information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

**Overview of This Information Collection**

(1) *Type of Information Collection:* Revision to a currently approved collection; comments requested.

(2) *Title of the Form/Collection:* Community Policing Self-Assessment (CP–SAT)

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice Office of Community Oriented Policing Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Law Enforcement Agencies and community partners. The purpose of this project is to improve the practice of community policing throughout the United States by supporting the development of a series of tools that will allow law enforcement agencies to gain better insight into the depth and breadth of their community policing activities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that approximately 29,235 respondents will respond with an average of 17 minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated burden is 10,847 hours across 1,213 agencies.

If additional information is required contact: Lynn Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street, NE., Room 2E–808, Washington, DC 20530.

Dated: March 28, 2011.

**Lynn Murray,**

*Department Clearance Officer, PRA, U.S. Department of Justice.*

[FR Doc. 2011–7922 Filed 4–6–11; 8:45 am]

**BILLING CODE 4410–AT–P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Consent Decree Under Comprehensive Environmental Response, Compensation and Liability Act

Under 28 CFR 50.7, notice is hereby given that on April 1, 2011, a proposed Consent Decree in *United States* v. *Anacomp, Inc., et al,* No. 3:10–cv–1158, was lodged with the United States District Court for the District of Connecticut.

The proposed Consent Decree resolves claims of the United States, on behalf of the Environmental Protection Agency ("EPA"), under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9601 *et seq.,* in connection with the Solvents Recovery Service of New England, Inc. Superfund Site ("SRS Site") in Southington, Connecticut, against the defendant, Compagnone Holdings, Inc., f/k/a Mace Adhesives, Inc. The proposed Consent Decree requires the defendant to pay $30,463.

The Department of Justice will receive for a period of 30 days from the date of this publication comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Anacomp, Inc., et al,* No. 3:10–cv–1158, D.J. No. 90–7–1–23/10. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of RCRA, 42 U.S.C. 6973(d).

The proposed Consent Decree may be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed Consent Decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy of the proposed Consent Decree, please enclose a check in the amount of $4.75 (25 cent per page reproduction cost), payable to the U.S. Treasury.

**Ronald Gluck,**

*Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2011–8219 Filed 4–6–11; 8:45 am]

**BILLING CODE 4410–15–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 10–36]**

### Jacobo 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.

[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 21. While there is no evidence as to the amounts Respondent may have dispensed directly, there is such evidence, which is unrefuted, with respect to his prescriptions. As explained in my discussion of Respondent's Exceptions, an Expert witness testified as to the usual starting doses of oxycodone and Xanax and that the prescriptions Respondent issued for both drugs, even at the initial visit, greatly exceeded the usual starting doses and lacked a legitimate medical purpose. 21 CFR 1306.04(a). Moreover, there is also unrefuted evidence that Respondent's prescribing of drug cocktails of oxycodone and Xanax lacked a legitimate medical purpose. 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 20–21. 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

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 76, at 5–6.

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.

Next, Respondent contends that Dr. Kennedy's opinion testimony is entitled to no weight because it was based on only seventeen 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. Based on Dr. Kennedy's testimony that "'[i]t might not be fair'" to "'cherry-pick[]'" a small and non-random sample of charts out of a physician's patients because this might not provide "'a reasonable representation of what the practice was actually like,'" Respondent argues that "[e]ven improper prescribing practices reflected in a small and non-random sample of 17 charts * * * may 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. 645).

However, even acknowledging that two of the seventeen files reviewed by Dr. Kennedy with respect to Respondent were not randomly selected (one being 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), the Government 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 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; the practitioner can also argue that even

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 conclusion 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 33 (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 threat to public safety." ALJ at 34 (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. ALJ at 34.

