued over his COR to UC Patient Rix, UC Patient Hays, and UC Patient Barbaro, or shirked his responsibility as a COR registrant by taking no action to correct the illegality. Furthermore, the evidence fully supports the Government's theory that the Respondent issued controlled substance prescriptions in a manner that fell substantially below the standards required of a practitioner in Florida based upon the Government's expert's review of the patient charts maintained on Patients SL, CH, CC, and PL.

The Respondent, acting on the advice of counsel, invoked his Fifth Amendment right to remain silent. Tr. 334–35, 833–34. At a DEA administrative hearing, it is permissible to draw an adverse inference from silence, even in the face of a Fifth Amendment invocation. *See Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States v. Hale,* 422 U.S. 171, 176 (1975) (''Silence gains more probative weight where it persists in the face of accusation, since it is assumed in such circumstances that the accused would be more likely than not to dispute an untrue accusation.'')); *Joseph Baumstarck, M.D.,* 74 Fed. Reg. 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth. v. Woodward,* 523 U.S. 272, 286 (1998)). The Government's case presented credible evidence that the Respondent had evidence that UC Patient Rix had received controlled substance prescriptions under the

Respondent's COR before he even met him, and ratified that decision when Schwartz (as Patient Rix) directly told him so. His response to this information was to prescribe even more controlled substances at a higher dosage level. UC Patients Hays and Barbaro received controlled substances under the Respondent's COR without meeting him at all. This evidence was presented at the hearing, yet the Respondent presented no evidence in contradiction or diminishment. No competent evidence was received that could sustain a finding that the Respondent did not know of the misconduct accomplished with his COR. On the facts of this case, where the supported allegations are of a nature that a registrant would be more likely than not to dispute them if untrue, an adverse inference based on the Respondent's silence is appropriate. Accordingly, as an evidentiary matter, it should be, and will be assumed that if the Respondent had contrary testimony to offer, he would have presented it, and that the Government has established, by a preponderance of the evidence, that controlled substances were prescribed and dispensed under the Respondent's COR under circumstances where he knew it was done, *and* where he should have known it was done.

Readily Retrievable Records

Accurate and reliable records are an obvious bedrock safeguard that is essential to ensure the integrity of the closed regulatory system. Because controlled substance activity is tracked through records, it can only be regulated by insisting on adequate documentation. Paperwork anomalies that could be viewed as minor infractions in other contexts rarely can be considered as such in this environment. In fact, it is no overstatement that adequate recordkeeping is a vital component to regulating activity related to controlled substances. A truly closed system requires not only that certain records and inventories be kept by all those registrants who either generate or take custody of controlled substances in any phase of the distribution chain until they reach the ultimate user, but that those documents be subject to periodic inspection and ready retrieval for that purpose. Registrants, such as the Respondent, who are authorized to dispense controlled substances are required to keep such records and to maintain them in a manner that is ''readily retrievable'' upon demand of those DEA officials charged with conducting inspections. *See* 21 C.F.R. § 1304.04(g) & (f)(2) (2011); *see* 21 C.F.R. § 1304.03 (requiring recordkeeping set forth in § 1304.04 for dispensing physicians). Readily retrievable is defined in the regulations as ''records kept * * * in such a manner that they can be separated out from all other records in a reasonable time * * *.'' 21 C.F.R. § 1300.01(b)(38).

