DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–40]

Michael J. Aruta, M.D.; Decision and Order

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

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

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

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

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

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

With respect to factor five, "[s]uch other conduct which may threaten public health and safety," 21 U.S.C. 823(f)(5), the ALJ opined that "an adverse finding under this factor requires some showing that the relevant conduct *actually constituted* a threat to public safety." ALJ at 39 (emphasis added). Contrary to the ALJ's reasoning, Congress, by inserting the word "may" in factor five, clearly manifested its intent to grant the Agency authority to consider conduct which creates a probable or possible threat (and not only an actual) threat to public health and safety. *See Webster's Third New Int'l Dictionary* 1396 (1976) (defining "may" in relevant part as to "be in some degree likely to"); *see also The Random House Dictionary of the English Language* 1189 (1987) (defining "may" in relevant part as "used to express possibility"). While the ALJ misstated the applicable standard, his conclusion that Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances," ALJ at 39, is clearly supported by substantial evidence and warrants an adverse finding under factor five.

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

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, BA6733578, issued to Michael J. Aruta, M.D., be, and it hereby is revoked. I further order that any pending application of Michael J. Aruta, 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.
Bernard M. Cassidy., 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 BA6733578, of Michael J. Aruta, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also seeks revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 24, 2010, the Respondent timely requested a hearing, which was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[4] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

The issue ultimately to be adjudicated by the Deputy Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that Respondent's registration with the DEA should be revoked as inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and 824(a)(4). The Respondent's DEA practitioner registration expires by its terms on June 30, 2012.

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 had been conducting at American Pain, LLC (American Pain), has prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[5] under circumstances wherein he knew, or should have known, that the controlled substances were not prescribed and/or dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO

[4] Pursuant to an order issued on April 15, 2010, 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.

[5] A schedule II controlled substance.

further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances [6] surrounding the manner in which American Pain has been operated and the manner in which its physicians, to include the Respondent, has engaged in the practice of medicine. *Id.* The OSC/ISO also sets forth the Government's allegation 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 little or no medical examination." *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.[7] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. A review of the data relative to the Respondent on the Boca Drug Prescription Log reveals that from November 2, 2009 through November 25, 2009, 175 controlled substance prescriptions issued over the Respondent's signature, to eighty-nine patients, only five of whom resided in Florida. The remainder of the patients had listed addresses in Kentucky, Tennessee, Ohio, Georgia, Massachusetts, West Virginia, North Carolina, Virginia, and South Carolina.

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. Tr. 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* [8] 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.[9] Govt. Ex. 119 at 2.

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

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS) [10] and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010.[11] Govt. Ex. 2.

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 and Kentucky. Govt. Exs. 3, 4. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 210 controlled substance prescriptions issued over the Respondent's signature to fifty-five patients located in West Virginia, and 182 similar prescriptions provided to seventy-eight Kentucky-based patients were filled between January 1, 2009 and April 4, 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

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

[7] 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.

[8] 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.

[9] 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.

[10] GS Langston explained that through the ARCOS system, "[d]rug manufacturers and distributors are required to report the sale of certain controlled substances to DEA," and the system "shows the history of a drug from the point of manufacture through the distribution chain to the retail dispensing level." Tr. at 685–86.

[11] For reasons that were never made clear, the ARCOS report begins with a 2006 entry. Govt. Ex. 2 at 1.

of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case.

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 [12] set up outside the clinic. *Id.* at 815–17. These pole cameras, which were in operation during a three week period from January to February 2010, were initially in operation on a 24 hour basis, but Burt testified that they were later activated only between the hours of 7 a.m. through 6 p.m. due to an observed lack of activity at the clinic outside of that time period. *Id.* at 820–21. The pole camera recordings were not offered into evidence at the hearing or made available to opposing counsel.

