the Government, through its expert, has alleged that the Respondent's charts do not reflect genuine analysis, but rather (at least in its view and the opinion of its expert), a sort of sham-by-check-box form designed specifically to present a false impression of a compliant registrant, it is precisely the type of allegation that would naturally all but oblige a registrant to spring to offer a contradictory account. The Respondent's choice to remain silent in the face of such allegations, where he could have related his version of his practice as a registrant, adds at least some additional credence to the factual and analytical views of the Government's expert in this regard.

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

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

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

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

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

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

Recommendation

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

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

Dated: August 10, 2010.

John J. Mulrooney, II,

U.S. Administrative Law Judge.

[FR Doc. 2011–8340 Filed 4–6–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–35]

Beau Boshers, M.D.; Decision and Order

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

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

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

rulings, findings of fact, conclusions of law, and recommended Order.

Respondent raises two exceptions to the ALJ's recommended decision. First, he argues that "he was denied the ability to present his positive experience in dispensing controlled substances." Resp. Exc. at 1. More specifically, he argues that he was denied "access to files seized" by the Government which show that he discharged patients, and that "[w]ithout access to those files," he was left "with his hands tied behind his back and [was] unable to demonstrate his successful treatment of patients with controlled substances." *Id.* at 1–2. Respondent contends that this "effectively crippl[ed] his ability to present any evidence of his positive, or successful, experience in dispensing and treating patients with controlled substances." *Id.* at 1.

As support for his contention that he is entitled to present evidence of his "positive experience," Respondent cites the Agency's decision on remand in *Jayam Krishna-Iyer,* 74 FR 459 (2009). That decision addressed an unpublished decision of the United States Court of Appeals for the Eleventh Circuit, which vacated the Agency's Order revoking a practitioner's registration on the ground that it failed to consider the practitioner's "experience with twelve patients whose medical charts were seized by the DEA, or with thousands of other patients. In short, the DEA did not consider any of the Petitioner's positive experience in dispensing controlled substances." *Id.* (quoting *Krishna-Iyer* v. *DEA,* 249 Fed. Appx. 159, 160 (11th Cir. 2007)).

While this Agency complied with the Eleventh Circuit's order, unpublished decisions are "not precedential." *United States* v. *Shaw,* 560 F.3d 1230, 1241 (11th Cir. 2009). Moreover, as I noted in *Krishna-Iyer,* "[t]he Court of Appeals did not cite to any decision of either this Agency or another court defining the term 'positive experience.' Nor did the Court offer any guidance as to the meaning of this term, which is not to be found in the" Controlled Substances Act. 74 FR at 460.

I thus assumed—even though there was no evidence (except for twelve patient files) in the record regarding the legitimacy of the practitioner's prescribing of controlled substances to the "thousands of other patients" she had treated—that her prescribings to these patients constituted "positive experience." *Id.* at 460–61. However, the practitioner's "prescribings to thousands of other patients [did] not * * * render her prescribings to the undercover officers any less unlawful, or any less acts which 'are inconsistent with the public interest.'" *Id.* at 463 (quoting 21 U.S.C. 823(f)).[2]

As *Krishna-Iyer* explained, because the CSA limits registration as a practitioner "to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career." *Id.; see also* 21 U.S.C. 823(f) (registration limited to a practitioner "authorized to dispense * * * controlled substances under the laws of the State in which he practices"). I further noted that "in past cases, [DEA] has given no more than nominal weight to a practitioner's evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion." *Id.* (quoting *Paul J. Caragine, Jr.,* 63 FR 51592, 51599 (1998) ("[T]he Government does not dispute that during Respondent's 20 years in practice he has seen over 15,000 patients. At issue in this proceeding is Respondent's controlled substance prescribing to 18 patients."); *id.* at 51600 ("[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future."); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (2008) (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)).