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 29 (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 is necessarily dependent 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.

though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation. *See Paul Caragine,* 63 FR 51592 (1998) (granting restricted registration where practitioner did not engage in intentional misconduct, patients had legitimate medical conditions requiring treatment, and practitioner accepted responsibility and testified as to remedial measures he had undertaken). *See also Dewey C. MacKay,* 75 FR at 49977 (revoking registration based on intentional acts of diversion to two patients); *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; *Alan H. Olefsky,* 57 FR 928, 929 (1992) (revoking registration based on physician's single act of presenting two fraudulent prescriptions to pharmacist where physician failed to acknowledge wrongdoing).[5] Accordingly, there is no merit to Respondent's exception.

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 patient's intensity of pain, current and past treatments for pain, and the effect of pain on physical and psychological function." *Id.* at 4–5. 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 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 15, 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.[6] *See* GX 76, at 5–6.

In any event, Respondent produced no 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, the patients whose files he reviewed were relatively young (with an average age of 36), and most were from out-of-state, with some travelling up to 1200 miles,[7] even though Respondent had no specialized training in pain management. *Id.* at 15–16. Yet, Respondent did not obtain reports from the prescription monitoring programs run by the States where his patients lived. *Id.* at 1–2; 14. 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 4, 8–9.

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 15. 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 his patients' medical records "was well outside the boundaries of medical practice and below the standard of medical care," especially because the patients were 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 14–15.

Moreover, notwithstanding the doses the patients were seeking, Respondent rarely referred a patient to another physician or health care professional for a consultation.[9] As Dr. Kennedy explained, "[a]lternative 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.* at 14. 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 15.

Dr. Kennedy also 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. *See id.* at 11, 14. Moreover, the drug screens were rarely performed other than at the patient's initial visit and lacked quality controls.[10] *Id.* at 14.

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 high doses of controlled substances with the same regimen of drugs (oxycodone and Xanax) prescribed in nearly every case. *Id.* at 4, 6–7, 13. And while Respondent referred two patients to

[5] Consistent with DEA's longstanding precedent, *see* ALJ at 17, 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.

[6] Even after *Gonzales* v. *Oregon,* 546 U.S. 243 (2006), several 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* * * *."). To similar effect, 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 seventeen patients, only four were from Florida. Of the remaining patients, five were from Kentucky, three were from Ohio, two were from Tennessee and West Virginia, and one was from Georgia. GX 76, at 1.

[8] Dr. Kennedy explained that referring a patient to obtain an MRI prior to having some contact is unusual and medically inappropriate. Tr. 71–73.

[9] In only two of the seventeen files is there an indication that Respondent referred the patient to another physician.

[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 76, at 14; Tr. 100–01.

their primary care physicians because they had high blood pressure, *see* GXs 78, 79; he never referred any patients for consultations with specialists, or for physical, occupational, or mental health therapy. GX 76, at 11.

Dr. Kennedy noted that Respondent frequently prescribed "drug cocktails" of two strengths of oxycodone immediate release and a high dose of Xanax, a benzodiazepine. *Id.* at 4, 9, 13. 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 M.B., 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 9.

Dr. Kennedy further noted 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., twice per day, to fifteen of the seventeen patients (including M.B.); another patient B.R. (GX 87) received Xanax 2 mg. once per day.[11] *Id.* at 9–10; GXs 78–86, 88–93. Moreover, Respondent prescribed this dose even for patients who had not been on the drug either before or recently and "no matter the [patient's] age or clinical situation." GX 76, at 10. While Xanax is used as an anti-anxiety agent, Respondent's medical records did not support the prescribing because "[h]e did not list * * * many important factors that could cause anxiety * * * such as depression, life stressors, psychosocial situation, caffeine intake, sleep disturbance [and] previous medical evaluation;" he also did not refer these patients for evaluation by a mental health professional. *Id.* With respect to M.B., Dr. Kennedy observed not only that "there was no specific reason stated in the medical record" for prescribing Xanax, but also that Respondent's prescribing of a very high dose of the drug "was clearly not within the boundaries of professional practice." *Id.* at 9–10.