Based on these surveillance efforts, SA Burt testified concerning various activities he observed occurring outside the Boca and Lake Worth clinic locations, which were open to the public from 8 a.m. to 5 p.m. At the Boca location, Burt stated that on any given day, beginning at 7 a.m. in the morning, automobiles could be seen pulling into the parking lot and approximately twenty to thirty people were routinely lined up outside of the clinic waiting to gain admittance. Additionally, there was a steady stream of automobile and foot traffic in and out of the clinic throughout the day. *Id.* at 817, 821. Burt testified that in his estimation, approximately 80–90 percent of the automobiles had out-of-State tags, predominantly from Kentucky, Ohio, West Virginia and Tennessee. *Id.* at 817–18. Burt also observed security personnel with "staff" written on their shirts [13] 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) [14] 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" [15] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day" [16] in this manner.[17] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some [18] of the video and audio recordings made by an undercover agent (UC) who assumed the name Luis Lopez capturing activity inside of American Pain.[19] 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.[20] *Id.* at 827, 898. During the course of an interview where Burt was present, Dr. Sollie related various "concerns about how the practice was being handled or managed." *Id.* at 827–28. These concerns included medical records being, in his opinion, annotated inadequately by the doctors, and what he perceived as a lack of supervision during patient urinalysis testing, where patients would "go[] to the bathrooms together, bringing items with them to the bathrooms that could possibly disguise the urinalysis." According to Burt, Sollie explained that he perceived that patients were substituting urine produced by other persons that contained the metabolites

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

[13] Tr. at 910.

[14] 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.

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

[16] 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.

[17] 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. To proceed otherwise would deny the Respondent the ability guaranteed by the APA "to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. 556(d); *see Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[18] Tr. at 1002–05.

[19] 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.

[20] On cross-examination, SA Burt stated that he did not know whether it was true that the Respondent began working at the clinic in 2009 (a representation made by Respondent's counsel, but not in evidence), which (at least according to the question posed) would have been after Sollie's employment at the clinic had already ended. Tr. at 898.

for controlled substances that the patients claimed to be legitimately taking, with a view towards falsely providing evidence to the American Pain doctors showing that they were actually taking prescribed medications and not diverting them. *Id.* at 828–29. During cross-examination, Burt explained that Dr. Sollie told him he had raised these concerns with Christopher George, the owner of American Pain, and that Burt had no evidence that the deficient practices that Sollie had objected to continued through 2010. *Id.* at 900, 906. Burt also acknowledged that he was aware Dr. Sollie had been involved in litigation with Mr. George and that their relationship was strained. *Id.* at 1009. Dr. Sollie was not called as a witness by either party.

SA Burt also provided testimony concerning three confidential sources (only one of whom was seen by the Respondent) and their contacts with doctors at American Pain. Relative to the Respondent, Burt testified concerning his April 2009 debriefing of a confidential source of information (CS2) based in Kentucky who came to Burt's attention through his Kentucky law enforcement contacts. *Id.*at 866–67. Burt assisted the source's Kentucky handlers with arranging for CS2 to visit American Pain, at which time she was able to obtain a prescription for oxycodone from the Respondent. Burt testified that during the debriefing, CS2 told him the Respondent instructed her "not to go out of the State of Florida and try to get this pain medication [prescription] filled," and that it should instead be filled within Florida. *Id.* at 869. According to Burt, CS2 also indicated that she did not have a legitimate medical need for the controlled substances when they were acquired from the Respondent. The Government did not submit evidence of, or provide opposing counsel access to, a patient file reflecting CS2's visit with the Respondent, or a copy of the prescription allegedly issued.[21] Burt indicated CS2's cooperation in this investigation was as a result of "working off" criminal charges she was subject to. *Id.* at 895. Burt also declined to disclose the name of CS2 when queried on cross-examination. *Id.* at 893.[22]

SA Burt also testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[23] Burt's record testimony indicates that DEA Task Force Officer[24] (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.[25] 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.[26] 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.[27] Dr. Kennedy, who testified that he is board certified by the American Board of Pain Medicine and the American Board of Anesthesiology,[28] was offered and accepted as an expert in the field of pain medicine. Tr. at 39.