At the hearing, DI Milan testified that the West Palm Beach Sheriff's Office seized records on February 23, 2011 pertaining to the Respondent, and that she was tasked with reviewing controlled substance transaction records associated with the Respondent's COR. Tr. 441–42. DI Milan further testified that, in her view, the Respondent's records were not readily retrievable, in contravention to applicable federal regulations. Tr. 442. However, DI Milan did not specify which records were not readily retrievable (or what regulation required them to be so). Furthermore, and more fundamentally, Milan acknowledged that no one ever asked the Respondent to produce any records. Tr. 444. It is not necessary, in this case, to reach a conclusion as to the reasonable parameters of when records can be accessed to meet the regulatory requirement of being ''readily retrievable,'' because the Respondent was never asked to retrieve any records. On these facts, where Milan testified that she had not reviewed all documents seized by the West Palm Beach Sherriff's Office from NPPM, and never made a demand of any kind for the production of any records from the Respondent, and was not present during the execution of the state criminal search warrant seizing the records that she reviewed, it would be illogical to find that the Respondent violated the requirement to have any records, much less that his records were unsatisfactory because they were not readily retrievable. Furthermore, the records were seized from NPPM five months after the Respondent was separated from his employment there. Tr. 441, 473, 865, 892. There is no evidence as to who had access to the records during the five months that they were out of the Respondent's control. Under the circumstances present in this record, it would border upon the surreal to sustain a finding that records that were out of the Respondent's control for five months, never fully inventoried by the Government before, during, or after seizure, or ever even requested of the registrant, were absent or delinquent in that they were not maintained in a readily retrievable manner. *See, e.g., Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6598 (2007) (recognizing that readily retrievable does not mean ''instantaneously produced'' and finding no basis to conclude that records and inventory records were not ''readily retrievable'' during inspection where evidence reflected neither how long DEA personnel waited for records nor total time present at clinic).

The Respondent's Prescribing and Dispensing

While true that the CSA authorizes the ''regulat[ion] of medical practice so far as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood,'' *Gonzales,* 546 U.S. at 266–67, an evaluation of cognizant state standards is essential, *Joseph Gaudio, M.D.,* 74 Fed. Reg. 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 Fed. Reg. 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 Fed. Reg. 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be ''tethered securely'' to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled substances to treat chronic pain sufferers. *Volkman v. DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bona fide doctor-patient relationship in order to act ''in the usual course of * * * professional practice'' and to issue a prescription for a legitimate medical purpose.'' *Dewey C. Mackay, M.D.,* 75 Fed. Reg. 49956, 49973 (2010); *Stodola,* 74 Fed. Reg. at 20731; *Shyngle,* 74 Fed. Reg. at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA generally looks to state law to determine whether a bona fide doctor-patient relationship was established and maintained. *Stodola,* 74 Fed. Reg. at 20731; *Shyngle,* 74 Fed. Reg. at 6058; *Garces-Mejias,* 72 Fed. Reg. at 54935; *United Prescription Servs.,* 72 Fed. Reg. at 50407.

Under Florida law, grounds for disciplinary action or denial of state licensure include ''prescribing * * * any controlled substance, other than in the course of the physician's professional practice,'' and prescribing such substances ''inappropriately or in excessive or inappropriate quantities [as it] is [presumed to] not [be] in the best interest of the patient and is not in the

course of the physician's professional practice, without regard to his or her intent.'' Fla. Stat. § 458.331(1)(q) (2010). Florida law further provides that grounds for such disciplinary action also include:

> Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician * * * and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

Id. § 458.331(1)(m).[94]

In exercising its rulemaking function,[95] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing ''Standards for Adequacy of Medical Records'' applicable to all physicians. Fla. Admin. Code Ann. r. 64B8–9.003 (2010). That regulation provides, in pertinent part:

> (2) A licensed physician shall maintain patient medical records in English, in a legible manner and with sufficient detail to clearly demonstrate why the course of treatment was undertaken.
> (3) The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, patient histories; examination results; test results; records of drugs prescribed, dispensed or administered; reports of consultations and hospitalizations; and copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.
> (4) All entries made into the medical records shall be accurately dated and timed. Late entries are permitted, but must be clearly and accurately noted as late entries and dated and timed accurately when they are entered in to the record * * *.

Id.

With respect to defining the parameters of what constitutes ''professional practice'' in the context of pain management prescribing, Florida state law provides:

> Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[96] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

Fla. Stat. § 458.326. Moreover, the Florida Board has adopted,[97] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*), a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenants of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable federal and state law.

