Respondent's counsel, or any other lay source would be a dangerous course and more importantly, a plainly erroneous one.

Accordingly, after carefully balancing the admitted evidence, the evidence establishes, by a preponderance of the evidence, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

To the extent that the Respondent's prescribing practices fell below the requisite standard in Florida, that conduct also impacts upon the Fifth statutory factor. Under Factor 5, the Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). Although this factor authorizes consideration of a somewhat broader range of conduct reaching beyond those activities typically associated with a registrant's practice, an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety. *See Holloway Distrib.,* 72 FR 42118, 42126 (2007).

The evidence establishes that the Respondent engaged in a course of practice wherein he prescribed unsafely high doses of controlled substances to patients irrespective of the patients' need for such medication and ignoring any and red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to his obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of his obligations as a DEA registrant and Federal and State laws related to controlled substances militate in favor of revocation.

By routinely prescribing unsafely high doses of controlled substances to opioid-naïve patients and ignoring his responsibilities to monitor the controlled substance prescriptions he was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway Distrib.,* 72 FR at 42124 (a policy of "see no evil, hear no evil" is fundamentally inconsistent with the obligations of a DEA registrant). Agency precedent has long recognized that "[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription." *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Floyd A. Santner, M.D.,* 55 FR 37581 (1988).

Agency precedent has consistently held that where, as here, the Government has met its burden to establish a prima facie case that a registrant has committed acts demonstrating that continued registration is inconsistent with the public interest, acceptance of responsibility is a condition precedent to continued registration. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Medicine Shoppe,* 73 FR at 387. The record contains no evidence that the Respondent has either acknowledged or accepted responsibility for the misconduct at issue in these proceedings.

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. A balancing of the statutory public interest factors supports the revocation of the Respondent's Certificate of Registration and a denial of his application to renew. The Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that the Deputy Administrator should continue to entrust him with a Certificate of Registration.

Accordingly, the Respondent's Certificate of Registration should be *revoked* and any pending applications for renewal should be *denied.*

Dated: August 10, 2010.

John J. Mulrooney, II,
U.S. Administrative Law Judge.

[FR Doc. 2011–8348 Filed 4–6–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–37]

Roni Dreszer, M.D.; Decision and Order

On August 10, 2010, Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached recommended decision.[1] Thereafter, Respondent filed exceptions to the decision.

Having reviewed the entire record including the ALJ's recommended decision and Respondent's exceptions, I have decided to adopt the ALJ's rulings, findings of fact,[2] conclusions of law,[3] and recommended Order.

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[1] All citations to the ALJ's Decision (ALJ) are to the slip opinion as issued on August 10, 2010, and not to the attached decision which has been reformatted.

[2] The ALJ found that there is "no evidence that the Respondent 'prescribe[d] and dispense[d] *inordinate* amounts of controlled substances." ALJ at 26. While there is no evidence as to the amounts that Respondent directly dispensed, there is evidence, which is unrefuted, that Respondent prescribed inordinate amounts of controlled substances. In his report, an Expert witness explained that the usual starting dose of Xanax is .25 to .5 mg. once to twice per day and yet Respondent prescribed Xanax 2 mg. twice per day to patients "who had not had Xanax before or recently," and that he did so without documenting that he had considered any of the possible underlying causes of his patients' complaint that they had anxiety; moreover, Respondent did not refer the patients to a mental health professional. GX 5, at 9–10. As the Expert explained, "[t]he treatment was with a very high dose of the controlled substance Xanax. This was clearly not within the boundaries of professional practice." *Id.* at 10. There is also unrefuted evidence that Respondent's prescribing of drug cocktails of oxycodone and Xanax lacked a legitimate medical purpose. *Id.* at 13. In this manner, Respondent did prescribe inordinate amounts.

[3] I do not, however, adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites cases involving list chemical I distributors, a different category of registrant. *See* ALJ at 25–26. As the Agency has previously made clear, DEA can revoke based on a single act of intentional diversion and "evidence that a practitioner has treated thousands of patients" in circumstances that do not constitute diversion "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest." *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). *See also Dewey C. MacKay,* 75 FR 49956, 49977 (2010); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest'"), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). As I further explained, "[w]hile such evidence may be [entitled to] some weight in assessing whether a practitioner has credibly shown that [he] has reformed his practices," it is entitled to no weight where a practitioner fails to acknowledge his wrongdoing. *Krishna-Iyer,* 74 FR at 463.

In any event, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusions that Respondent violated the CSA's prescription requirement because he dispensed controlled substance prescriptions that were not "within 'the usual course of [his] professional practice,'" ALJ at 39 (quoting 21 CFR 1306.04(a)), and that "the evidence under the [experience] * * * factor[] support[s]" the revocation of his registration, is consistent with Agency precedent. *Id.*

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actually constituted* a

Respondent first takes exception to the ALJ's acceptance of L. Douglas Kennedy, M.D., as an expert on the proper prescribing of controlled substances. Respondent contends that Dr. Kennedy should not have been permitted to opine on his prescribing practices because he does not hold a DEA registration in Florida, has not prescribed a controlled substance since 2004, does not currently have either a medical office or hospital privileges in Florida, and "has never practiced medicine regularly in Florida and has not practiced medicine in Florida at all in over 10 years." Resp. Exc. at 1.

Respondent's contention is unavailing as Dr. Kennedy was clearly qualified to render an expert opinion on the proper practice for prescribing controlled substances to treat pain and whether Respondent's controlled substance prescriptions were issued in the usual course of professional practice and for a legitimate medical purpose. *See* 21 CFR 1306.04(a). Dr. Kennedy currently holds a Florida medical license, is a diplomate of both the American Board of Pain Medicine and the American Board of Anesthesiology, and is currently on the faculty of the University of Miami's Miller School of Medicine. GX 117, at 1, 10. Previously, Dr. Kennedy was a Fellow with the Pain Therapy Unit of the Cleveland Clinic, served as the Director of Chronic Pain Management at the University of Kentucky Medical Center, and, for fourteen years, was the Medical Director of a multidisciplinary pain medicine and rehabilitation practice. *Id.* at 1–2.

Dr. Kennedy has published several articles and book chapters on pain management issues and has made several dozen presentations on pain management issues at professional meetings.[4] *Id.* at 3–7. In addition, he is a member of several professional organizations including the American Academy of Pain Medicine, the American Board of Pain Medicine, the American Pain Society, the International Association for the Study of Pain, the American Society of Addiction Medicine, the American Board of Anesthesiology, and the American Society of Anesthesiology. *Id.* at 10; Tr. 22. Finally, Dr. Kennedy explained that he was familiar with the Florida Board of Medicine's standards for prescribing controlled substances to treat pain and that he had reviewed them prior to preparing his report. Tr. 24–26; GX 101, at 6–7.

Thus, Dr. Kennedy was clearly qualified to provide expert testimony. I therefore agree with the ALJ that Dr. Kennedy's testimony was sufficiently reliable to constitute substantial evidence on the issue of whether Respondent acted within the usual course of professional practice and had a legitimate medical purpose in prescribing controlled substances to the patients whose files he reviewed and reject this exception. ALJ at 17.

Next, Respondent contends that Dr. Kennedy's opinion testimony is entitled to no weight because it was based on only sixteen patient charts, which Respondent maintains were not randomly selected and is too small a sample to draw sufficient conclusions about the validity of his prescribing practices. Resp. Exc. at 2. In support of this contention, Respondent relies on Dr. Kennedy's testimony that "'[i]t might not be fair'" to "'cherry-pick[]'" sixteen charts out of a physician's patients because those might be the "the only people out of 2,000" and that the problems found would "be 'an administrative issue for education with the Board of Medical License and not'" necessarily justify the revocation of Respondent's medical license (or DEA registration). *Id.* (quoting Tr. 612–13).

However, even acknowledging that one of the sixteen files reviewed by Dr. Kennedy with respect to Respondent was not randomly selected because it was that of an undercover officer, the ALJ found credible the Diversion Investigator's testimony that the files were not specially selected to enhance the strength of the Government's case. ALJ at 5 (citing Tr. 768). More importantly, the requirement of Federal law that a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," 21 CFR 1306.04(a), applies to each and every prescription issued by a practitioner. Thus, contrary to the Expert's understanding, in determining whether a practitioner has committed acts which render his "registration inconsistent with the public interest," 21 U.S.C. 824(a)(4), DEA is not required to randomly select the files which it will base its case on.

For example, where the Government has developed information that particular patients are drug dealers or engaged in self-abuse, it is not required to ignore the files pertaining to these patients and base its case on a random sample of files. Rather, it can lawfully select the files pertaining to those patients and base its case entirely on them. Moreover, where the Government has seized files, it can review them and choose to present at the hearing only those files which evidence a practitioner's most egregious acts. Of course, where, as here, the Government's case relies so heavily on a chart review, the practitioner can put on his own evidence and argue that the Government's evidence does not establish that he violated the prescription requirement or that his conduct was not so egregious as to warrant revocation. *See Paul Caragine,* 63 FR 51592 (1998). *See also Dewey C. MacKay,* 75 FR at 49977; *Krishna-Iyer,* 74 FR at 463 (holding that DEA can revoke based on a single act of diversion); *Medicine Shoppe-Jonesborough,* 73 FR at 386 & n.56.[5] Accordingly, there is no merit to Respondent's contention.

Finally, Respondent takes exception to the ALJ's findings that he violated Florida's standards for prescribing controlled substances. Resp. Exceptions at 4–5. More specifically, Respondent contends that he complied with the standards set forth under Florida regulations and that he "took a complete medical history and conducted a physical evaluation that was documented," that he maintained "medical records documenting the

threat to public safety." ALJ at 39 (emphasis added). Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances," ALJ at 39, is clearly supported by substantial evidence and warrants an adverse finding under factor five.