Dr. Kennedy prepared a report in connection with the Government's case against the Respondent, which is dated April 30, 2010, and was admitted into evidence during his testimony. Govt. Ex. 5. The report describes a general analysis of fifteen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government[29] from among an

[21] On cross-examination, SA Burt responded in the negative when asked if he had "anywhere" in his possession a copy of the prescription at issue and whether he had supplied Government counsel with a copy of this individual's patient file. Tr. at 894.

[22] In light of the inability to identify the name of this source of information to opposing counsel, and the lack of detail and corroborating evidence related to the information derived from her, no weight can be assigned to SA Burt's testimony concerning information provided by CS2, beyond the fact that this interaction may have informed the course of DEA's investigation. To proceed otherwise would deny the Respondent the ability guaranteed by the APA "to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d); *see Richardson* v. *Perales,* 402 U.S. 389, 402 (1971); *J.A.M. Builders* v. *Herman,* 233 F.3d 1350, 1354 (11th Cir. 2000); *Keller* v. *Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991); *Calhoun* v. *Bailar,* 626 F.2d 145, 149 (9th Cir. 1980).

[23] 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.

[24] 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.

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

[26] ALJ Ex. 6.

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

[28] Tr. at 17.

[29] Dr. Kennedy testified that he asked that the charts be selected randomly and not be "cherry picked" or selected with a view towards influencing his conclusions. Tr. at 214. As discussed, above, GS Langston testified that the reviewed charts were not selected with a view toward influencing Dr. Kennedy's opinion. Tr. at 768.

unspecified number of patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis).

In Dr. Kennedy's expert opinion, based on a documentary review of the patient charts from the Respondent's practice that he reviewed, the Respondent's prescribing practices fell below the standards set forth by the Florida Medical Board. Tr. at 118. Furthermore, Dr. Kennedy testified that after reviewing the charts, he was unable to identify any legitimate basis for prescribing any of the controlled substance medications prescribed to the patients named in the charts. *Id.*

During the course of his testimony, Dr. Kennedy explained that he 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 testimony. That being said, Dr. Kennedy highlighted numerous features in the Respondent's chart documentation that he found wanting, or at least remarkable.

While acknowledging that some standardization and utilization of forms is not, standing alone, improper,[30] Dr. Kennedy took issue with what he perceived as flaws in the forms utilized by the Respondent to document patient care. According to Dr. Kennedy, the forms inadequately distinguished between the history and physical examinations, and failed to sufficiently document an adequate pain assessment. *Id.* at 79–80, 128–31. According to Dr. Kennedy, the charts also did not document activities that improved or exacerbated pain symptoms, and did not document self-described patient limits, neurological signs and objective observations, such as gait and station. *Id.* at 81. Dr. Kennedy testified that the chart entries 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. *Id.* at 160–61.

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 44. 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 47–48. 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 49–51. Although the Respondent's charts routinely contained a form which purports to require patients to see their primary care physicians, Dr. Kennedy testified that none of the files contained any record of any communication with any primary care physician from any patient. *Id.* at 114–16.

Kennedy also explained the importance of establishing a differential or working diagnosis on the first visit and modifying and reviewing that diagnosis as more information and results become available. *Id.* at 52. Similarly, a diagnostic plan is a systematic methodology of eliminating possible causes of symptoms to allow the treating physician to accurately determine what is causing them so that a successful treatment plan can be developed. *Id.* at 52–53. In other words, the diagnostic plan allows the treating doctor to eliminate or confirm items on the differential diagnosis. *Id.* at 54.