DEA has thus revoked a practitioner's registration based on a single act of presenting two fraudulent prescriptions to a pharmacy for filling; *see Alan H. Olefsky,* 57 FR 928, 928–29 (1992), and DEA can revoke based on a single act of diversion. *Dewey C. MacKay,* 75 FR 49956, 49977 (2010). *See also Sokoloff* v. *Saxbe,* 501 F.2d 571, 576 (2d Cir. 1974) (upholding revocation of practitioner's registration based on *nolo contendre* plea to three counts of unlawful distribution). Undoubtedly, each of these practitioners could have pointed to evidence of having treated a large number of patients in circumstances in which he did not divert controlled substances to drug abusers or drug dealers.

Consistent with these precedents, I held in *Krishna-Iyer* that "evidence that a practitioner has treated thousands of patients in circumstances which do not constitute diversion," and has even refused to prescribe to certain patients,[3] "does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest."[4] 74 FR at 463. I further held

[2] As I also explained in *Krishna-Iyer*, while Congress directed the Agency to consider all of the section 823(f) factors, I am entitled to give each factor the weight I deem appropriate and the courts of appeals have recognized that findings under a single factor are sufficient to support the revocation of a registration. 74 FR at 462 (citing *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–174 (DC Cir. 2005). As I further explained, ''this 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; what matters is the seriousness of the registrant's misconduct." *Id.* at 462.

[3] In *Krishna-Iyer*, I noted that the practitioner had discharged several patients. 74 FR at 462. However, I held that this evidence was not probative of the practitioner's intent in prescribing to the other patients who were focus of the proceeding. *Id.* & n.6.

[4] I do not adopt the ALJ's discussion of the standards applied by the Agency in assessing a practitioner's experience in dispensing controlled substances, which cites primarily to cases involving list chemical I distributors, a different category of registrant. *See* ALJ Dec. at 25–26. As one example as to why, DEA routinely issues registrations to newly-licensed practitioners even though they cannot point to any experience in dispensing controlled substances (provided they have not previously violated controlled substance laws.). Conversely, DEA has never held that a practitioner's lengthy experience in dispensing controlled substances without diverting precludes a finding (where supported by substantial evidence showing that he did divert) that a practitioner has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4).

In any event, as discussed above, Respondent offered no evidence on the issue of his experience in dispensing controlled substances and the ALJ's ultimate conclusion that Respondent violated the CSA's prescription requirement because he dispensed controlled substance prescriptions that were not "within" 'usual course of [his] professional practice,'' ALJ at 41 (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 *actuallys constituted* a threat to public safety." ALJ at 41 (emphasis added and citation omitted.) 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

that while such evidence may be entitled to some weight in assessing "whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, such evidence is entitled to no weight." *Id.*

Respondent's exception is neither factually nor legally well taken. Contrary to his assertion that his hands were "tie[d] behind his back" and that he was "effectively cripple[ed]" from "present[ing] any evidence of" what he terms "his positive * * * experience,"[5] Respondent could have testified about his dispensing practices and addressed those instances in which he refused to prescribe controlled substances; his decision to not put on evidence on this issue was not a matter "of impossibility," but of "choice." Resp. Exc. at 1.

Most significantly, Respondent could have testified regarding his prescribing practices with respect to the patients whose files were reviewed by the Government's Expert and which formed the basis for the latter's (and the ALJ's) conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to them. *See* ALJ Dec. at 41 (citing 21 CFR 1306.04(a)). Alternatively, he could have retained his own expert to review the files and called the expert to testify. Notably, Respondent makes no claim that the files, which were reviewed by the Government's Expert, were not timely provided to him.[6]

Respondent also takes exception to the ALJ's finding that he was not prejudiced by the Government's failure to turn over "the discharged patient files," as well as evidence pertaining to a second undercover officer to whom he refused to prescribe. Resp. Exc. at 2. Respondent asserts that his right to Due Process was violated because this evidence "could have exonerated" him, "or at the very least, given him an opportunity to meaningfully defend against the Government's allegations," and that prejudice "must [be] assume[d] * * * because neither he nor the Court were ever given access to it." *Id.*

As an initial matter, while there is evidence that Respondent refused to prescribe to a second undercover officer, there is no evidence establishing that there were, in fact, "discharged patient files." Respondent neither testified, nor offered any other evidence such as an affidavit establishing, that such files exist. Most significantly, in his Exceptions, Respondent does not cite any authority for the proposition that the Agency is required to provide broad discovery in a proceeding under sections 303 and 304 of the CSA. *See generally* Resp. Exc. Indeed, Respondent's contention far exceeds what the Supreme Court has held that an agency must do to comply with the Due Process Clause. *See, e.g., Goldberg* v. *Kelly,* 397 U.S. 254, 270 (1970).