The ALJ also opined that "[i]t is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' resort must be had to an expert." ALJ at 34 (quoting 21 CFR 1306.04(a)). While the ALJ properly noted the importance of expert testimony in this case, in which the Government primarily relied on a review of the medical charts, whether expert testimony is needed in any case necessarily depends on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law.

[4] He also co-edited and contributed to the State of Kentucky's Guidelines for Prescribing Controlled Substances, 2nd Edition. GX 117, at 9.

[5] Consistent with DEA's longstanding precedent, *see* ALJ at 19, a respondent is also entitled to put on evidence as to his acceptance of responsibility and any remedial measures he has undertaken to prevent the re-occurrence of similar acts.

patient's intensity of pain, current and past treatments for pain, and the effect of pain on physical and psychological function." *Id.* at 4. He further argues that "[h]e set out a written treatment plan, discussed the risks and benefits of controlled substances and conducted periodic reviews" as also required by Florida's regulations. *Id.* at 4–5.

While it is true that Dr. Kennedy acknowledged that he was not familiar with the specific standard imposed by the State of Florida for excessive prescribing and that he had not reviewed any Florida Medical Board decisions addressing the issue of what is an adequate medical history, *see* ALJ at 17; as noted above, in his report Dr. Kennedy discussed at length the Florida Board of Medicine's *Standards for the Use of Controlled Substances for the Treatment of Pain,* Fla. Admin. Code 64B8–9.013. *See* GX 101, at 6–7.[6] Nor did Respondent produce any evidence that his recordkeeping and prescribing complied with the standards of the Florida Medical Board. Moreover, there is substantial evidence to support the conclusion that Respondent was not engaged in legitimate medical practice and was diverting drugs.

As Dr. Kennedy explained, most of the patients were from out-of-state, with some travelling up to 1200 miles,[7] even though Respondent had no specialized training in pain management, and yet, Respondent did not obtain reports from the prescription monitoring programs run by the States where his patients lived. *Id.* at 16–17. Moreover, Respondent did not obtain adequate medical histories and perform adequate physical examinations; he also never obtained medical records from other treating physicians (or even contacted them) for any of the patients whose files are in evidence. *Id.* at 14–17.

As Dr. Kennedy explained, while "[t]he chart was set up to give the appearance of a legitimate medical practice in an attempt to justify the initial and continued prescription and dispensing of high dose multiple controlled substances ('drug cocktails')," and that while "on the surface [the charts] were adequate for evaluating and treating a patient," on closer review, "the actual contents in the charts, clearly evidence[] just the opposite" as the charts "were very difficult * * * to read [with] many sections left blank or incompletely filled in." *Id.* at 17. Continuing, Dr. Kennedy explained that "[t]he notes were not within the standard of care; all were outside the boundaries of professional practice, lacking significant information and ignoring significant history that was present." *Id.* Moreover, Respondent's failure to obtain patients' medical records "was well outside the boundaries of medical practice and below the standard of medical care," especially for patients receiving "very high dose[s]" of controlled substances. *Id.*

The evidence further shows that this case is not simply a matter of inadequate record keeping. While Respondent apparently required his patients to obtain an MRI, in multiple instances the MRI was obtained before the patient was even evaluated by Respondent, and generally, no other imaging studies such as x-rays or CT scans were done.[8] *Id.* at 16. Moreover, Respondent rarely referred a patient to another physician or health care professional for a consultation.[9] As Dr. Kennedy explained, "alternative opinions should have been sought in order to better diagnose and treat; not to do so was outside the boundaries of professional practice and not within the standard of care." *Id.* Dr. Kennedy thus concluded that Respondent's "diagnoses were usually very vague and/or without medical merit" and were done in an "attempt[] to justify what controlled substances he prescribed." *Id.* at 17.

Dr. Kennedy further observed that while Respondent performed urine drug screens, he ignored the results even when they were inconsistent with other information provided by the patients such as when a patient tested positive for controlled substances which he had previously indicated that he was not currently taking. *Id.* at 14–15; ALJ at 15–16. Moreover, the drug screens were rarely performed other than at the patient's initial visit and lacked quality controls.[10] GX 101, at 15.

Also, although the charts indicate that Respondent discussed doing yoga and stretching, using an anti-inflammatory diet, and taking several over-the-counter supplements (fish oil and glucosamine chondroitin), Respondent's treatment plan primarily involved prescribing "drug cocktails" of high doses of controlled substances with the same regimen of drugs (typically two strengths of oxycodone immediate release and Xanax) prescribed in nearly every case. *Id.* at 5, 13, 15. Most significantly, Respondent never referred any of the sixteen patients for consultations with specialists related to their pain complaints, or for physical, occupational or mental health therapy. GX 101, at 13.

Dr. Kennedy further observed that while the typical starting dose of Xanax is 0.25 to 0.5 mg., once to twice per day, Respondent prescribed Xanax 2 mg., once or twice per day to fourteen of the sixteen patients, and he did so even with patients who had not been on the drug either "before or recently" and "no matter the age or clinical situation." *Id.* While Xanax is used as an anti-anxiety agent, Respondent's medical records did not support the prescribings because "[h]e did not list important factors that could cause anxiety * * * such as depression, life stressors, psychosocial situation, caffeine intake, sleep disturbance [and a] previous medical evaluation"; he also did not refer these patients for evaluation by a mental health professional. *Id.* And with respect to J.S., Dr. Kennedy concluded that Respondent's prescribing of this very high dose of Xanax "was clearly not within the boundaries of professional practice." *Id.*

Finally, Dr. Kennedy noted that beginning with a patient's first visit, Respondent prescribed very high initial doses of oxycodone. Dr. Kennedy explained that the usual starting dose for an opioid naïve patient in moderate to severe pain was five milligrams of oxycodone taken every four hours as needed for a total of thirty milligrams per day. *Id.* at 9. Yet at J.S.'s first visit, Respondent prescribed (in addition to 60 Xanax), 180 Roxicodone 30 mg. (with

[6] Even after *Gonzales* v. *Oregon,* 546 U.S. 243 (2006), multiple courts of appeals, including the Eleventh Circuit, "have applied a general-practice standard when determining whether the practitioner acted in the 'usual course of professional practice.'" *United States* v. *Smith,* 573 F.3d 639, 647–48 (8th Cir. 2009); *see also id.* at 648 (discussing *United States* v. *Moore,* 423 U.S. 122 (1975); "Thus informed by the Supreme Court and other controlling and persuasive precedent, we believe that it was not improper to measure the 'usual course of professional practice' under § 841(a)(1) and [21 CFR] 1306.04 with reference *to generally recognized and accepted medical practices* * * *."). Likewise, the Eleventh Circuit has held that "[t]he appropriate focus * * * rests upon whether the physician prescribes medicine 'in accordance with *a standard of medical practice generally recognized and accepted in the United States.'*" *United States* v. *Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *Moore,* 423 U.S. at 139).

[7] Of the sixteen patients, only five were from Florida. Of the remaining patients, five were from Kentucky, two were from Tennessee, and one was from each of the following States: North Carolina, Ohio, Massachusetts, and Georgia. GX 101, at 9.

[8] Dr. Kennedy explained that referring a patient to obtain an MRI prior to having some contact is unusual and medically inappropriate. Tr. 71–72.

[9] While Respondent referred one patient to his primary care physician for jaundice, and another to the Emergency Room to be evaluated for cellulitis, according to their respective medical records, both of these patients went to Respondent because of lower back pain. *See* GX 108, at 9; GX 109, at 1.

[10] Dr. Kennedy explained that the urine drug screens did not indicate the temperature and specific gravity of the specimen, whether the giving of the sample had been observed, or the type of drug screen used. GX 101, at 4; Tr. 100–03.

one tablet to be taken every four hours), as well as sixty Roxicodone 15 mg. (one tablet, twice a day, as needed for pain), an amount that is seven times the usual starting dose. *Id.* at 19. While J.S. had noted on his medication contract that three months earlier, he had been prescribed 210 oxycodone 30 mg., 90 oxycodone 15 mg., and 90 Xanax 2mg., which was "almost exactly what [Respondent] prescribed[,]" Respondent did not identify the name of the physician who had issued the prescriptions and did not attempt to confirm them. *Id.* at 11.

At each of J.S.'s subsequent visits, Respondent prescribed an additional thirty tablets of oxycodone 30 mg. (for a total of 210), along with sixty tablets of oxycodone 15 mg. and 60 tablets of Xanax 2 mg. *Id.* at 19. While Dr. Kennedy acknowledged that prescribing an additional strength of oxycodone could be legitimate if it was done to treat breakthrough or episodic pain on an as-needed basis, with respect to J.S., who received prescriptions for oxycodone 30 mg. and 15 mg., "there was no specific reason stated in the medical record" for prescribing both drugs. *Id.* at 12. And with respect to all of the patients whose files he reviewed, Dr. Kennedy explained that Respondent's prescribing of drug cocktails of "a very high dose opioid" (including two forms of oxycodone) and a "high dose * * * benzodiazepine" (Xanax) lacked "any legitimate medical purpose." *Id.* at 15.

As Dr. Kennedy concluded, Respondent "was not engaged in the practice of medicine," and "[t]he vast majority of [his] prescriptions for controlled substances was not for a legitimate medical purpose and w[as] beyond the boundaries of professional practice." *Id.* at 18. His "routine and excessive prescription of multiple controlled substances * * * and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the patients he saw as well as * * * to other people in their communities." *Id.* I thus reject this exception as well.

Finally, I also reject Respondent's exception to the ALJ's ultimate finding that Respondent has committed acts which render his registration inconsistent with the public interest. Resp. Exc. 5. Because the record establishes that Respondent has repeatedly violated Federal law by issuing controlled substance prescriptions which lacked a legitimate medical purpose and were issued outside of the usual course of professional practice, 21 CFR 1306.04, and Respondent has offered no evidence establishing that he has accepted responsibility for his misconduct and that he has reformed his practice, *see Steven M. Abbadessa,* 74 FR 10077, 10081 (2009), I adopt the ALJ's recommendation that Respondent's registration be revoked.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, FD1201196, issued to Roni Dreszer, M.D., be, and it hereby is, revoked. I further order that any pending application of Roni Dreszer, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: March 31, 2011.