Dr. Kennedy testified that, in his expert opinion, the medical histories taken by the Respondent in the reviewed files were insufficiently detailed to meet the standards set by the Florida Board of Medicine to justify the prescribing of controlled substances. *Id.* at 81–82. The histories and pain assessment evaluations, as documented in the charts, were also "not adequate on the initial or ongoing basis," because the forms used and the manner in which they were completed did not sufficiently catalogue key aspects, such as

> [the] particular pain level, where the pain was located, what it felt like, when was it worse, what made it better, what it made it worse, what have you done to alleviate or past treatments, and what can you not do with the pain? Observations on physical examination about how the person walks, gait and station. Consistency of neurologic and inadequacy of pathologic reflexes particularly, presence or absence, and adequate sensory examination. Musculoskeletal examination. And height and weight many times were not present.

Id. at 80–81, *see also id.* at 128–32.

Similarly, Dr. Kennedy opined that Respondent's treatment plans, as they were reflected in the reviewed records, were "grossly inadequate" in that the use of controlled substances was the single option considered and employed, "[s]o everybody got essentially the same treatment regardless of their complaint, severity, physical examination [and] history." *Id.* at 82–83. In Kennedy's view, combining controlled substance medications that were utilized in the charts was not "bad by itself, but it was done across the board with everybody. * * * [with] essentially the same drugs at the same doses for all the individuals" *Id.* at 98. In Dr. Kennedy's view, there were a panoply of other treatment options that could and should have been documented and discussed with the Respondent's pain patients. *Id.* 162–64.

Dr. Kennedy also made the ironic observation that although to the "extremely rare" [31] extent controlled substance medication adjustments were ever effected by the Respondent, they went up, and the forms utilized by the Respondent (and the practice in general) only provided a checkbox for reduction, or weaning. *Id.* at 95–96. This is essentially inconsistent with the normal practice of starting controlled substance treatment at the lowest dose possible to attain the desired result and adjusting upwards. *Id.* The form used by the Respondent seems to presume that the controlled substance doses would generally progress downward. Dr. Kennedy testified that he saw no evidence of medication adjustment to accommodate treatment, or "titration," in any of the charts he examined. *Id.* at 174.

Although Dr. Kennedy conceded that it is the judgment of the examining physician that is generally relied upon in determining the necessity and appropriateness of diagnostic testing,[32] he also testified that the Respondent's practice of routinely ordering magnetic resonance imaging (MRI) procedures before he met with the patients was inappropriate because an MRI is not always required and not always appropriate. *Id.* at 71–73, 153–54. In Kennedy's opinion, a physician has an obligation to meet with the patient before including this procedure as part of the utilized diagnostic tools. *Id.*

Dr. Kennedy opined that the Respondent's prescribing of opioids lacked a legitimate medical purpose in that he routinely prescribed oxycodone in initial 30 milligram (mg) doses that significantly exceeded the recommended 0.5 to 2.5 mg starting dosage.[33] *Id.* at 86–87. Kennedy

[30] Tr. at 74.

[31] Tr. at 96.

[32] Tr. at 59.

[33] Dr. Kennedy testified that the recommended starting dosages are found in the medication product insert and divined through clinical knowledge. Tr. at 100.

explained that a patient who has never had opioids, or has been off them for two to four weeks is classified as "opioid naïve" and would feel the affects of the medication with smaller doses that can be increased as needed. *Id.* at 83–86. The dosage levels prescribed by the Respondent, in Dr. Kennedy's view, would always require significant monitoring of the medication's effect on the patient, generally done in an office or hospital, and not an outpatient setting. *Id.* at 86–88.