Dr. Kennedy further noted that beginning with M.B.'s first visit, Respondent "prescribed very high initial and subsequent high doses of oxycodone and Xanax" and that these drugs "were prescribed excessively and inappropriately without medical justification." *Id.* at 9. Sections of the history and physical examination form "were grossly incomplete or missing entirely," and Respondent did not identify "past treating and prescribing physicians" and communicate them regarding M.B.'s previous treatment (and obtain medical records) even though M.B. had indicated that he had previously seen a doctor and had physical therapy for his condition. *Id.* at 9; GX 78, at 16.

While M.B. apparently told Respondent that he was taking 210 to 240 oxycodone 30 mg. per month, which he had obtained "off the street," and he also tested positive for the drug in a urine drug screen (UDS) done at his initial visit, Respondent prescribed 180 Roxicodone 30 mg., 60 Roxicodone 15 mg., and 60 Xanax 2 mg. to M.B. at each of the seven visits he made between August 20, 2009 and February 4, 2010. GX 78, at 7, 9, 13, 18–24.

M.B.'s statement that he was getting "large quantities of oxycodone 30 mg. pills 'off the street'" was a clear "warning sign" that he was "at high risk for drug abuse, addiction and/or diversion." GX 76, at 12; *see also id.* at 8. Yet, as Dr. Kennedy observed, Respondent "did not appropriately act on the initial UDS" and M.B.'s admission that he had obtained drugs off the street by requiring him to undergo "[f]urther testing." *Id.* at 11. Indeed, "[t]here were no other UDS tests obtained [after the initial visit] nor other toxicology testing." *Id.* Dr. Kennedy further noted that Respondent "did not obtain any pharmacy drug profiles [from] where [M.B.] had his prescriptions filled," his chart did not indicate where he was filling his prescriptions, and he did not obtain prescription monitoring reports from States where M.B. may have filled prescriptions. *Id.* He also did not obtain prescription monitoring reports for any of the other sixteen patients. *Id.*

Finally, Dr. Kennedy explained that the "drug cocktails" Respondent prescribed of "very potent, high doses" of oxycodone and Xanax (or Valium), *id.* at 11, are "attractive to 'patients' who abuse, are addicted and/or divert (sell or trade) their prescribed controlled substances. They might take them all together to achieve a 'high,' sell some for cash, or trade some for other drugs they prefer." *Id.* at 9. Dr. Kennedy also noted that "[w]hen opioids and benzodiazepines are used in combination, the potential for [a] drug overdose and death is increased," and "[t]he risk of abuse, addiction and/or diversion is also significantly increased." *Id.* at 7. As Dr. Kennedy observed, "[t]hese 'drug cocktails' were clearly not for any legitimate medical purpose." *Id.* at 13.

As Dr. Kennedy concluded, Respondent "was not engaged in the practice of medicine," and "[t]he vast majority of his prescriptions for controlled substances w[as] 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 therefore reject this exception as well.

I therefore 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. at 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, AD7585865, issued to Jacobo Dreszer, M.D., be, and it hereby is, revoked. I further order that any pending application of Jacobo 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 AD7585865, of Jacobo Dreszer, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging

[11] The remaining patient, L.A., received Valium 10 mg. GX 77.

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 [12] 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.[13] 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).

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,[14] 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 [15] 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.* 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.* Lastly, in its Prehearing Statement, the Government further alleges that one of the Respondent's patients died from an overdose of oxycodone and alprazolam [16] one day after obtaining prescriptions for those same controlled substances from a visit to the Respondent at American Pain. *Id.*

At the hearing, the Government presented the testimony of three witnesses, DEA Miami Field Division (MFD) Group Supervisor (GS) Susan 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.[17] *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 one of the other co-Respondents (his son), 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* [18] 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.[19] 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 an 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

[12] Although the Respondent's COR expired on July 31, 2010, the parties stipulated that a timely renewal application has been submitted by the Respondent. ALJ Ex. 31.