Michele M. Leonhart,

Administrator.

Larry P. Cote., Esq., for the Government

Sean M. Ellsworth., Esq., for the Respondent

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

John J. Mulrooney, II, Administrative Law Judge. On February 25, 2010, the Deputy Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO), immediately suspending the DEA Certificate of Registration (COR), Number FD1201196, of Roni Dreszer, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also sought revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 22, 2010, the Respondent timely requested a hearing, which, pursuant to a change of venue granted at his request was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[11] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Deputy 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's DEA practitioner registration expires by its terms on June 30, 2011.

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions below.

The Evidence

The OSC/ISO issued by the Government alleges that the Respondent, through the medical practice he participated in at American Pain, LLC (American Pain), prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[12] under circumstances where he knew, or should have known, that the prescriptions were not dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances [13] surrounding the manner in which American Pain is operated and the manner in which its physicians, including Respondent, engaged in the practice of medicine. *Id.* Respondent is also alleged to have provided undercover law enforcement personnel with controlled substances, including, *inter alia,* oxycodone and alprazolam,[14] after cursory or no medical examinations, and therefore without a legitimate medical purpose. *Id.* The Government also alleges that Respondent's former patients have apprised law enforcement personnel that "they were able to obtain prescriptions for controlled substances from [the Respondent] for other than a legitimate medical purpose and with the intention of selling the controlled substances and/or personally abusing the drugs." *Id.*

At the hearing, the Government presented the testimony of three witnesses, DEA Miami Field Division (MFD) Group Supervisor (GS) Susan

[11] Pursuant to an order issued on April 15, 2010, with the consent of the Respondent, the hearing in this matter was consolidated with the cases of four other registrants who were working at the same clinic as the Respondent and who were also issued OSC/ISOs on February 25, 2010, alleging similar and related conduct.

[12] A schedule II controlled substance.

[13] The majority of which are supported by no evidence introduced by the Government during the course of these proceedings.

[14] A schedule IV controlled substance.

Langston, DEA Special Agent (SA) Michael Burt, and L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.

GS Langston testified that the investigation of the American Pain Clinic had its origins on November 30, 2009, during a routine inspection that she and a subordinate diversion investigator conducted at Appurtenance Biotechnology, LLC, a pharmacy doing business under the name Boca Drugs (Boca Drugs), and located a few blocks away from one of the former locations of American Pain. Tr. at 713, 717–20. According to Langston, an examination of the prescriptions seized from Boca Drugs revealed that the majority of those prescriptions were for oxycodone and alprazolam authorized over the signature of physicians associated with American Pain.[15] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. However, inasmuch as the Boca Drugs Prescription Log fails to distinguish between the Respondent, and another registrant with the same last name, the document is of no utility in reaching a disposition of the present case.

GS Langston also testified that, on March 3, 2010, a criminal search warrant was executed on the American Pain Clinic simultaneously with the OSC/ISO that initiated the present case. Tr. at 735. According to Langston, the items seized from American Pain included a sign that had been posted in what she believes to have served as the urinalysis waiting room. *Id.* at 735–37. The seized sign set forth the following guidance:

ATTENTION PATIENTS

Due to increased fraudulent prescriptions, [i]t's best if you fill your medication in Florida or your regular pharmacy. Don't go to a pharmacy in Ohio when you live in Kentucky and had the scripts written in Florida. The police will confiscate your scripts and hold them while they investigate. This will take up to 6 months. So only fill your meds in Florida or a pharmacy that you have been using for at least 3 months or more.

Govt. Ex. 119 at 1. This sign is attached, apparently by some sort of tape, to the top portion of two other signs, posted at the same location, the first of which reads:

ATTENTION:

Patients

Please do *NOT* fill your prescriptions at any *WALGREENS PHARMACY*[16] or *OUTSIDE* the STATE OF FLORIDA.

Id. The final attachment to the composite sign bears the words "24 Hour Camera Surveillance." *Id.* A photograph of the composite sign was admitted into evidence.

Langston also testified that while she was present in the American Pain offices, she noticed that each physician's desk was equipped with a group of stamps, each of which depicted a controlled substance medication with a corresponding medication usage instruction (sig). Tr. at 738–39. A photograph of one set of prescription script stamps was admitted as an exhibit.[17] Govt. Ex. 119 at 2.

GS Langston also testified that a great number of medical charts were seized from the American Pain offices, and that she and her staff selected a number of these files to be analyzed by a medical expert procured by the Government. Tr. at 762. According to GS Langston, after the execution of the warrant, the charts from the entire office were placed into piles in alphabetical order, and not separated by physician. Langston testified that she and three of her diversion investigators reviewed the seized files with a view towards choosing approximately fifteen files for each doctor with the aspirational criteria that each would reflect at least three to four visits by that doctor with a patient. Each investigator was empowered to place a chart on the selected pile, and when the target number (or about that number) was reached for each physician, the selection effort relative to that physician was deemed accomplished. *Id.* at 765. Langston credibly testified that there was no effort to specially select files under some prosecution-enhancement or "cherry picking" purpose. *Id.* at 768.

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS) and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010. Govt. Ex. 97.

In the same fashion, Langston explained the purposes of and circumstances behind the generation of state prescription monitoring reports (PMPs) relative to the Respondent maintained by West Virginia, Kentucky, and Ohio. Govt. Exs. 98–100. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 167 controlled substance prescriptions issued over the Respondent's signature to fifty-four patients located in West Virginia, 110 similar prescriptions provided to fifty-seven Kentucky-based patients were filled between January 1, 2009 and April 4, 2010, and sixty-six such prescriptions pertaining to twenty-eight patients located in Ohio were filled between April 1, 2008 and April 19, 2010. *Id.*

No evidence was introduced at the hearing that would provide any reliable level of context regarding the raw data set forth in the databases received into evidence at the Government's request. Other than the observations noted above, no witness who testified at the hearing ever explained the significance of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case. As discussed above, the fact that the Boca Drugs Prescription Log prepared by the agents does not distinguish between prescriptions authorized by the Respondent and another registrant of the same name deprives the document of virtually any relevance regarding the enforcement action against this Respondent.[18]

GS Langston provided evidence that was sufficiently detailed, consistent and plausible to be deemed credible in this recommended decision.

SA Michael Burt testified that he has been employed by DEA since March 2004 and has been stationed with the Miami Field Division (MFD) since September 2004. Tr. at 813–14. Burt testified that he is the lead case agent for DEA in the investigation of American Pain Clinic and has participated in the investigation since the latter part of 2008. According to Burt, American Pain, which was previously known by the name South Florida Pain, has conducted business at four different locations, and

[15] Although GS Langston testified that DEA immediately suspended the COR that had been issued to Boca Drugs, Tr. at 715, and that a voluntary surrender by that registrant followed a day later, *id.* at 776, no evidence has been presented that would lend that fact any particular significance related to any issue that must or should be found regarding the disposition of the present case.

[16] GS Langston testified that she was unaware of the location of the closest Walgreens to American Pain's offices. Tr. at 779. No evidence was presented that would tend to establish that any Walgreens or any other pharmacy has taken a position regarding its willingness to fill prescriptions authorized by American Pain.

[17] Although GS Langston testified that she did not actually take the photographs taken during the search warrant execution at American Pain, she did provide sufficient, competent evidence to support the admission of the photographs that were ultimately received into evidence. Tr. at 737, 739–41.

[18] Remarkably, although this unfortunate aspect of this document was brought to light during the course of the hearing, Tr. at 732, no effort on the part of the Government was made to provide additional details or explanation that might tend to differentiate between the respondents.

he surveilled the Boca Raton and Lake Worth locations both in person and by periodic live review of video captured via pole cameras [19] set up outside the clinic. *Id.* at 815–17. These pole cameras, which were in operation during a three week period from January to February 2010, were initially in operation on a 24-hour basis, but Burt testified that they were later activated only between the hours of 7 a.m. through 6 p.m. due to an observed lack of activity at the clinic outside of that time period. *Id.* at 820–21. The pole camera recordings were not offered into evidence at the hearing or made available to opposing counsel.

Based on these surveillance efforts, SA Burt testified concerning various activities he observed occurring outside the Boca and Lake Worth clinic locations, which were open to the public from 8 a.m. to 5 p.m. At the Boca location, Burt stated that on any given day, beginning at 7 a.m. in the morning, automobiles could be seen pulling into the parking lot and approximately twenty to thirty people were routinely lined up outside of the clinic waiting to gain admittance. Additionally, there was a steady stream of automobile and foot traffic in and out of the clinic throughout the day. *Id.* at 817, 821. Burt testified that in his estimation, approximately 80–90 percent of the automobiles had out-of-state tags, predominantly from Kentucky, Ohio, West Virginia and Tennessee. *Id.* at 817–18. Burt also observed security personnel with "staff" written on their shirts [20] riding around the exterior of the building in golf carts and who, in Burt's assessment, appeared to be directing patients into the American Pain facility. Burt indicated his surveillance of the Lake Worth location yielded similar observations. *Id.* at 818.