Like the *Model Policy,* which was promulgated ''to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion,'' Florida's regulation providing ''Standards for the Use of Controlled Substances for the Treatment of Pain'' (Florida Standards), Fla. Admin. Code Ann. r. 64B8–9.013, recognizes that ''inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use,'' *id.* at 9.013(d). The language employed by the regulation under the preamble section titled ''Pain [M]anagement [P]rinciples'' makes clear that the standards ''are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice''* (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management within the state. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes within the bounds of being ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,'' [98] on the facts presented here,[99] input from an expert witness was helpful in some respects.

The Florida Standards direct that ''[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes,'' *id.* at 9.013(1)(d), and provide that the prescribing of controlled substances for pain will be considered

> To be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on *clear documentation* of unrelieved pain and in compliance with applicable state or federal law.

Id. at 9.013(1)(e) (emphasis supplied).

The Florida Standards further provide that the validity of prescribing will be judged ''based on the physician's treatment of the patient and *on available documentation,* rather than on the quantity and chronicity of prescribing'' (emphasis supplied). *Id.* at 9.013(1)(g). Furthermore, the Standards advise that physicians should not fear disciplinary action for ''prescribing * * * controlled substances * * * for a legitimate medical purpose and that is supported by *appropriate documentation* establishing a valid medical need and treatment plan'' (emphasis supplied), or ''for failing to adhere strictly to the provisions of these standards, *if good cause is shown for such deviation.'' Id.* at 9.013(1)(b), (f) (emphasis supplied).

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also promulgated a separate set of documentation requirements in the Florida Standards applicable

[94] An additional ground recently amended to the statute is failing to comply with the requirements of 21 U.S.C. § 821 *et seq.* (Drug Abuse Prevention and Control Act). Fla. Stat. § 458.331(1)(oo)(2010). However, the alleged conduct in this matter precedes the effective date of the amendment, October 1, 2010.

[95] Rulemaking authority regarding the practice of medicine within the state of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1) (2010).

[96] Florida defines ''intractable pain'' to mean ''pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.'' *Id.* § 458.326(1).

[97] Pursuant to authority vested in the Florida Board by the Florida legislature specifically to promulgate rules regarding state standards for pain management clinical practice. *Id.* § 458.309(5).

[98] 21 C.F.R. § 1306.04(a).

[99] Although the Agency has acknowledged the directive from the federal courts that a mere disagreement between experts cannot, standing alone, ordinarily form the basis of an adverse action against a practitioner's privilege to handle control substances, *Volkman v. DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274), it has also stated that expert testimony is not mandated ''[w]here, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals * * *.'' *Cadet,* 76 Fed. Reg. at 19450 n.3; *R. Dreszer,* 76 Fed. Reg. at 19434 n.3; *Aruta,* 76 Fed. Reg. at 19420 n.3; *J. Dreszer,* 76 Fed. Reg. at 19386–87 n.3.

specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading ''Medical Records,'' state that ''[t]he physician is required to keep *accurate and complete records''* (emphasis supplied) including, though not limited to:

1. The medical history and physical examination, including history of drug abuse or dependence, as appropriate;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic reviews.

Id. at 9.013(3)(f). The same section directs that ''[r]ecords must remain current and be maintained in an acceptable manner and readily available for review.'' *Id.*

The Florida Standards similarly emphasize the need for proper documentation in the patient evaluation context by specifying:

A complete[100] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

Furthermore, the Florida Standards require a written treatment plan that ''should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.'' *Id.* at 9.013(3)(b). Subsequent to the initiation of treatment, ''the physician should *adjust* drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.'' *Id.* (emphasis supplied).

Another standard adopted by the Florida Board, under the subheading ''Informed Consent and Agreement for Treatment,'' is the directive that

[T]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:
1. Urine/serum medication levels screening when requested;
2. Number and frequency of all prescription refills; and
3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

Id. at 9.003(3)(c).

The Florida Standards contain a further requirement to periodically review ''the course of pain treatment and any new information about the etiology of the pain.'' *Id.* at 9.013(3)(d). The Florida Standards explain the importance of periodic review in the following manner:

Continuation or modification of therapy should depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication *adjustments,* the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

Id. (emphasis supplied).