In *Goldberg,* the Supreme Court held that "'where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, *the evidence used to prove the Government's case* must be disclosed to the individual so that he has an opportunity to show that it is untrue.'" 397 U.S. at 270 (quoting *Greene* v. *McElroy,* 360 U.S. 474, 496 (1959) (emphasis added)). The Court has further explained that "[a] party is entitled * * * to know the issues on which [the] decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it. Indeed, the Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation." *Bowman Transp., Inc.,* v. *Arkansas-Best Freight System, Inc.,* 419 U.S. 281, 288 n.4 (1974).

It is well settled, however, that neither the Due Process Clause, nor the Administrative Procedure Act (nor DEA's rules of procedure) require the Agency to provide a general right of discovery in administrative proceedings. *See Echostar Comm. Corp.* v. *FCC,* 292 F.3d 749, 756 (DC Cir. 2002); *Mister Discount Stockbrokers, Inc.,* v. *SEC,* 768 F.2d 875, 878 (7th Cir. 1985); *Nicholas A. Sychak, d/b/a/ Medicap Pharmacy,* 65 FR 75959, 75961 (2000). While "discovery must be granted if in the particular situation a refusal to do so would so prejudice a party as to deny him due process," *McClelland* v. *Andrus,* 606 F.2d 1278, 1285–86 (DC Cir. 1979), the party seeking discovery must rely on more than speculation and must show that the evidence is relevant, material, and that the denial of access to the documents is prejudicial. *See Echostar,* 292 F.3d at 756; *Silverman* v. *CFTC,* 549 F.2d 28, 34 (7th Cir. 1977).

In this case, the ALJ based his conclusion that Respondent issued numerous prescriptions outside of the usual course of professional practice in violation of both Federal and State laws and thus had committed acts which render his registration inconsistent with the public interest, *see* ALJ Dec. at 39–42, on the Expert's testimony and report regarding the various patients files the latter reviewed, each of which was provided to Respondent. Accordingly, the evidence which was the basis of the decision was disclosed to him, and contrary to his contention, *see* Resp. Exc. at 2, Respondent had a meaningful "opportunity to show that it is untrue."[7] *Goldberg,* 397 U.S. at 270. Respondent offers no explanation as to why other patient files would have "exonerated" him from the allegations that his prescriptions to the patients, whose files were reviewed by the Expert, were issued outside of the usual course of professional practice and lacked a legitimate medical purpose. Nor does Respondent offer any legal authority for his contention that prejudice—which he cannot show—

Respondent repeatedly ignored "red flags" indicative of likely diversion and thus "created a significant potential conduit for the unchecked diversion of controlled substances" is clearly support by substantial evidence and warrants an adverse finding under factor five. ALJ at 42.

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 37 (quoting 21 CFR 1306.04(a)). While the ALJ properly noted the importance of expert testimony in this case, in which the Government primarily relied on a review of the medical charts, whether expert testimony is needed is necessarily dependent on the nature of the allegations and the other evidence in the case. Where, for example, the Government produces evidence of undercover visits showing that a physician knowingly engaged in outright drug deals, expert testimony adds little to the proof necessary to establish a violation of Federal law.

[5] Nor is it clear what Respondent means by "positive experience." Resp. Exc. at 1. While at various points Respondent refers to files which he asserts show that he discharged patients, he then maintains that his lack of access to the files prevent him from presenting "any evidence of his positive, or successful, experience in dispensing and *treating patients* with controlled substances." *Id.* (emphasis added). He likewise contends that he was "unable to demonstrate his *successful treatment* of patients with controlled substances." *Id.* at 2 (emphasis added). However, it is not DEA's role to assess whether a practitioner has successfully treated patients, but rather, to determine whether a practitioner is either diverting drugs or engaging in practices (whether intentional or not) that create a substantial risk of diversion. *See Caragine,* 63 FR at 51601 ("Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation [or a registration] or denial" of an application).