Based on his review of some (but not all) [21] of the audio and video tapes made by agents and informers sent into the clinic by the Government at various times, SA Burt also testified about his understanding of the process by which patients obtained controlled substance prescriptions at American Pain. According to Burt, after entering the clinic, a patient would meet with the receptionist, who would determine if the patient had an MRI. If not, the receptionist would issue that individual an MRI prescription in exchange for a $50 cash payment, and the patient "would be directed to a place to obtain an MRI." *Id.* at 822. Burt testified that one such MRI location was Faye Imaging, which was a mobile MRI trailer located behind a gentlemen's club several miles away from American Pain. *Id.* at 822–23. The cost for the MRI was $250, and the patient could pay an additional fee "to have the MRI expedited and faxed over to American Pain." *Id.* at 823–24. Once the MRI was procured and faxed to American Pain, the patient would return to the clinic and be seen by a doctor. According to Burt, the clinic accepted what he referred to as "*predominantly* cash only" [22] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day" [23] in this manner.[24] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some [25] of the video and audio recordings made by an undercover agent (UC) named Luis Lopez capturing activity inside of American Pain.[26] In those recordings, Burt observed who he believed to be an American Pain employee inside the facility standing up in a waiting room full of patients and directing them "not to have their prescriptions filled out of state, not to go out into the parking lot and snort their pills," and directing the patients to have their prescriptions filled "in house" (meaning at American Pain), at "a pharmacy they have in Orlando, Florida," or at "a pharmacy they have down the street," which, in Burt's view, was a reference to Boca Drugs. *Id.* at 825–26. Burt further testified that the purported employee on the recording told the patients to "obey all the traffic laws; do not give the police a reason to pull you over." *Id.* Although Burt testified as to the contents of these recordings, the physical recordings were not offered into evidence by the Government or made available to opposing counsel.

SA Burt also testified that he received information from Dr. Eddie Sollie, a former physician employed during the time period American Pain was doing business as South Florida Pain, who terminated his employment at the Oakland Park clinic location in November or December 2008 after working there for approximately two and a half to three months. *Id.* at 827, 898. During the course of an interview where Burt was present, Dr. Sollie related various "concerns about how the practice was being handled or managed." *Id.* at 827–28. These concerns included medical records being, in his opinion, annotated inadequately by the doctors, and what he perceived as a lack of supervision during patient urinalysis testing, where patients would "go[] to the bathrooms together, bringing items with them to the bathrooms that could possibly disguise the urinalysis." According to Burt, Sollie explained that he perceived that patients were substituting urine produced by other persons that contained the metabolites for controlled substances that the patients claimed to be legitimately taking, with a view towards falsely providing evidence to the American Pain doctors showing that they were actually taking prescribed medications and not diverting them. *Id.* at 828–29. During cross-examination, Burt explained that Dr. Sollie told him he had raised these concerns with Christopher George, the owner of American Pain, and that Burt had no evidence that the deficient practices that Sollie had objected to continued through 2010. *Id.* at 900, 906. Burt also acknowledged that he was aware Dr. Sollie had been involved in litigation with Mr. George and that their relationship was strained. *Id.* at 1009. Dr. Sollie was not called as a witness by either party.

SA Burt also provided testimony concerning three confidential sources (only one of whom was seen by the Respondent) and their contacts with doctors at American Pain. Relative to the Respondent, based on the investigative assistance he provided to the Palm Beach County, FL, Sheriff's Office (PBSO), Burt testified regarding the circumstances surrounding a confidential source's (CS3) visit to obtain controlled substances from

[19] SA Burt described the pole cameras as "covert cameras that are installed to observe the activity in the clinic." Tr. at 816. Burt testified that he was able to use a laptop to access the live video feed from the cameras after inputting a username and password. The camera video was also recorded to DVR. *Id.* at 821.

[20] Tr. at 910.

[21] SA Burt conceded that although he is the designated lead case agent for DEA, he did not review all the audio and video tapes made in the case or even review the transcripts. Tr. at 1002–05.

[22] Later on cross-examination, SA Burt admitted that the clinic also accepted payment via credit card. Tr. at 916.

[23] Inasmuch as the Government provided no information from which any specific number of patients seen by any given clinic doctor on any day could be derived, or any expert testimony regarding a reasonable number of pain patients that could or should be seen per day, the value of providing the raw number of patients walking through the door at the clinic is negligible.

[24] Burt further testified that the doctors were paid $75.00 per patient visit, *id.* at 884, but because he indicated that he could not disclose his basis of knowledge for this information, this portion of his testimony can be afforded no weight. *See Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[25] Tr. at 1002–05.

[26] The fact that these recordings were made during the course of seven different office visits by an undercover agent to both the Boca Raton and Lake Worth locations was established on cross-examination. Tr. at 900, 985.

American Pain in October 2009.[27] Burt stated that he was approached by an unnamed PBSO officer who advised that he had a confidential source "that could go into American Pain and purchase oxycodone from one of the doctors." *Id.* at 870. Burt met CS3 at a predesignated location, at which time the source was searched for contraband and provided with a recording device prior to entering American Pain to visit the Respondent, whom he had a scheduled appointment with and had previously been seen by at the clinic. *Id.* at 871, 877, 1050. At a subsequent debriefing, Burt testified that "the source told [him] that he went into the office with [the Respondent], put on the blood pressure cuff himself, took his own blood pressure, was given no physical exam by the doctor, and left with a prescription of oxycodone." *Id.* at 878. Burt testified that he was not able to simultaneously listen to the audio capturing the details of this office visit, and further admitted that has not reviewed the associated audio recording; instead, Burt's testimony was based on his review of a PBSO detective's written report and Burt's participation in the debriefing of CS3. Burt's testimony revealed that the investigative assistance of CS3 was secured as part of his cooperation with PBSO in relation to a pending criminal charge. *Id.* at 1047. Burt declined to disclose the name of CS3 when queried on cross-examination. *Id.* at 1045. The audio recording made by CS3 was not introduced by the Government into evidence or provided to opposing counsel.[28] SA Burt was extremely vague and sketchy regarding the details of his encounter with CS3 relative to the Respondent. *Id.* at 870–82. In fact, without a refreshment of his recollection, Burt was not even sure that CS3 met with the Respondent, and not another American Pain physician with the same last name. *Id.* at 871–77. This portion of his testimony was received over the vociferous objections of Respondent, based on lack of relevance, unfair prejudice, and the inability for meaningful cross-examination based on a lack of access to either the recorded audio or even a witness who has heard the audio (or even knew the details of the visit), in conjunction with the absence of evidence of the name that would be on the patient chart reflecting the office visit. Tr. at 877–82. Under the circumstances present here, including the tentative nature of his testimony as well as the manner in which it was produced, which, categorically denied the Respondent of any meaningful opportunity for the cross-examination required by the A.P.A.,[29] this aspect of Burt's testimony may be accorded no weight. To proceed otherwise would deny the Respondent the ability guaranteed by the APA "to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. 556(d); *see Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980); see Tr. at 882.

SA Burt also testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[30] Burt's record testimony indicates that DEA Task Force Officer[31] (TFO) Barry Adams informed him that a Kentucky resident named TY overdosed in Kentucky from oxycodone intoxication induced by medication procured at American Pain. Burt testified that this information was furnished pursuant to a working law enforcement relationship between the Kentucky State Police, Kentucky FBI, Kentucky DEA and Miami DEA aimed at addressing "the brunt of the pill problem" centered within the state of Kentucky relative to illegal use and resale of prescription pain medications. *Id.* at 833–35. However, in his testimony, Burt was unable to recall the name of the doctor from whom TY obtained his pills, and, thus, no admissible evidence was presented by the Government with respect to TY's death.[32] Likewise, the record evidence concerning SM did not implicate prescribing activity by the Respondent.

Perhaps among the more striking aspects of SA Burt's performance on the witness stand is the anticipated testimony which he did not provide. When viewed in its entirety, SA Burt's record testimony was stunningly sparse when compared with his proposed testimony as noticed in the Government's prehearing statement.[33] That certain information may be unavailable for reasons related to other litigation forums or other equally valid reasons are of no moment with respect to the evaluation that must be made at this administrative forum. Equally important, such considerations do not alter the burdens imposed upon the respective parties. Simply put, the admitted evidence must succeed or fail on its own merits, irrespective of extraneous considerations.

Even apart from the marked contrast between the Burt testimony as proffered and as realized, his testimony was marred by periodic memory failures on significant issues and an inability to supply details to an extent that it could arguably have diminished the weight that could be fairly attached to those aspects of his own investigation that he did manage to recollect. During his testimony, SA Burt acknowledged his own marked lack of preparation and unfamiliarity with the investigation and confessed simply that "[t]here's no excuse . * * *" *Id.* at 1003–05.

Even acknowledging its obvious suboptimal aspects, SA Burt's testimony had no apparent nefarious motivation or indicia of intentional deceit. Burt came across as an earnest and believable witness, who, regarding the aspects of the case that he did recall, was able to impart substantial information about the investigation and activities involving American Pain and its doctors. While frequently lacking in detail, his testimony was not internally inconsistent or facially implausible, and although the legal weight I have assigned to certain portions of Burt's testimony varies given the issues described, I find his testimony to be credible overall.

The Government presented the bulk of its case through the report and testimony of its expert, L. Douglas Kennedy, M.D., D.A.B.P.M., Affiliate Clinical Assistant Professor at the University of Miami, Miller School of Medicine.[34] Dr. Kennedy, who testified that he is board certified by the American Board of Pain Medicine and the American Board of Anesthesiology,[35] was offered and accepted as an expert in the field of pain medicine. *Id.* at 39.

Dr. Kennedy testified that after a review of a group of selected patient files from those seized at the Respondent's practice that were to him provided by the Government, he

[27] Tr. at 1046.

[28] Astonishingly, although SA Burt was offered by the Government as the proponent of all of the information relative to CS3, he conceded that he never listened to the audio tape created as a result of the wire worn by the informant. Tr. at 1051. According to Burt, the sum total of his awareness about the details regarding CS3 was gleaned from his presence at the post-encounter debriefing. *Id.*

[29] 5 U.S.C. 556(d).

[30] Although similar testimony concerning the overdose death of a third individual, OB, was noticed in the Government's prehearing statement, it was not offered by the Government at the hearing. ALJ Ex. 6 at 8.

[31] According to SA Burt, a "task force officer" is a local police officer or sheriff's deputy that is assigned to work on a DEA task force, rather than a sworn DEA criminal investigator. Tr. at 1031.

[32] *See* Tr. at 836–53 (addressing exclusion of Govt. Ex. 27 and associated testimony).

[33] ALJ Ex. 6.