[13] Pursuant to an order issued on April 15, 2010, with the consent of the Respondent, ALJ Ex. 9, 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.

[14] A schedule II controlled substance.

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

[16] A schedule IV controlled substance.

[17] 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.

[18] 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.

[19] 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.

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. 71.

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. 72–74. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 229 controlled substance prescriptions issued over the Respondent's signature to seventy-three patients located in West Virginia, 135 similar prescriptions provided to fifty-three Kentucky-based patients were filled between January 1, 2009 and April 4, 2010, and 144 such prescriptions pertaining to sixty-three 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.[20]

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 he surveilled the Boca Raton and Lake Worth locations both in person and by periodic live review of video captured via pole cameras[21] 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 6:00 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[22] 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)[23] 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"[24] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day"[25] in this manner.[26] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some[27] of the video and audio recordings made by an undercover agent (UC) who assumed the name Luis Lopez, capturing activity inside of American Pain.[28] 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

[20] 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.

[21] 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 user name and password. The camera video was also recorded to DVR. *Id.* at 821.

[22] Tr. at 910.

[23] 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.

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

[25] 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.

[26] 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).

[27] Tr. at 1002–05.

[28] 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.

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 testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[29] Burt's record testimony indicates that DEA Task Force Officer [30] (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.[31] 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.[32] 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.[33] Dr. Kennedy, who testified that he is board certified by the American Board of Pain Medicine and the American Board of Anesthesiology,[34] 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 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 579–82.

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 also 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. 76; Tr. at 579. The report describes a general analysis of seventeen 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 seventeen files reviewed by Dr. Kennedy, much of the analysis is directed toward a chart prepared in connection with MB,[35] one of the Respondent's patients.

Dr. Kennedy's report makes it unambiguously clear that, in his opinion, all seventeen of the Respondent's charts that he reviewed suffered from the same shortcomings.[36]

[29] 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.

[30] 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.

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

[32] ALJ Ex. 6.

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

[34] Tr. at 17.

[35] 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.

[36] 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*

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 [MB] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 76 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"; [37] (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; [38] (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"; [39] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain; [40] (5) failed to adequately 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' "; [41] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described"; [42] (8) reflected "no real therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood)"; [43] (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"; [44] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all"; [45] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and was outside the boundaries of professional practice." [46]

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. 76 at 14. 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.* For instance, Dr. Kennedy notes that MB's patient file contains a notation about the patient getting Roxicodone "off the street," along with an initial positive urinalysis screen for oxycodone, yet the Respondent continued to prescribe MB with additional Roxicodone during his initial and subsequent visits. *Id.* at 8–9, 11; *see also* Govt. Ex. 87 at 4, 9; 90 at 3, 9; 91 at 4, 8; 93 at 5, 10 (similar notations involving other patient's acquiring controlled substances "off the street"). 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.*

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,[47] incomplete history information provided by the patients, periodically significant gaps between office visits,[48] referrals from friends, relatives, or advertising, but not other physicians,[49] 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.[50]

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. 76 at 3, 16. 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 16. Significantly, however, when asked, Dr. Kennedy acknowledged that he conducts his own current medical practice on a cash-only basis. Tr. at 151.

A review of the seventeen 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

*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.

[37] Govt. Ex. 76 at 4.

[38] Govt. Ex. 76 at 4. In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite not being within the standard of care for histories, physical examinations and/or absent past medical records." *Id.* at 7.

[39] Govt. Ex. 76 at 4.

[40] Govt. Ex. 76 at 3. 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 3–4. 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.

[41] Govt. Ex. 76 at 7. In Dr. Kennedy's opinion, Respondent in effect, acted as a 'barrier' for [MB] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) could mask or cover up [MB's] underlying disease process(s), making them more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis[] and no plan to obtain one, [the Respondent] was masking the symptoms. *Id.* at 10–11.

[42] Govt. Ex. 76 at 7.

[43] Govt. Ex. 76 at 7.