_____Under the subheading ''Consultation,'' the Florida Board promulgated the instruction that

[t]he physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

Id. at 9.013(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances, as well as documentation regarding risks, benefits, and side effects of prescribed medications. Conscientious, legible documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the physician's prescribing practices are ''within the usual course of professional practice.''

In *Sergio Rodriguez, M.D.,* Fla. Bd. of Med., No. 2008–20504 (Jan. 7, 2011), the Florida Board considered a case with many striking similarities to the case presented here. In *Rodriguez,* the respondent-practitioner had repeatedly seen an undercover agent, and without the benefit of a physical examination, medical history, tests, or treatment plan, and with incomplete and incorrect documentation, prescribed controlled substances. The Board adopted the state Administrative Law Judge's conclusion that the doctor's ''relationship with [the undercover patient] consisted solely of his writing prescriptions for controlled substances [and found that the doctor] was not prescribing these medications in the course of his professional practice.'' *Id.,* ALJ Dec. at 14.

The Government's evidence establishes that the Respondent issued controlled substance prescriptions to undercover law enforcement personnel posing as patients and other patients at his Florida office beginning in October 2009 and continuing until August 2010. As discussed at length elsewhere in this decision, in addition to the fact that controlled substances were prescribed and dispensed to patients without the Respondent even meeting them, the physical examinations were either cursory or non-existent, and the histories and documentation were inconsistent, incomplete, for the most part abjectly illegible, woefully inadequate, and frequently outright false. Much like the evidence that sustained the criminal conviction in *Moore,*[101] the examinations were inadequate and the patient records are devoid of any indication that steps were taken to safeguard against misuse and diversion. The uncontroverted and persuasive testimony of the Government's expert, Dr. Rubenstein, established, by a preponderance of the evidence, that the Respondent's prescribing practices fell well below the applicable standard in Florida regarding the controlled substances prescribed and dispensed to the undercover agents,

[100] The original *Model Policy* version of the guidelines does not contain a reference to the need for a *complete* medical history, instead only requiring a medical history generally. Thus, the Florida Board has adopted a higher standard than the measure that has been set in the *Model Policy* by the FSMB.

[101] 423 U.S. at 142–43.

as well as to the patients whose charts he reviewed.

On this record, the Government has established that the Respondent employed his COR and/or allowed/enabled others to do so in a manner where controlled substances were prescribed and dispensed for other than a legitimate medical purpose or outside the usual course of professional practice, based on the absence of acceptable physician-patient relationships and even minimal due care in documentation as those concepts are dealt with under federal and Florida state law.

Ryan Haight Act

Under the Ryan Haight Act, it is a violation of federal law to ''deliver[], distribute[], or dispense[][102] a controlled substance by means of the Internet without a valid prescription.'' 21 U.S.C. § 829(e). For a prescription to be valid under the meaning of this provision, it must have been ''issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least one in-person medical evaluation of the patient.[103] *Id.* An in-person medical evaluation is defined as ''a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.'' *Id.* at § (2)(B)(i).