[34] Dr. Kennedy's CV was admitted into evidence. Govt. Ex. 117.

[35] Tr. at 17.

concluded that the Respondent's physical examinations, treatment plans, and patient histories were below the standard fixed by the Florida Medical Board and that that controlled substances was not for a legitimate medical purpose. *Id.* at 585–88.

Dr. Kennedy took professional issue with several aspects of the Respondent's patient care as reflected in the charts regarding the prescribing of controlled substances. It is apparent from his testimony that Dr. Kennedy's analysis is restricted to those matters which can be gleaned from an examination of the written word in that subset of the Respondent's patient charts provided by the Government for his review, and that limitation perforce circumscribes the breadth of his input. That being said, Dr. Kennedy highlighted numerous features in the Respondent's chart documentation that he found wanting, or at least remarkable.

Dr. Kennedy explained that there are basic elements to practicing pain medicine. The acquisition of a thorough history and physical examination is important. *Id.* at 41–42. He also stressed the vital importance of obtaining past medical records to evaluate what treatments, therapies, medications, and dosages have been utilized in the past so that correct current treatment decisions can be made. *Id.* at 45–46. Reliance upon the patient's memory of these elements without the prior medical records, in Dr. Kennedy's view is not reliable or acceptable. *Id.* at 46–47. Dr. Kennedy acknowledged that physicians customarily accept patients at their word, but on the subject of verifying a patient's subjective complaint and medication history, Dr. Kennedy explained that

> [s]ometimes you have to help people understand why they're suffering or what their problems are. A person with an addiction or drug abuse problem is no worse a human being than me. I'm not any better than them. But it's your job as a doctor to sit down and find out what the truth is as well as you reasonably can under the circumstances.

Id. at 357.

Dr. Kennedy prepared a report in connection with the Government's case against the Respondent, which is dated April 30, 2010, and was admitted into evidence. Govt. Ex. 101; Tr. at 585. The report describes a general analysis of sixteen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government from among patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis). Although this report purports to describe practices common to all sixteen files reviewed by Dr. Kennedy, much of the analysis is directed toward a chart prepared in connection with JS,[36] one of the Respondent's patients.

Dr. Kennedy's report makes it unambiguously clear that, in his opinion, all sixteen of the Respondent's charts that he reviewed suffered from the same shortcomings.[37] The Patient Charts Analysis states that the Respondent's patient charts that Dr. Kennedy reviewed "are essentially the same with regard to review issues; as stated in the report of [JS] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 101 at 2.

In Dr. Kennedy's opinion, the patient charts he reviewed that were prepared by the Respondent reflected care that fell below the applicable standard on multiple levels. In his report, Dr. Kennedy noted that the treatment notes in the charts: (1) Contained no typewritten clinical notes and were "very brief, difficult to read (often impossible) and not within the standard of care due to their brevity and quality";[38] (2) reflected prescriptions, right from the initial patient visit, that "were almost entirely for controlled substances, most often one or two immediate release oxycodone pills * * * with Xanax," and which were, in Dr. Kennedy's view, inappropriate and more powerful than justified by the objective signs documented in the written notes;[39] (3) showed that "the same or very similar 'drug cocktails' were prescribed [among all patients in the reviewed files] in the same or very similar doses, [directions] * * * with a 30-day supply," and were affixed to the prescription scripts with a few prepared stamps utilized by all American Pain physicians that reflected "drug, dose, sig (directions) and quantity dispensed";[40] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain;"[41] (5) failed to document the efficacy of the prescribed medication; (6) did not set forth a "diagnostic plan except to obtain an occasional MRI, the results of which made no difference in the 'treatment' ";[42] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described";[43] (8) reflected "no real therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood)";[44] (9) did not reflect "consultations with other physicians or specialists outside the American Pain group [which] could have and in some cases should have included orthopedics, neurology, neurosurgery, psychiatry, addiction medicine and psychology";[45] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all";[46] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and was outside the boundaries of professional practice."[47]

[36] At the request of the Government, a protective order was issued that is designed to minimize the risk of the dissemination of identifying information related to patients and their relatives associated with this case. Accordingly, initials have been substituted for the names of individuals within the protection of the protective order throughout the body of this decision. ALJ Ex. 15.

[37] The Government's tactical decision to essentially unload a pile of charts that are explained only by the representations and generalizations in a report, with no attempt whatsoever to have its expert witness explain the applicable aspects of most charts to this tribunal or any future reviewing body is clearly at odds with the directive provided by the Deputy Administrator in *Gregg & Son Distributors* that "it is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding." 74 FR 17517 n.1.

[38] Govt. Ex. 101 at 5.

[39] Govt. Ex. 101 at 5. In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite not being within standard of care for histories, physical examinations and/or absent past medical records." *Id.* at 8.

[40] Govt. Ex. 101 at 5.

[41] Govt. Ex. 101 at 4. As an example of the failure to adhere to the terms of the medication contract, Dr. Kennedy cites a contract term that provides notice that the physician may stop prescribing opioids or change treatment if pain or activity improvement is not demonstrated, and points out that pain and activity levels are routinely not documented in treatment notes. *Id.* at 4. Similarly, Dr. Kennedy references a medication contract warning that termination of services may result from failure to make regular follow-up appointments with primary care physicians, and notes that the American Pain charts contain no notes from primary care physicians or medical records generated by them. *Id.* at 4–5.

[42] Govt. Ex. 101 at 8. In Dr. Kennedy's opinion, Respondent "in effect, acted as a 'barrier' for [JS] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) may have masked [JS's] underlying disease process(s), making them more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis, all [the Respondent] was doing was, again, masking or covering up the symptoms. *Id.* at 13.

[43] Govt. Ex. 101 at 8.

[44] Govt. Ex. 101 at 8.

[45] Govt. Ex. 101 at 8.

[46] Govt. Ex. 101 at 17. JS's chart did not contain any past medical records, save for a Lumbar report from an MRI performed the day before JS's first clinic visit to see the Respondent. *Id.* at 11.

[47] Govt. Ex. 101 at 15.

Dr. Kennedy found the Respondent's controlled substance patient monitoring to be deficient in numerous respects. From the reviewed patient charts, Dr. Kennedy gleaned that an initial, in-office urine drug screen was frequently executed during the patients' initial visit to the office but repeated only occasionally. Govt. Ex. 101 at 15. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-state prescription monitoring program or outside pharmacy drug profiles. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.* at 15–16.

The identified shortcomings of controlled substance patient monitoring systems was of particular significance where Dr. Kennedy identified specific evidence that he identified as "red flags" of possible or likely diversion. Red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age of the Respondent's chronic pain patients,[48] incomplete history information provided by the patients, periodically significant gaps between office visits,[49] referrals from friends, relatives, or advertising, but not other physicians,[50] and the fact that a relatively high number of patients were traveling significant distances to American Pain for pain treatment, although no physician employed at that facility had any specialized training in pain management.[51]

Dr. Kennedy also found it remarkable that each American Pain patient file provided notice to its patients that American Pain did not accept any form of health care insurance. Govt. Ex. 101 at 3, 17. Dr. Kennedy's report set forth his opinion that this practice was designed to "effectively keep [the physicians at American Pain] 'off the radar' from monitoring by any private health care insurance company as well as all state and federal agencies (Medicaid and Medicare respectively). *Id.* at 17. Significantly, however, when asked, Dr. Kennedy acknowledged that he conducts his own current medical practice on a cash-only basis. Tr. at 151.

Regarding the discomfiture that Dr. Kennedy expressed regarding non-physician referrals in his report, during his testimony at the hearing, he clarified that it was not unusual for a physician to treat patients that have been referred by relatives and friends. Tr. at 154. Further, Kennedy conceded while in the course of his own medical practice he has treated patients referred by family and friends, and that in his report he was focusing on what he perceived as a lack of any referrals by physicians in the files he reviewed, or what he perceived as "trends" or "patterns." Tr. at 154–55. Given Dr. Kennedy's acknowledgement that such referrals are not unusual, coupled with the absence of any record-evidence way to measure the relative percentage of physician referrals in the Respondent's practice, the observations regarding referral sources are of limited value here.[52]

A review of the sixteen patient files that informed the analysis, findings and conclusions offered in Dr. Kennedy's written report and testimony does reflect the presence of at least some of the red flag issues he identified therein, but there was not the unanimity among the files that he repeatedly urges. For instance, in terms of evidence related to therapeutic plans, it is notable that Respondent's patient files contain at least some indications of recommended treatment modalities in addition to the Respondent's exclusive use of controlled substances for pain management. There are notations in the charts reflecting a patient was to see a "PCP," or primary care physician, regarding jaundice, Govt. Ex. 108 at 9; in another patient file, a note listed under referrals reads "ER for eval of Cellulite + Possible IV ATBx." Govt. Ex. 109 at 1.

An examination of the reviewed patient charts does reveal the presence of other red flags that should have inspired additional diligence or inquiry on the part of the Respondent. RR's patient file, for example, contains a form indicating a positive UDS for oxycodone and benzodiazepine from 11/20/08, yet on the same date, the medication contract signed by RR is blank in that portion of the form designated for the patient to reveal any medications he or she is currently taking. Govt. Ex. 105 at 15, 31; *see also* Govt. Exs. 107 at 8–9, 21; 109 at 46, 54–55; 114 at 8–9, 20 (similar issues). Patient RS's file indicates a positive test for oxycodone on 9/10/09, yet on her medication contract sharing the same date, she crosses out her handwritten listings of Percocet and Xanax, and notes "*Sorry am not currently taking*." Govt. Ex. 110 at 10, 26. DS's patient file indicates a positive UDS for oxycodone and benzodiazepine only on January 14, 2010; however, the patient indicates elsewhere on a medical form filled out on the same date, in response to a question concerning whether she has taken any illegal or illicit drugs in the last 30 days, that she "smoked some marijuana because of [her] cancer." This disclosure notwithstanding, the lack of an indication of a positive "THC" result on the aforementioned UDS form is not addressed by the Respondent anywhere in the patient file. Govt. Ex. 112 at 10, 19. Patient JR's 7/17/09 UDS indicates a negative test for all listed substances, yet on two different forms dated 7/13/09 she indicates she is currently taking hydrocodone or Lortab, a discrepancy which raises questions about the validity of the testing procedures and/or the patient's candor. Govt. Exs. 106 at 12–13, 30; *see also* Govt. Ex. 113 at 11–12, 29[53] (similar issue). Patient CA's[54] UDS form, on the other hand, lists a positive test result for oxycodone only on 11/3/09, yet the patient states she is also currently taking Xanax elsewhere on the medical forms from the same date. Govt. Ex. 103 at 10–11, 24; *see also* Govt. Ex. 116 at 17–18, 42 (same issue). A prescribed controlled substance that is not reflected in a drug screen should have raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file. At a minimum, these observations support the conclusion there was a general lack of vigilance on the part of the Respondent regarding his obligations as a registrant to minimize the risk of controlled substance diversion.