In this regard, Dr. Kennedy highlighted the chart of patient JR.[34] Govt. Ex. 7. JR's patient chart reflects his disclosures that he had not been prescribed pain medication within the twenty-eight days preceding his first appointment with the Respondent. *Id.* at 20. A notation on JR's pain contract indicates that he was not currently taking any medications at the time of his appointment. *Id.* at 23. Notwithstanding the fact that JR, at least by his representations, presented as an opioid naïve patient, the Respondent issued prescription scripts for 30 mg of Roxicodone and 2 mg of Xanax. *Id.* at 17. Kennedy characterized prescribing these controlled substances as "absolutely dangerous if [the patient] took that as prescribed. There would be a significant incident of respiratory depression, drug overdose and potentially death." Tr. at 90. When pressed on the relative likelihood of adverse effects, Dr. Kennedy responded this way:

> If the records that the patient filled out themselves [sic] are correct, then that especially given with the Xanax, which is a benzodiazepine like Valium[,] [i]ts generic name is alprazolam[,] [a]nd that's a high dose of Xanax as well. [] [T]he typical starting dose of Xanax is .25 to 0.5 [mg]. So, that's four to eight times higher than the usual dose on that, and that's given twice daily. Given that they work different areas in the nervous system and they both can cause sedation and potentially respiratory depression, there's at least an additive if not a synergistic effect between when you mix different components of an opioid like oxycodone, a narcotic pain reliever, with a benzodiazepine like Xanax, alprazolam, especially at those doses in a naïve person for both drugs, that makes it even more dangerous.

Id. at 91. Dr. Kennedy was asked to clarify whether this was an area where reasonable medical professionals could differ and provided this emphatic clarification:

> No sir, this isn't even close. There's no room, wiggle room on this. This is absolutely beyond the pale.

Id. at 92.

Notwithstanding his expressed concerns over the potency of some of the controlled substances prescribed by the Respondent, Dr. Kennedy was struck by the fact the charts of several of the Respondent's patients reflected no indication that any acceptable measure of mental status, cognitive ability and response time was undertaken. *Id.* at 102–07.

On cross-examination, Dr. Kennedy agreed that the reviewed charts reflected objective signs that arguably supported medically determinable impairments that could cause chronic pain conditions, and that the controlled substance medications that were prescribed by the Respondent were among those that could be correctly employed to treat chronic pain. *Id.* at 132–33, 135–37, 140–42, 144–45, 148–51. However, Dr. Kennedy remained steadfast in his dual views that the Respondent's medical records simply did not contain enough information for a physician to reach the conclusion that the prescribing was appropriate and that the medication doses were simply too high. *Id.* at 123, 126–27, 166. Kennedy was also consistent in his position that MRI results, standing alone, are not a reliable indicator of an impairment indicating the utilization of controlled substance medications. *Id.* at 55–63, 130–31, 164–66.

In his Patient Charts Analysis, Dr. Kennedy focuses on a patient chart related to GA, one of the Respondent's patients, and opines that the flaws identified in GA's chart are common to all fifteen of the Respondent's files that he reviewed. Specifically, the Patient Charts Analysis states that the charts he reviewed "are essentially the same with regard to review issues; as stated in the report of [GA] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 5 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 bounds of professional practice due to their brevity and quality";[35] (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;[36] (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";[37] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain;[38] (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' ";[39] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described;[40] (8) reflected "inadequate therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood) with the prescription of

[34] 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.

[35] Govt. Ex. 5 at 4.

[36] Govt. Ex. 5 at 4. In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite being outside the bounds of professional practice for histories and physical examinations and absent past medical records." *Id.* at 7.

[37] Govt. Ex. 5 at 4.

[38] Govt. Ex. 5 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 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.*

[39] Govt. Ex. 5 at 7. In Dr. Kennedy's opinion, Respondent "in effect, acted as a 'barrier' for [GA] 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 [GA's] underlying disease process(s), making them more difficult to diagnose, and allowing the disease(s) to unnecessarily worsen. Without an accurate diagnosis, all [the Respondent] was doing was, again, masking or covering up the symptoms." *Id.* at 10.