[44] Govt. Ex. 76 at 7.

[45] Govt. Ex. 76 at 15. MB's chart did not contain any past medical records, save for a Lumbar report from an MRI performed six weeks before MB's first clinic visit to see the Respondent. *Id.* at 8.

[46] Govt. Ex. 76 at 14.

[47] Govt. Ex. 76 at 16.

[48] Govt. Ex. 76 at 13.

[49] Govt. Ex. 76 at 8, 15.

[50] Govt. Ex. 76 at 16.

controlled substances for pain management. For example, Respondent included notations in the records of referring patients to see a "PCP," or primary care physician, for elevated blood pressure. Govt. Exs. 78 at 1–3, 6; 79 at 1. Furthermore, some of the patient history and physical exam forms contain some effort in documenting medication efficacy. Govt. Exs. 83 at 7; 92 at 2.

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. LA's patient file, for example, contains a form indicating a positive UDS for oxycodone and benzodiazepine from 5/18[/09], yet on the same date, the medication contract signed by LA is blank in the section where a patient is supposed to list any medications they are currently taking; likewise, the similarly worded section on the "Patient Comfort Assessment Guide" form also has no medications listed. Govt. Ex. 77 at 12–13, 30; *see also* Govt. Exs. 78 at 13–14, 32; 86 at 14–15, 30; 89 at 8–9, 22 (similar issues). CR's patient file, on the other hand, indicates a positive UDS for "THC" in addition to benzodiazepine and hydrocodone, yet the patient does not disclose marijuana as a "medication" he is currently taking on any of the relevant forms, and, in fact, this positive test is not addressed by the Respondent in any discernible manner in the chart. Govt. Ex. 79 at 9. Patient KL's 7/17/09 UDS indicates a negative test for all listed substances, yet on two different forms dated 7/13/09 he indicates he is currently taking two strengths of oxycodone along with Xanax. Govt. Ex. 82 at 13–14, 31. The UDS form in patient GE's file reflects circled positive results for benzodiazepines, opiates, and oxycodone. This is noteworthy in that the currently-taking list of medications includes seven other drugs, but not these three. Govt. Ex. 80 at 9, 24–25. Patient BR's UDS form, on the other hand, lists a positive test result for oxycodone only on July 24, 2009, yet the patient states she is also currently taking Xanax elsewhere on the medical forms from the same date. Govt. Ex. 88 at 11–12, 25; *see also* Govt. Exs. 90 at 9–10, 22; 92 at 8–9; 93 at 5, 10–11, 26 (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. *See* Govt. Ex. 92 (no pain management agreement, medication contract, or diversion policy present).

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. 76 at 16.

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,[51] 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.[52] 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[53] 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.

[51] Tr. at 628.

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

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

(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 (DC 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 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 (DC 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 (DC 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 (DC 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[54] 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.

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 8th largest practitioner purchaser of oxycodone in the United States."[55] 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,[56] or advising them to comply with vehicle and traffic laws,[57] 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

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

[55] ALJ Ex. 6 at 11–12.

[56] Tr. at 825.

[57] Tr. at 826.

apparently never explained to Burt,[58] 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,[59] which the CSA defines as "to deliver a controlled substance to an ultimate user[60] * * * 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 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,[61] 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.

[58] Tr. at 898.

[59] 21 U.S.C. 823(f).

[60] "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).

[61] 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).

(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,[62] 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,[63] 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 tenets 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 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," [64] 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 [65] 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

[62] 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).

[63] 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).

[64] 21 CFR 1306.04(a).

[65] 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.

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 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 [66] 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 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 not render it so fundamentally defective as to completely undermine his credibility and viability as within the scope of what a litigant may depend upon.[67] 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 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,

[66] 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.

[67] 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.

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 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 all 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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**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 10–35]**

### Beau Boshers, 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 record in its entirety including Respondent's exceptions, I have decided to adopt, except as explained below, the ALJ's

[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 had been reformatted.