In addition to the lack of adequately completed forms in some patient files noted by Dr. Kennedy, other patient files appear to be missing key documentation altogether. For instance,

[48] Govt. Ex. 101 at 17.

[49] Govt. Ex. 101 at 15.

[50] Govt. Ex. 101 at 10, 17.

[51] Govt. Ex. 101 at 17.

[52] Dr. Kennedy did not testify that a referral that emanated from a source other than a physician could or should be a basis for a diversion red flag on a given case. His opinion was limited to culling some manner of a trend or pattern. In view of the fact that the record contains no development of the numbers of files with non-physician referrals versus the total number of files, or even an acceptable metric upon which the issue could be evaluated, there is very little useful analysis that can come from Dr. Kennedy's observation regarding the files he reviewed.

[53] Although the disclosed date the medications were last prescribed could provide a plausible explanation for the discrepancy, this misses the point. These types of inconsistencies raise potential red flags that require a prudent registrant to make additional inquiry and document, at a minimum, how the issue has been resolved to the satisfaction of the registrant before controlled substance prescriptions are issued.

[54] It is notable that patient "CA" is referred to using three different last names in the patient file records covering the period of time from 11/3/09 to 2/4/10, only one of which is present on her driver's license. *See* Govt. Ex. 103 at 1–2, 4, 8. This discrepancy is not addressed in any manner in the documentation.

patient RR's file contains a South Florida Pain Management Clinic physical examination form that was not filled out, and no physical examination form is present in the file reflecting such an exam was conducted by the Respondent. *See* Govt. Ex. 105 at 9–10.

Dr. Kennedy concluded his report regarding the Respondent's prescribing practices with the following summary:

> [The Respondent] was not engaged in the practice of medicine, rather he was engaged in an efficient, "[a]ssembly [l]ine" business. His "patients" were revenue streams, not true patients. This business allowed him to collect cas[h] for office visits as well as being a "[d]ispensing [p]hysician" for controlled substances. He prescribed controlled substances so that "patients" would return to his office on a regular basis, allowing him to generate further revenue. [The Respondent's] routine and excessive prescription of multiple controlled substances (oxycodone and Xanax) and lack of arriving at a valid medical diagnosis and treatment most likely caused harm to the "patients" he saw. Drug diversion most likely caused a "mushroom" effect of increased drug abuse, drug addiction, drug overdoses, serious bodily injury and death in those communities spread over several different states. [The Respondent's] continued ability to prescribe controlled substances will only perpetuate the suffering and be a threat to the public.

Govt. Ex. 101 at 18.

On cross examination, Dr. Kennedy agreed that he assumed, for the purposes of his analysis, that where the Respondent's charts reflected an entry or a procedure, that the event actually occurred. Tr. at 654. Kennedy also acknowledged that every one of the patient files he reviewed contained at least a complaint of chronic pain symptoms by the patient and MRI results that could support such a diagnosis. *Id.* at 655–57.

The Government's presentation of Dr. Kennedy's testimony at the hearing was substantially consistent with the conclusions included in the Patient Charts Analysis, but Dr. Kennedy's presentation was clearly not without its blemishes. Although he testified that he was familiar with prescribing practices in Florida, and that he utilized the medical standards applicable to Florida practice,[55] he was unable to identify the documentation standard in the Florida Administrative code with any degree of particularity, and he also acknowledged that he was not aware of what the standard is in Florida Medical Board administrative decisions regarding the overprescribing of medication or what constitutes an adequate medical history. *Id.* at 149–51, 233, 304. While, overall, Kennedy presented testimony that appeared candid and knowledgeable, there were areas in his written report that rang of hyperbole and over-embellishment. The reasoning behind some of the seemingly critical observations in the written report, such as the "cash basis" of the Respondent's practice and the absence of doctor referrals among the reviewed patient files, did not well survive the crucible of cross examination at the hearing. However, overall, Dr. Kennedy's testimony was sufficiently detailed, plausible, and internally consistent to be considered credible, and, consistent with his qualifications, he spoke persuasively and with authority on some relevant issues within his expertise, and notwithstanding the Respondent's objections relative to his Florida-related experience, he is currently an assistant professor teaching at a Florida Medical School. It may well be that the greatest and most significant aspect of Dr. Kennedy's opinion is that on the current record, it stands unrefuted. Thus, his opinion is the only expert opinion available for reliance in this action.[56] Accordingly, Dr. Kennedy's expert opinion that the Respondent's controlled substance prescribing practices, at least as evidenced through his examination of the patient charts he reviewed, fell below the standards applicable in Florida, and that the controlled substance prescriptions contained in those files were not issued for a legitimate medical purpose is unrefuted on this record and (although by no means overwhelming) is sufficiently reliable to be accepted and relied upon in this recommended decision.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4), the Deputy Administrator[57] may revoke a registrant's DEA Certificate of Registration if persuaded that the registrant "has committed such acts that 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).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy 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* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). The Deputy 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 FR 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 CFR 1301.44(e). 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 FR 72, 311 (1980). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to

[55] Tr. at 628.

[56] The Respondent did not testify on her own behalf.

[57] This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104.

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 FR 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 Deputy Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, that are attendant upon the lack of registration are not a relevant consideration. *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 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; *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR 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 Deputy Administrator's factual findings will be sustained on review to the extent they are supported by "substantial evidence." *Hoxie,* 419 F.3d at 481. While "the possibility of drawing two inconsistent conclusions from the evidence" does not limit the Deputy 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., Inc.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S.Ct. 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 Deputy Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Deputy Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *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. 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 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 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 FR 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 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not state officials. *Stodola,* 74 FR at 20375. Thus, on these facts, the fact 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.

Similarly, regarding Factor 3, while testimony was received at the hearing that indicated that a criminal search warrant was executed regarding the Respondent and American Pain, the record contains no evidence that the Respondent has ever been convicted of any crime or even arrested in connection with any open criminal investigation. Thus, consideration of the record evidence under the first and third factors does not militate in favor of revocation.

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 managed that part of his practice relative to prescribing and dispensing controlled substances and acts allegedly committed in connection with his practice at American Pain. 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, 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 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 certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest.

There are two principal considerations embedded within a consideration of this public interest factor. In considering a similar factor under the List I chemical context, the Agency has recognized that the level of experience held by those who will be charged with recognizing and taking steps to minimize diversion factors greatly in determining whether entrusting a COR will be in the public interest. *See Volusia Wholesale,* 69 FR 69409, 69410 (2004); *Xtreme Enters., Inc.,* 67 FR 76195, 76197–98 (2004); *Prachi Enters.,* 69 FR 69407, 69409 (2004); *J&S Distribs.,* 69 FR 62089, 62090 (2004); *K.V.M. Enters.,* 67 FR 70968, 70969 (2002). The Agency has also recognized that evidence that a registrant 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, this factor can be outweighed by acts held to be inconsistent with the public interest. 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 particular registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against its registration is not compelled by public interest concerns. Likewise, evidence presented by the Government that the proven allegations are consistent with a consistent past pattern of poor behavior can enhance the Government's case.

In this case, the Respondent introduced no evidence regarding his level of knowledge and experience, or even the quality or length of his experience as a physician-registrant, but the Government has elected to do so.

Regarding the Government's presentation, Agency precedent has long held that in DEA administrative proceedings that "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.,* 61 FR 728, 730 (1996); *see also Roy E. Berkowitz, M.D.,* 74 FR 36758, 36759–60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). That being said, however, the marked difference between the amount of evidence that the Government noticed in its OSC/ISO and the amount that it introduced at the hearing is striking. For example, contrary to its allegations, there was no evidence that the Respondent "prescribe[d] and dispense[d] *inordinate* amounts of controlled substances," that the "*majority*" of the Respondent's patients were "from states other than Florida," and there was no evidence that American Pain patients were issued "*pre-signed* prescriptions to obtain MRI[s]," nor was there evidence that individuals positioned outside the American Pain building were there to "monitor the activity of patients in the parking lot *to prevent patients from selling their recently obtained controlled substances.*" Likewise, no evidence was introduced at the hearing that could support the allegations that "employees of American Pain [] *frequently* ma[d]e announcements to patients in the clinic advising them on how to avoid being stopped by law enforcement upon departing the pain clinic" and "*frequently* ma[d]e announcements [] advising [patients], among other things, not to attempt to fill their prescriptions at out-of state pharmacies and warning them against trying to fill their prescriptions at particular local retail pharmacies." ALJ Ex. 1 (emphasis supplied).