[40] Govt. Ex. 5 at 7.

controlled substance 'cocktails'";[41] (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/or psychology";[42] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all";[43] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and outside the boundaries of professional practice."[44]

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. 5 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.* 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, and expressed concern that the in-house urinalysis documentation that was maintained did not provide sufficient detail regarding the procuring and maintaining of the sample to meaningfully gauge its reliability. *Id.;* Tr. at 107–111. Kennedy expressed his view that the whole drug testing process at the Respondent's office was inadequate. 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,[45] incomplete history information provided by the patients, periodically significant gaps between office visits,[46] referrals from friends, relatives, or advertising, but not other physicians,[47] 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.[48] During his testimony, Dr. Kennedy conceded that, standing alone, the Respondent's treating out-of-State patients has no particular significance, and that when he was engaged in the practice of medicine in Kentucky he had patients who traveled to his office from Florida.[49] Tr. at 116. Regarding the Respondent's Kentucky patients, Dr. Kennedy observed that there were numerous medical and osteopathic schools that were much closer to the homes of these patients that could have provided pain management. *Id.* at 116–17.

Although Dr. Kennedy's report and testimony appear to attach some significance to referrals that originated in family and friends, he later clarified that it was not unusual for a physician to treat patients that have been referred by relatives and friends. *Id.* at 154. Further, Kennedy conceded while in the course of his own medical practice he has treated patients referred by family and friends, and that in his report he was focusing on what he perceived as a lack of any referrals by physicians in the files he reviewed, or what he perceived as "trends" or "patterns." *Id.* at 154–55. Given Dr. Kennedy's acknowledgement that such referrals are not unusual, coupled with the absence of any way to measure the relative percentage of physician referrals in the Respondent's practice based on the record evidence, the observations regarding referral sources are of limited value here.[50]

During his testimony as well as his report, Dr. Kennedy highlighted several features of particular charts that, at least in his view, bore the indicia of some red flags that should have signaled an increased risk of controlled substance diversion. Kennedy detailed several controls that should have been, but were apparently not utilized by the Respondent to monitor diversion risks in a pain management practice. *Id.* at 111. Some examples of expected diversion controls that were available to, yet absent from the Respondent's practice included random pill counts, communication with family members, blood tests to supplement urinalysis drug screens, communication with patient pharmacists and the acquisition of pharmacy readout sheets to evaluate the prescriptions filled and sources of those prescriptions, and the acquisition of printouts from prescription monitoring programs (PMPs) in some of the States[51] where his patients resided. *Id.* at 111–13.

Although not touched upon by Dr. Kennedy in his testimony or report,[52] there were other indications of potential red flags and related anomalies among the charts admitted into evidence. For example, patient JR's chart contains a form indicating a positive UDS for oxycodone and opiates from 12/30/09, yet on the same date, the medication contract signed by JR reflects a handwritten "N/A" notation in the section where a patient is supposed to list any medications they are currently taking. Govt. Ex. 7 at 10, 23; *see also* Govt. Ex. 19 at 10–11, 23 (similar issue). Patient MR's file, on the other hand, indicates a positive UDS for oxycodone only, yet the patient indicates he is currently taking Xanax (a benzodiazepine that should have triggered a positive UDS reading) on two different documents, a discrepancy which raises questions about the validity of the testing procedures and/or the patient's candor. Govt. Ex. 8 at 13–14, 28; *see also* Govt. Exs. 10 at 9, 22; 12 at 12, 26; 17 at 12–13 (similar discrepancies present in other patient

[41] Govt. Ex. 5 at 7.

[42] Govt. Ex. 5 at 7.

[43] Govt. Ex. 5 at 15. The only past medical record contained in GA's chart was a report from an MRI conducted one day prior to the patient's initial office visit at American Pain. *Id.* at 8.

[44] Govt. Ex. 5 at 14.

[45] Govt. Ex. 5 at 15.

[46] Govt. Ex. 5 at 13.

[47] Govt. Ex. 5 at 7, 15.

[48] Govt. Ex. 5 at 15; Tr. at 67–68.

[49] Although the Government elicited testimony from Dr. Kennedy concerning his perceived significance to a "majority" of patients coming from out of State, Tr. at 116–17, since there was no evidence regarding what percentage of the Respondent's patients were from outside Florida, this inquiry and its responses have been given no weight.