[6] Indeed, it appears that the patient files (which the expert reviewed) were provided to Respondent nearly two months before the hearing.

[7] The Government also attempted to introduce evidence that Respondent prescribed to a member of a Boston-based drug trafficking organization, who had been arrested with 3,000 oxycodone tablets in his possession, and who stated that he did not have a legitimate medical need for the drugs he obtained from Respondent. Tr. 829–32. For the reasons stated in his decision, the ALJ properly gave this testimony no weight. *See* ALJ Dec. at 10 n.23.

must be assumed. *See Mister Discount Stockbrokers,* 768 F.2d at 878 (rejecting challenge to discovery procedures in administrative proceeding noting that party failed "to demonstrate *any* prejudice * * * let alone prejudice to a significant degree so as to result in a denial of due process").

There is likewise no merit to Respondent's contention that he was prejudiced by the Government's failure to turn over the patient file of the undercover officer to whom he refused to prescribe. A Special Agent testified that Respondent had refused to prescribe to a second undercover officer and the Government failed to put forward any evidence regarding the circumstances of this visit (such as what the officer said to Respondent). For this reason alone, it was proper for the ALJ to draw an inference adverse to the Government and conclude that Respondent properly complied with the rules of the Florida Board of Medicine in evaluating the undercover officer. *See* ALJ at 32 (citing *UAW* v. *NLRB,* 459 F.2d 1329, 1335–39 (D.C. Cir. 1972)).[8] However, as the ALJ held, that Respondent refused to prescribe controlled substances in this single instance does not refute the Government's *prima facie* showing that Respondent repeatedly violated the prescription requirement of Federal law as established by the Expert's review of eighteen patient files. *See id.* at 41 (quoting 21 CFR 1306.04(a)) ("after carefully balancing the admitted evidence, [and] even applying an adverse inference that permits the assumption that the Respondent was approached by an undercover agent and acted appropriately, the evidence establishes, by a preponderance, that the prescriptions the Respondent issued * * * were not issued within 'the usual course of [the Respondent's] professional practice' ").

As noted above, Respondent did not testify. Nor did he offer the testimony of an expert. Thus, Respondent did not refute the opinion testimony of the Government's Expert that he repeatedly violated the prescription requirement of Federal law. Because Respondent failed "to testify in response to [the] probative evidence offered against" him, I conclude (as did the ALJ) that it is appropriate to draw an adverse inference against him and hold that he knowingly issued prescriptions in violation of 21 CFR 1306.04(a). *Baxter* v. *Palmigiano,* 425 U.S. 308, 316 (1976); *see also The Lawsons, Inc.,* 72 FR 74334, 74339 (2007). Because Respondent failed to testify, I also conclude that he has not accepted responsibility for his misconduct nor demonstrated that he will not engage in future misconduct, and therefore, he has not rebutted the Government's *prima facie* showing that his continued registration is inconsistent with the public interest.[9] *See Medicine Shoppe-Jonesborough,* 73 FR at 387; *Samuel S. Jackson,* 72 FR 23848, 23853 (2007). I thus reject Respondent's Exceptions and adopt the ALJ's recommended Order.

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, FB0254918, issued to Beau Boshers, M.D., be, and it hereby is revoked. I further order that any pending application of Beau Boshers, 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
Jose M. Quinon, 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 FB02549187, of Beau Boshers, M.D. (Respondent), as a practitioner, pursuant to 21 U.S.C. 824(d), alleging that such registration constitutes an imminent danger to the public health and safety. The OSC/ISO also sought revocation of the Respondent's registration, pursuant to 21 U.S.C. 824(a)(4), and denial of any pending applications for renewal [10] or modification of such registration, pursuant to 21 U.S.C. 823(f), alleging that the Respondent's continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). On March 22, 2010, the Respondent timely requested a hearing, which, pursuant to a change of venue granted at his request, was conducted in Miami, Florida, on July 7, 2010 through July 9, 2010.[11] The immediate suspension of the Respondent's COR has remained in effect throughout these proceedings.