In like fashion, the Government's prehearing statement proffered that SA Burt would testify to several of the items described but not established in the OSC/ISO. Among the list of allegations that were not supported by any evidence introduced at the hearing, were representations that SA Burt would testify concerning the following:

> Law enforcement in Florida and [other states that correspond to license plates seen in the American Pain parking lot] frequently arrest people for illegal possession and/or illegal distribution of controlled substances who have obtained the controlled substances from American Pain;
>
> American Pain hired individuals to "roam" the parking lot of the clinic to dissuade people from selling their recently obtained controlled substances on the property;
>
> [The reason American Pain placed] signs within American Pain warning individuals not to have their prescriptions filled at Walgreens pharmacies [is] because Walgreens refuses to dispense the prescriptions;
>
> Walgreens has flagged all American Pain doctors and will not fill any of their prescriptions;
>
> [Physical exams at American Pain are] usually no more than a blood pressure check and some bending and stretching;
>
> Dismissed patients would be routed to other doctors within the clinic;
>
> [There was] co-mingling of [American Pain] physician's drugs;
>
> [American Pain maintained] no inventories of drugs dispensed;
>
> [Details surrounding] the death of [American Pain] patient OB [where] [t]he cause of death was determined to be drug intoxication—opiate and benzodiazepine;
>
> [Information] from a confidential source [who indicated] that she traveled to American Pain in order to obtain controlled substances that were later sold in Kentucky for $25 per pill[,] [that] [the American Pain physician she encountered] did not spend any significant time conducting a physical examination of [her] [,] [that she would simply ask questions regarding [her] well being and would then "stamp" a prescription for [controlled substances][,] * * * that on one visit [during a power failure a] security guard working for the clinic instructed everyone to be patient and that the doctors would be with them shortly to "get your fix."

ALJ Ex. 6 at 3–9.

To be clear, it is not that the evidence was introduced and discredited; no evidence to support these (and other) allegations was introduced at all. To the extent the Government had this evidence, it left it home. While the stunning disparity between the allegations proffered and those that were supported with any evidence does not raise due process concerns, it is worthy of noting, without deciding the issue, that Agency precedent has acknowledged the Supreme Court's recognition of the applicability of the *res judicata* doctrine in DEA administrative proceedings. *Christopher Henry Lister, P.A.,* 75 FR 28068, 28069 (2010) (citing *Univ. of Tenn.* v. *Elliot,* 478 U.S. 788, 797–98 (1986) ("When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*[.]")

The evidence the Government did present raises issues regarding not only Factor 2 (experience dispensing [58] controlled substances), but also Factors 4 (compliance with federal and state law relating to controlled substances) and 5 (other conduct which may threaten public health and safety). Succinctly put, the Government's evidence related to the manner in which the Respondent practiced, and whether his practice complied with the law and/or was a threat to the public.

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

While true that GS Langston convincingly testified about the course of her investigation and laid an adequate foundation for numerous database results, the Government provided no foundational context for any relevant uses for those database results. Even apart from the unfortunate reality that one of the databases contained data that could not be directly tied to this Respondent as opposed to another with the same last name, without some insight into what types of results from these databases should be expected when compared to similarly-situated registrants engaged in acceptable prescribing practices, the raw data is without use. In short, there was no evidence elicited wherein the percentage of the Respondent's in-state to out-of state patients could be assessed, and no reasonable measuring stick based on sound principles upon which to evaluate such data. Likewise, there was no reliable yardstick upon which to measure the amount of controlled substances reflected in the databases compared to what a reasonable regulator would expect to see regarding a compliant registrant. To the extent Langston possessed this information (and she well may have) it was not elicited from her. The same could be said of the allegation set forth in the Government's Prehearing Statement that alleges that from a given period the Respondent "was the 20th largest practitioner purchaser of oxycodone in the United States." [59] No evidence to support that allegation (or its relevance) was ever brought forth at the hearing. To the extent that fact may have been true or relevant, it was never developed. What's more, the Florida Administrative Code specifically eschews pain medication prescribing analysis rooted only in evaluation of medication quantity. Fla. Admin. Code r. 64B8–9.013(g). Lastly, there was no indication that despite Langston's obvious qualifications to do so, that she or anyone else ever conducted an audit of the controlled-substance-inventory-related recordkeeping practices at American Pain.

SA Burt testified that, during a temporally limited period of time, he observed some of the images captured by a pole camera positioned outside American Pain, and that he observed what in his view was a high percentage of vehicles in the parking lot with out-of-state license tags. This testimony arguably provides some support for the Government's contention that out-of-state patients (or at least patients being dropped off by cars with out-of-state tags) were being seen at the clinic, but his testimony did not provide much else in terms of relevant information. In any event, recent Agency precedent holds that details such as "where [a registrant's] patients were coming from," without additional factual development, can support a "strong suspicion that [a] respondent was not engaged in a legitimate medical practice" but that "under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999, n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939).

Likewise, without additional details or at least some context, Burt's testimony that individuals with "staff" written on their shirts appeared to be directing patients into the clinic reveals virtually nothing about the Respondent's prescribing practices. Tr. at 818, 910. Furthermore, that Burt observed an individual on a videotape, who he believed to be an American Pain employee, on a single occasion, instruct patients not to "snort [their] pills" in the parking lot,[60] or advising them to comply with vehicle and traffic laws,[61] does not shed illumination on the Respondent's prescribing practices. There was no evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, was also not received in a manner that could meaningfully assist in the decision process. According to Burt, Sollie told him that some (unnamed) physicians at American Pain were inadequately documenting their patient charts in some manner that was apparently never explained to Burt,[62] and that some patients were intentionally evading the American Pain urinalysis process. Sollie did not specifically name the Respondent or any physician as being connected with his allegations of misconduct. Tr. at 853. Thus, this tribunal is at something of a loss as to how the information, as presented, would tend to establish a fact relevant to whether the continuation of the Respondent's authorization to handle controlled substances is in the public interest.

The Government's evidence targeted not only the Respondent's experience practicing under Factor 2, but also his compliance with applicable state and federal laws relating to controlled substances under 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 U.S.C. 829; 21 CFR 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,[63] which the CSA defines as "to deliver a controlled substance to an ultimate user [64] * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 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 FR 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

[59] ALJ Ex. 6 at 11–12.

[60] Tr. at 825.

[61] Tr. at 826.

[62] Tr. at 898.

[63] 21 U.S.C. 823(f).

[64] "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).

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).

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 FR 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 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 a bonafide doctor-patient relationship in order to act "in the usual course of * * * professional practice" and to issue a prescription for a legitimate medical purpose." *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6057–58 (citing *Moore,* 423 U.S. at 141–43). The CSA looks to state law to determine whether a bonafide doctor-patient relationship existed. *Stodola,* 74 FR at 20731; *Shyngle,* 74 FR at 6058; *Garces-Mejias,* 72 FR at 54935; *United Prescription Servs.,* 72 FR at 50407. It was Dr. Kennedy's uncontroverted opinion that his evaluation of chart entries convinced him that they were so defective that the Respondent did not establish a sufficient doctor-patient relationship to justify the prescribing of controlled substances, and that "this was not the practice of medicine in [his] opinion." Tr. at 160–61.

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 is not 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(q) (2009). 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(m).

In exercising its rulemaking function,[65] the Florida Board of Medicine (Florida Board) promulgated a regulation addressing "Standards for Adequacy of Medical Records" applicable to all physicians. Fla. Admin. Code r. 64B8–9.003 (2009). 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 * * *.

Fla. Admin. Code r. 64B8–9.003 (2009).

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,[66] 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 (2009). Moreover, the Florida Board has adopted,[67] 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 Treatment of Pain," Fla. Admin. Code r. 64B8–9.013 (2009) (Florida Standards), 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." The language employed by the regulation under the preamble section titled "Pain Management Principles" 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

[65] 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) (2009).

[66] 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." Fla. Stat. § 458.326 (2009).

[67] Pursuant to authority vested in the Florida Board by the Florida legislature to promulgate rules regarding State standards for pain management clinical practice specifically. Fla. Stat. § 458.309(5) (2009).

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 being within the bounds of being "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," [68] resort must be had to an expert.

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*" (emphasis supplied). *Id.* at 9.013(1)(b),(f).

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 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 [69] 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." (emphasis supplied). *Id.*

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 the 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 or the patient's state of health." *Id.* at 9.013(3)(d). The Florida Standards explain the importance of periodic review in the following manner:

> Continuation or modification of therapy depends 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.

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 9.003(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. Conscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the

[68] 21 CFR 1306.04(a).

[69] 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.

physician's prescribing practices are "within the usual course of professional practice." Here, the uncontroverted expert opinion of Dr. Kennedy, the only expert opinion presented [70] in these proceedings, reflects that the documentation he reviewed in the Respondent's patient charts reflected care that was markedly below the standard of care set by the Florida Medical Board. Dr. Kennedy's expert assessment was consistent with the state statutory and regulatory guidance. In Kennedy's view, the Respondent's charts demonstrated minimalistic, incomplete, and otherwise medically inadequate documentation of his contacts with his patients, and the prescribing rationale for his issuance of controlled substance prescriptions to those patients for alleged pain management purposes. The boilerplate-style, "one high-dosage controlled substances treatment plan fits all" nature of nearly all of the patient medical records at issue, at least in the view of the uncontroverted expert, evidences a failure on the part of the Respondent to conduct his practice of medicine in a manner to minimize the potential of controlled substance abuse and diversion, and supports a conclusion that he failed to even substantially comply with the minimum obligations for professional practice imposed under the Florida Standards, and without "good cause [] shown for such deviation." *Id.* at 9.013(1)(f).

In his Post-Hearing Brief (Respondent's Brief), the Respondent's counsel has prepared and submitted a thoughtful and detailed review of one of the patient charts that was analyzed by Dr. Kennedy in his report. Respt's Br. at 22–26. While counsel argues that the patient chart entries were, at least by his interpretation of his client's obligations, satisfactory, the expert's opinion at the hearing remained unchanged. Even acknowledging, as this recommended decision does, that Dr. Kennedy's presentation was not without its deficiencies, its shortcomings do render it so fundamentally defective as to completely undermine his credibility and viability as within the scope of what a litigant may depend upon.[71] As recognized in the Respondent's Brief, "the [G]overnment, like any party in a contested hearing, is free to hire an expert to advocate its position." Respt's Br. at 12. Unfortunately, counsel's analysis of the patient chart prepared by the Respondent is the product of a lay evaluation of standards applicable to the nuanced and sophisticated science that is the practice of medicine. Where his opinion and that of the only accepted medical expert to provide an expert opinion conflict, his opinion cannot and will not be afforded controlling deference. Argument supplied by counsel (albeit a diligent and persuasive counsel) that the relevant standards were satisfactorily applied as evidenced by the protocols and procedures documented in the patient charts cannot supplant the unrefuted view of an accepted expert witness.