The Government alleged that the Respondent issued ''controlled substance prescriptions to patents in states other than Florida and that the controlled substances were being shipped into the resident state of these patients and that this was being accomplished in violation of the Ryan Haight Act and [sic] in 21 U.S.C. § 829(e).'' ALJ Ex. 6 at 6. As it unfolded at the hearing, the Government's evidence sought to establish that the Respondent issued controlled substance prescriptions to twenty-eight out-of-state individuals in fourteen states without providing an in-person physical examination to a single one. Gov't Ex. 37. Without question, to the extent that these prescriptions were issued without the benefit of an in-person physical examination, their issuance would constitute violations of the CSA as amended by the Ryan Haight Act, as well as the laws of many of the states where they were received by the end users. Without physical examinations, the Respondent may well have violated state prescribing proscriptions in several states, including (but not limited to) Alabama,[104] California,[105] Illinois,[106] Louisiana,[107] Mississippi,[108] and others. It is also unquestionably true that these controlled substance prescriptions were issued by the Respondent in a sufficiently high number and in a relatively brief period such that the evidence would be more than ample to support the adverse COR action sought by the Government in this matter. However, the Government's allegation that the Respondent prescribed controlled substances contrary to the Ryan Haight Act was dependent upon it establishing that the Respondent prescribed anabolic steroids without providing a physical examination and without a legitimate doctor-patient relationship. The only evidence tending to support that possibility was the shipping information of the steroids to arguably remote destinations outside Florida. However, evidence which may provide ample underpinnings to sustain a reasonable suspicion is not the same quantum required to support a finding of substantial evidence. Under the substantial evidence test, the evidence, such as the circumstantial evidence here, must ''do more than create a suspicion of the existence of the fact to be established.'' *Alvin Darby, M.D.,* 75 Fed. Reg. 26993, 26999 n.31 (2010) (quoting *NLRB v. Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939)). Here, there is a missing link. There is no evidence that a single patient that received a controlled substance under the Respondent's COR outside the state of Florida was not examined by him. It is not that evidence was presented and found lacking; it is that no evidence was presented on the issue at all. A Ryan Haight violation sustained under the evidence presented would allow the Government to establish that no in-person physical examination occurred based on shipping label addresses and double hearsay business practice testimony from a diversion investigator who interviewed an individual who was an employee of a now-defunct company who did business with the Internet providers. In short, on the present record, it would be tantamount to sustaining a Ryan Haight violation based upon the mere fact that controlled substances were shipped to locations outside the registrant's home state. Unlike other similar cases, no documentary or reliable testimonial evidence was introduced regarding the nature of the Respondent's relationship with the Internet providers. While an adverse inference based on the Respondent's failure to testify is admittedly a possible evidentiary mechanism available to the Government on these facts, such an inference should not, on the present record, be utilized to establish an element upon which the Government presented no evidence.[109] Thus, the record compels a finding that the Government did not establish a violation of the Ryan Haight Act.

Factors 2, 4, and 5 Considered

The Government's evidence under these factors, as discussed above, present something of a mixed bag. On the one hand, there is insufficient evidence to support its allegations that the Respondent failed to maintain required records in a readily retrievable manner, in violation of regulatory requirements to do so, or its allegations that the Respondent prescribed in violation of the Ryan Haight Act. Thus, the evidence introduced on these issues, like the statistical data elicited through the head of its ARCOS Unit, does not impact a consideration of Factors 2, 4, or 5 (or any other relevant consideration in these proceedings) in any way.

On the other hand, the Government's evidence does establish that the Respondent was profoundly delinquent

[102] The statutory definition of the term ''dispense'' includes the prescribing and administering of controlled substances. 21 U.S.C. § 802(10).

[103] Provisions of the law dealing with the authorization of a ''covering practitioner'' and ''telemedicine'' practice have no applicability to the facts developed at this hearing. *See id.* at §§ 2(A)(ii), (C), 3(A).

[104] Ala. Code §§ 34–24–50(1), -51, -53, -343, -501, -502(a) (2010); Ala. Admin. Code r. 540-x-9-.11 (2010).

[105] Cal. Bus. & Prof. Code §§ 2052, 2060, 2242, 2242.1 (West 2010); Carlos Gustavo Levy (Med. Bd. of Cal. Jan. 28, 2003) (citation order); Carlos Gustavo Levy (Med. Bd. of Cal. Nov. 30, 2001) (citation order); Joan Jerzak, *Drugs on the Information Highway,* 88 Med. Bd. of Cal. Action Rep., Feb. 2004, at 4, available at *http://www.medbd.ca.gov/licensee/internet_prescribing.html.*

[106] 225 Ill. Comp. Stat. 60/49, 49.5 (2010).

[107] La. Rev. Stat. Ann. §§ 37:1262, 37:1271, 37:1290, 40:1238.4 (2010); La. Bd. of Med. Exam'rs, Statement of Position on Internet/Telephonic Prescribing (2000), *http://www.lsbme.louisiana.gov/Statements%20of%20Position/InternetTelephonicPrescribing.pdf.*

[108] Miss. Code Ann. §§ 73–25–1, -25–34, -43–11 (West 2010); 30–17 Miss. Code R. § 1:21(100), (102) (LexisNexis 2010).