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

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

The Evidence

The OSC/ISO issued by the Government alleges that the Respondent, through the medical practice he participated in at American Pain, LLC (American Pain), prescribed and dispensed inordinate amounts of controlled substances, primarily oxycodone,[12] under circumstances where he knew, or should have known, that the prescriptions were not dispensed for a legitimate medical purpose. ALJ Ex. 1. The OSC/ISO further charges that these prescriptions were issued outside the usual course of professional practice based on a variety of circumstances [13] surrounding the manner in which American Pain is operated and the manner in which its physicians, including the Respondent, engaged in the practice of medicine. *Id.* The Respondent is also alleged, on several occasions, to have provided undercover law enforcement personnel with controlled substances, including, *inter alia,* oxycodone and

[8] The ALJ explained that drawing an adverse inference was "appropriate under the circumstances of this case where the evidence of the unsuccessful US was clearly within the Government's control and should, to maintain the integrity of the proceedings, have been disclosed if not produced." ALJ at 32. It is unclear whether the ALJ believed that disclosure of this evidence was required as a matter of Due Process as the ALJ did not cite any authority for his reasoning and numerous courts (as well as this Agency) have held that *Brady* v. *Maryland*, 373 U.S. 83 (1963), does not apply to administrative proceedings. *See Mister Discount Stockbrokers,* 768 F.2d at 878; *NLRB* v. *Nueva Engineering, Inc.,* 761 F.2d 961, 969 (4th Cir. 1985); *Nicholas A. Sychak*, 65 FR 75,959, 75960–61 (2000). Even if this evidence is of the type which a refusal to disclose "would so prejudice a party as to deny him due process," *McClelland* v. *Andrus*, 606 F.2d at 1286, the evidence was disclosed through the testimony of the Special Agent. Respondent thus cannot show prejudice.

[9] A registrant's obligation to accept responsibility and demonstrate that he will not engage in future misconduct applies even where the Government's evidence does not establish that a registrant has committed intentional acts. *See Krishna-Iyer*, 74 FR at 464 n.9; *Caragine*, 63 FR at 51601 (granting restricted registration where physician showed that he underwent remedial "training to become better educated in controlled substances and how to deal with drug-seeking patients"). Thus, even if I had concluded that the evidence did not establish that Respondent knowingly diverted controlled substances, I would still revoke his registration because he failed to rebut the Government's *prima facie* case.

[10] Although the Respondent's COR expired on July 31, 2010, the parties stipulated that a timely renewal application has been submitted by the Respondent. ALJ Ex. 40.

[11] 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.

[12] A schedule II controlled substance.

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

alprazolam,[14] after cursory or no medical examinations, and therefore without a legitimate medical purpose. *Id.* The Government's OSC/ISO also alleges that the Respondent's former patients 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.* Lastly, as an additional ground for the OSC/ISO, the Government cites the death of one of the Respondent's patients from an overdose of controlled substances one day after obtaining prescriptions for some of those same controlled substances during a visit to the Respondent at American Pain, and that the investigation determined the deceased patient and two companions obtained those substances "for other than a legitimate medical purpose with the intention of selling the controlled substances in Kentucky." *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.[15] *Id.* at 721. Under Langston's supervision, DEA diversion investigators catalogued the prescriptions seized at Boca Drugs (Boca Drugs Prescription Log). Govt. Ex. 118. 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, 166 controlled substance prescriptions issued over the Respondent's signature, to seventy-five patients, only six of whom resided in Florida. The remainder of the patients had listed addresses in Kentucky, Tennessee, Ohio, Georgia, Indiana, Alabama and West Virginia. The data in the log further reflected that the Respondent issued three prescriptions for non-controlled substances during that time period.

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

ATTENTION PATIENTS

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

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

ATTENTION

Patients

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

Id. The final attachment to the composite sign bears the words "24 Hour Camera Surveillance."

Id. A photograph of the composite sign was admitted into evidence.

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

GS Langston also testified that a great number of medical charts were seized from the American Pain offices, and that she and her staff selected a number of these files to be analyzed by an medical expert procured by the Government. Tr. at 762. According to GS Langston, after the execution of the warrant, the charts from the entire office were placed into piles in alphabetical order, and not separated by physician. Langston testified that she and three of her diversion 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.[18] *Id.* at 768.