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

[51] Dr. Kennedy testified that although Florida does not have a PMP, several of the States where some of the Respondent's patients resided did have such programs, and that the Respondent would have had access to obtain information about his patients in this manner. Tr. at 113.

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

files with respect to those drugs present on UDS in comparison to current medications listed in medication contract and other forms). Patient BS's UDS indicates a negative test for all listed substances, yet on two different forms she indicates she is currently taking two strengths of Roxycodone along with Xanax. Govt. Ex. 16 at 6–7, 18. 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. The UDS form in patient TS's file reflects circled positive results for benzodiazepines, opiates, and oxycodone on "2/12," yet the words "Neg Test" is handwritten and circled in the margin. Govt. Ex. 13 at 9. Numerous patient files also reflected notations that patients "requested" specific types and/or strengths of controlled substances. Govt. Exs. 6 at 6; 7 at 2; 8 at 4; 17 at 2; 20 at 3; 21 at 3. 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.

Interestingly, in his report, 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. 5 at 3, 16. The report reflected Kennedy's view 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.

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. 5 at 16.

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,[53] 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. Tr. 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.[54] Dr. Kennedy testified that based on his review of the selected patient charts from the Respondent's medical practice, in his expert opinion, he "couldn't find any legitimate basis for [the Respondent] prescribing medications to any of the [patients] and that the Respondent's prescribing practices "were not in compliance at all from the very first visit on" with the standards set forth by the Florida Medical Board. *Id.* at 118. 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[55] may revoke a registrant's DEA Certificate of Registration if persuaded that the registrant "has committed such acts that would render * * * registration under section 823 * * * inconsistent with the public interest * * *." The following factors have been provided by Congress in determining "the public interest":

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

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

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors * * *." *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (DC Cir. 2005). The

[53] Tr. at 628.

[54] The Respondent did not testify on his own behalf.

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

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, 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 both 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 "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.

The Government's Prehearing Statement also represented that it would

be presenting the testimony of Intelligence Analyst (IA) Janet Hines, who would relate her encounter with a confidential source who allegedly obtained controlled substances from the Respondent with minimal or no physical examinations and intentionally diverted them. ALJ Ex. 6. The Government never called IA Hines and never offered an explanation for the differences between the expansive proffers and the less-expansive ultimate presentation.

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 *University of Tennessee* 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 [56] 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. 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 16th largest practitioner purchaser of oxycodone in the United States." [57] 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, as ably pointed out by Respondent's counsel,[58] 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).[59] 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. 818, 910. Furthermore, that Burt observed an individual on a videotape, who he believed to be an American Pain employee, on a single occasion, instruct patients not to "snort [their] pills" in the parking lot,[60] or advising them to comply with vehicle and traffic laws,[61] does not shed illumination on the Respondent's prescribing practices. There was no evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, were also not received in a manner that could meaningfully assist in the decision process. According to Burt, Sollie told him that some (unnamed) physicians at American Pain were inadequately documenting their patient charts in some manner that was apparently never explained to Burt,[62] and that some patients were intentionally evading the American Pain urinalysis process. Sollie did not work at American Pain at the same time the Respondent did, and did not specifically name any physician as being connected with his allegations of misconduct. 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

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

[57] ALJ Ex. 6 at 11–12.

[58] Respt's Br. at 20.

[59] The Respondent's brief incorrectly sites subsection (f).

[60] Tr. at 825.

[61] Tr. at 826.

[62] Tr. at 898.

illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.*

A registered practitioner is authorized to dispense,[63] which the CSA defines as "to deliver a controlled substance to an ultimate user[64] * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor, as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 FR at 17541 (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006); *United States* v. *Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors "peddling to patients who crave the drugs for those prohibited uses." *Id.* The courts have sustained criminal convictions based on the issuing of illegitimate prescriptions where physicians conducted no physical examinations or sham physical examinations. *United States* v. *Alerre,* 430 F.3d 681, 690–91 (4th Cir. 2005), *cert. denied,* 574 U.S. 1113 (2006); *United States* v. *Norris,* 780 F.2d 1207, 1209 (5th Cir. 1986).