The Respondent, who was in a unique position to conclusively refute Dr. Kennedy's views and explain the format and nuances of the reviewed documentation, elected not to testify in this matter. At a DEA administrative hearing, it is permissible to draw an adverse inference from the silence of the Respondent, even in the face of a Fifth Amendment invocation. *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 FR 17525, 17528, n.3 (2009) (citing *Ohio Adult Parole Auth.* v. *Woodward,* 523 U.S. 272, 286 (1998)). On the facts of this case, where the 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. Where, as here, the Government, through its expert, has alleged that the Respondent's charts do not reflect genuine analysis, but rather (at least in its view and the opinion of its expert), a sort of sham-by-check-box form designed specifically to present a false impression of a compliant registrant, it is precisely the type of allegation that would naturally all but oblige a registrant to spring to offer a contradictory account. The Respondent's choice to remain silent in the face of such allegations, where he could have related his version of his practice as a registrant, adds at least some additional credence to the factual and analytical views of the Government's expert in this regard.

In the Social Security context, where an Administrative Law Judge has received Expert medical opinions on the issue of the claimant's ability to work and they are not repudiated in any respect by substantial evidence, an adverse decision should be set aside as based on "suspicion and speculation." *Miracle* v. *Celebrezze,* 351 F.2d 361, 378 (6th Cir. 1965); *see also Hall* v. *Celebrezze,* 314 F.2d 686, 689–90 (6th Cir. 1963); *cf. Harris* v. *Heckler,* 756 F.2d 431, 436 (6th Cir. 1985) (improper to reject uncontroverted evidence supporting complaints of pain simply because of claimant's demeanor at hearing). When an administrative tribunal elects to disregard the uncontradicted opinion of an expert, it runs the risk of improperly declaring itself as an interpreter of medical knowledge. *Ross* v. *Gardner,* 365 F.2d 554 (6th Cir. 1966). While in this case it is ironically true, much like in the Social Security context, that the opinion of a treating physician should be afforded greater weight than the opinion of an expert whose opinion is limited to a review of the patient file, *see Magallenes* v. *Bowen,* 881 F.2d 747, 751 (9th Cir. 1989), the treating-source Respondent in this case offered no evidence, not even his own opinion, regarding the treatment rendered. Thus, in this adjudication, the record contains no dispute between experts to be resolved; instead, there is but one, unrefuted, uncontroverted, credible expert opinion. To ignore that expert opinion on this record and replace it with the opinion of this tribunal, Respondent's counsel, or any other lay source would be a dangerous course and more importantly, a plainly erroneous one.

Accordingly, after carefully balancing the admitted evidence, the evidence establishes, by a preponderance, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

To the extent that the Respondent's prescribing practices fell below the requisite standard in Florida, that conduct also impacts upon the Fifth statutory factor. Under Factor 5, the

[70] Respondent, in his brief, correctly points out that (for reasons not readily apparent) the Government elicited no testimony from Dr. Kennedy regarding any patient treated by the Respondent. Respt's Br. at 10–11.

[71] Likewise, contrary to the position taken by the Respondent in his brief (Respt's Br. at 7), Dr. Kennedy's opinions are not invalidated by the size of the representative sample of files he reviewed or the manner in which they were selected. Firstly, SA Langston provided credible testimony regarding the selection process, which although admittedly not a paradigm of scientific sampling methodology, was likewise not designed to achieve a particular result. Secondly, contrary to the assertion in the Respondent's brief (Respt's Br. at 15), there is no baseline magic number of files or registrant actions that must be examined to support an expert opinion and ultimately an Agency determination as to whether a registrant has committed acts inconsistent with the public interest sufficient to merit adverse action relative to a DEA COR. *See Krishna-Iyer,* 74 FR at 464.

Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). Although this factor authorizes consideration of a somewhat broader range of conduct reaching beyond those activities typically associated with a registrant's practice, an adverse finding under this factor requires some showing that the relevant conduct actually constituted a threat to public safety. *See Holloway Distrib.,* 72 FR 42118, 42126 (2007).

The evidence establishes that the Respondent engaged in a course of practice wherein he prescribed controlled substances to patients irrespective of the patients' need for such medication and ignoring any and red flags that could or did indicate likely paths of diversion. The testimony of Dr. Kennedy, the DEA regulations, and the Florida Standards make clear that physicians prescribing controlled substances do so under an obligation to monitor the process to minimize the risk of diversion. The patient charts reflect that the Respondent, contrary to his obligations as a DEA registrant, did not follow up in the face of multiple red flags. The Respondent's disregard of his obligations as a DEA registrant and Federal and state laws related to controlled substances militate in favor of revocation.

By ignoring his responsibilities to monitor the controlled substance prescriptions he was authorizing to minimize diversion, and by participating in an insufficiently documented and thoughtful process for the issuance of potentially dangerous controlled substances, the Respondent created a significant potential conduit for the unchecked diversion of controlled substances. *See Holloway Distrib.,* 72 FR at 42124 (a policy of "see no evil, hear no evil" is fundamentally inconsistent with the obligations of a DEA registrant). Agency precedent has long recognized that "[l]egally, there is absolutely no difference between the sale of an illicit drug on the street and the illicit dispensing of a licit drug by means of a physician's prescription." *EZRX, LLC,* 69 FR 63178, 63181 (1988); *Floyd A. Santner, M.D.,* 55 FR 37581 (1988).

Agency precedent has consistently held that where, as here, the Government has met its burden to establish a prima facie case that a registrant has committed acts demonstrating that continued registration is inconsistent with the public interest, acceptance of responsibility is a condition precedent to continued registration. *Jeri Hassman, M.D.,* 75 FR 8194, 8236 (2010); *Medicine Shoppe,* 73 FR at 387. The record contains no evidence that the Respondent has either acknowledged or accepted responsibility for the misconduct at issue in these proceedings.

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. A balancing of the statutory public interest factors supports the revocation of the Respondent's Certificate of Registration and a denial of his application to renew. The Respondent has not accepted responsibility for his actions, expressed remorse for his conduct at any level, or presented evidence that could reasonably support a finding that the Deputy Administrator should continue to entrust him with a Certificate of Registration. Accordingly, the Respondent's Certificate of Registration should be revoked and any pending applications for renewal should be denied.

Dated: August 10, 2010.

John J. Mulrooney, II,
U.S. Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–34]

Cynthia M. Cadet, M.D.; Decision and Order

On August 10, 2010, Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached recommended decision.[1] The Respondent did not file exceptions to the decision.

Having reviewed the entire record including the ALJ's recommended decision, I have decided to adopt the ALJ's rulings, findings of fact,[2] conclusions of law,[3] and recommended Order.

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[1] All citations to the ALJ's Decision (ALJ) are to the slip opinion as issued on August 10, 2010, and not to the attached decision which has been reformatted.

[2] The ALJ found that there is "no evidence that the Respondent 'prescribe[d] and dispense[d] *inordinate* amounts of controlled substances." ALJ at 27. While there is no evidence as to the amounts Respondent may have dispensed directly, there is such evidence, which is unrefuted, with respect to her prescriptions. The Government's Expert specifically found that Respondent "prescribed very high initial and subsequent doses of oxycodone and Xanax to [R.A.] *excessively* and inappropriately without adequate medical justification." GX 55, at 9 (emphasis added). The Government's Expert further noted that "[t]he typical Xanax (alprazolam) starting dose is 0.25 to 0.5 mg. once to twice per day," yet Respondent prescribed "high dose[s] of Xanax" 2 mg. "once to three times per day to 12 of the 13 'patients' whose files [he] reviewed" without "consider[ing] many important factors that cause anxiety" and any "previous medical evaluation"; she also not refer these patients "to a mental health professional for evaluation." *Id.* at 10. The Expert thus concluded that "[t]he treatment was with a very high dose of the controlled substance Xanax" and "was clearly not within the boundaries of professional practice." *Id.* Finally, the Expert provided unrefuted evidence that Respondent prescribed "drug cocktails" of oxycodone and Xanax, which "were clearly not for any legitimate medical purpose." *Id.* at 13. I thus reject the ALJ's finding to the extent that it states that there was no evidence that Respondent prescribed inordinate amounts.

[3] I do not, however, adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites cases involving list chemical I distributors, a different category of registrant. *See* ALJ Dec. at 26–27. As the Agency has previously made clear, DEA can revoke based on a single act of intentional diversion and "evidence that a practitioner has treated thousands of patients" in circumstances that do not constitute diversion "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest." *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). *See also Dewey C. MacKay,* 75 FR49956, 49977 (2010); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (noting that pharmacy "had 17,000 patients," but that "[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest' "), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008). As I further explained, "[w]hile such evidence may be [entitled to] some weight in assessing whether a practitioner has credibly shown that [he] has reformed his practices," it is entitled to no weight where a practitioner fails to acknowledge her wrongdoing. *Krishna-Iyer,* 74 FR at 463.

In any event, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusion that Respondent violated the CSA's prescription requirement because she dispensed controlled substance prescriptions that were not "within 'the usual course of [her] professional practice,' " ALJ at 39 (quoting 21 CFR 1306.04(a)), and that "the evidence under the [experience] * * * factor[] support[s]" the revocation of her registration, is consistent with Agency precedent. *Id.* at 40.

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actually constituted* a threat to public safety." ALJ at 40 (emphasis added). Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances" is clearly supported by substantial evidence and warrants an adverse finding under factor five. *Id.* at 41.