[109] Inasmuch as the Ryan Haight Act became effective on April 13, 2009, the interpretive precedent regarding the law is predictably still in its nascent stages. It would not be unreasonable for the Agency to interpret the statute in such a way that a clear and convincing demonstration on the part of the Government that a practitioner has caused controlled substances prescribed and/or dispensed under his or her COR to be shipped to a remote, out-of-state location from the COR registered address would result in a burden of production on the part of the registrant to demonstrate that an in-person physical examination had been conducted. However, as of the date of this recommended decision, the Agency has not yet had the opportunity to evaluate the issue in this context.

in his responsibilities as a DEA registrant. He prescribed and dispensed controlled substances in the face of direct proof that others at NPPM were utilizing his COR to prescribe and dispense controlled pain medications and steroids. The evidence supports a finding that he knew that NPPM functionaries were busily prescribing and dispensing controlled substances under his COR while the enterprise compensated him as an employee. Under these conditions, the Respondent's salary appears, in many ways, to have been tantamount to the price of his complicity or willful ignorance. Patients were receiving dangerous and potentially addictive controlled substances while the Respondent was not present. The patient charts reviewed by the Government's expert demonstrated that the Respondent has been unwilling to take his responsibilities as a registrant regarding documented analysis related to the professional utilization and control of controlled substances in any way seriously. The patient charts maintained on the UCs contained out-and-out falsehoods. Most of the chart notes were illegible. The prescribing done by and allowed by the Respondent in the absence of valid physician-patient relationships, like the poor documentation in his charts, was done in violation of federal and state law, fell below the standard expected of a practitioner in the Florida, and resulted in the prescribing and dispensing of controlled substances outside the course of a professional practice and for illegitimate purposes. 21 C.F.R. § 1306.04(a). Consideration of the evidence of record under Factors 2 and 4 militate powerfully in favor of revocation.

The Fifth statutory factor, which plays a critical role in a disposition of this case given the facts presented, permits the Administrator to consider ''other conduct which may threaten the public health and safety.'' 21 U.S.C. § 823(f)(5). Under current Agency precedent, this factor has been held to be sufficiently broad as to encompass ''conduct which creates a probable or possible threat * * * to public health and safety. *Cadet,* 76 Fed. Reg. at 19450 n.3; *R. Dreszer,* 76 Fed. Reg. at 19434 n.3; *Aruta,* 76 Fed. Reg. at 19420 n.3; *J. Dreszer,* 76 Fed. Reg. at 19386–87 n.3.

The Respondent has used his COR, and allowed it to be used, in a manner where controlled substances were provided to individuals he never met, and where he has failed to provide even the most basic documentation to support his prescribing and dispensing. He has acted in a manner that was contrary to the most bedrock obligations attendant upon a registrant to guard against diversion, and has committed and endured conduct that allowed and facilitated powerful, addictive controlled substances to be prescribed and distributed without the benefits of the basic safeguards required to ensure a closed regulatory system. His actions created an environment where individuals were receiving potentially dangerous controlled substances without regard to whether such substances were medically required or in the best interests of the patients. Simply put, the Respondent has endangered the public and this factor militates strongly in favor or revocation.

Recommendation

Based on the foregoing, the evidence supports a finding that the Government has established that the Respondent has committed acts that are inconsistent with the public interest. In cases, such as the present case, where the Government has made out a *prima facie* case that the Respondent has committed acts that render his continued registration inconsistent with the public interest, Agency precedent has firmly placed acknowledgement of guilt and acceptance of responsibility as conditions precedent to merit the continued status as a registrant and avoid revocation. *Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (2010) (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 463 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008). Here, the Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented a shred of evidence that could reasonably support a finding that the Administrator should continue to entrust him with a Certificate of Registration. Under current Agency precedent, the evidence of record compels a recommendation that the Government's petition to revoke the Respondent's registration be sustained.

Accordingly, the Respondent's Certificate of Registration should be **REVOKED**, and any pending renewal applications should be **DENIED**.

Dated: July 18, 2011.

JOHN J. MULROONEY, II

Chief Administrative Law Judge

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