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

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

Under Florida law, grounds for disciplinary action or denial of State licensure include "prescribing * * * any controlled substance, other than in the course of the physician's professional practice," and prescribing such substances "inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent." Fla. Stat. § 458.331(q) (2009). Florida law further provides that grounds for such disciplinary action also include:

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

Id. § 458.331(m).

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

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

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

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

> Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V * * * to a person for the treatment of intractable pain,[66] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a

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

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

[65] Rulemaking authority regarding the practice of medicine within the State of Florida has been delegated to the Florida Board of Medicine (Florida Board). Fla. Stat. § 458.309(1) (2009).

[66] Florida defines "intractable pain" to mean "pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated." Fla. Stat. § 458.326 (2009).

reasonably prudent physician under similar conditions and circumstances.

Fla. Stat. § 458.326 (2009). Moreover, the Florida Board has adopted,[67] albeit in modified version, the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*), a document drafted by the Federation of State Medical Boards (FSMB) to provide professional guidelines for the treatment of pain with controlled substances. The standards adopted by Florida share the key tenants of the *Model Policy's* standards for pain management prescribing, including the emphasis on diligent efforts by physicians to prevent drug diversion, prescribing based on clear documentation of unrelieved pain and thorough medical records, and compliance with applicable Federal and State law.

Like the *Model Policy,* which was promulgated "to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion," Florida's regulation providing "Standards for the Use of Controlled Substances for Treatment of Pain," Fla. Admin. Code r. 64B8–9.013 (2009) (Florida Standards), recognizes that "inappropriate prescribing of controlled substances * * * may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use." The language employed by the regulation under the preamble section titled "Pain Management Principles" makes clear that the standards "are not intended to define *complete or best practice,* but rather to communicate what the [Florida Board] considers to be *within the boundaries of professional practice*" (emphasis supplied), *id.* at 9.013(1)(g); thus, the plain text supports an inference that the standards provide the *minimum* requirements for establishing conduct that comports with the professional practice of controlled substance-based pain management within the State. Likewise, the level of integral range of acceptable practice that is built into the regulation underscores the importance of seeking an expert professional opinion in reaching a correct adjudication of whether a registrant has met the applicable Florida standard. It is clear that in assessing whether the controlled substance prescribing practices of a Florida practitioner fall within the acceptable range of what constitutes being within the bounds of being "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," [68] resort must be had to an expert.

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

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

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

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

Although, as discussed above, the Florida Board instituted general guidance applicable to all physicians regarding medical records, it also promulgated a separate set of documentation requirements in the Florida Standards applicable specifically to those physicians who prescribe controlled substances in the pain-management context. The Florida Standards, under the subheading "Medical Records," state that "[t]he physician is required to keep *accurate and complete records*" (emphasis supplied) including, though not limited to:

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

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

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

> A complete [69] medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Id. at 9.013(3)(a).

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

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

> [t]he physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should employ the use of a written agreement between the physician and patient outlining patient responsibilities, including, but not limited to:
> 1. Urine/serum medication levels screening when requested;

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

[68] 21 CFR 1306.04(a).

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

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 witness to testify at 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 Argument, Proposed Findings of Fact and Proposed Conclusions of Law (Respondent's Brief), the Respondent's counsel has prepared and submitted a thoughtful and detailed analysis of the counsel's application of the relevant standards in Florida to the charts analyzed by Dr. Kennedy. Respt's Br. at 3–17. 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, 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 of the evidence, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

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

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

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

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

Recommendation

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

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

Dated: August 10, 2010.

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–37]

Roni Dreszer, M.D.; Decision and Order

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

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

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

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

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

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

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