Langston also explained DEA's Automated Record Consolidated Ordering System (ARCOS)[19] and testified that she generated an ARCOS report relative to the Respondent's ordering of controlled substances from January 2009 through February 2010. Govt. Ex. 23.

In the same fashion, Langston explained the purposes of and circumstances behind the generation of state prescription monitoring reports (PMPs) relative to the Respondent maintained by West Virginia, Kentucky and Ohio. Govt. Exs. 24–26. Review of the PMP report data reflects that during the time period of February 1, 2006 through February 11, 2010, pharmacies filled 259 controlled substance prescriptions issued over the Respondent's signature to sixty-eight patients located in West Virginia, 173 similar prescriptions provided to seventy-nine Kentucky-based patients were filled between January 1, 2009 and April 4, 2010, and ninety such prescriptions pertaining to sixty-one patients located in Ohio were filled between April 1, 2008 and April 19, 2010. *Id.*

No evidence was introduced at the hearing that would provide any reliable level of context regarding the raw data

[14] A schedule IC controlled substance.

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

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

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

[18] In his Discussion and Proposed Findings of Fact and Conclusions of Law (Respondent's Brief), the Respondent argues that the selection criteria employed by Langston deprived him of due process and somehow created an inaccurate portrayal of his practice. Respt's Br. at 4. However, the Respondent never explains the casual connection between the manner in which the files were selected, which was not based on any manner of targeting derogatory information regarding his patient care and why any due process right was compromised.

[19] 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.

set forth in the databases received into evidence at the Government's request. Other than the observations noted above, no witness who testified at the hearing ever explained the significance of the data set forth in any of these databases to any issue that must or should be considered in deciding the present case.

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 [20] 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 [21] 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) [22] 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" [23] for these office visits, and the six doctors at the clinic saw "anywhere from 200 upward to 375 patients a day" [24] in this manner.[25] *Id.* at 882–83 (emphasis supplied).

SA Burt also testified regarding his review of some [26] of the video and audio recordings made by an undercover agent (UC) who assumed the name Luis Lopez capturing activity inside of American Pain.[27] 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 Bart'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.

Although noticed in SA Burt's proposed testimony identified in the Government's prehearing statement, testimony regarding the specifics of the UC's visits to see the Respondent at American Pain was not elicited by the Government during its direct examination, but was brought out on cross-examination to meet the Government's admitted evidence consisting of a patient file kept by the Respondent relative to the UC and the accompanying expert report and testimony concerning that file provided by Dr. Kennedy. *Id.* at 985–86; Govt. Exs. 46 (Patient File for Luis Lopez), 131 (Supplemental Expert Report Regarding Undercover Patient Luis Lopez). Burt testified that he did not have the UC examined by a physician to determine his physical condition prior to going to the clinic, he did not ask him whether he had any prior back problems, and he did not ask him whether he had any past problems that caused a doctor to prescribe him controlled substances; instead, Burt relied solely on the UC's representations he was not currently in any pain before sending him into the clinic. Tr. at 987–89. According to Burt, the only instructions he provided to the

[20] SA Burt described the pole cameras as "covert cameras that are installed to observe the activity in the clinic." Tr. 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 recirded to DVR. *Id.* at 821.

[21] Tr. at 910.

[22] 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.

[23] Later on cross-examination, SA Burt admitted that the clinic also accepted payment via credit card. Tr. at 916. The parameters of what the witness meant by "predominantly" was not the subject of further explanation.

[24] 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.

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

[26] Tr. at 1002–05.

[27] 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.

UC were to be "very vague regarding the pain," to "point to a general area" when asked about it, and to provide a urine sample if so requested by clinic staff. *Id.* at 989–90, 1001. It was further established that an MRI was taken of the UC at Faye Imaging prior to his seeing the Respondent. *Id.* at 990–91. Burt related that the UC's first visit to the clinic was approximately an hour and fifteen minutes, and his visit with the Respondent was ten to thirteen minutes long. *Id.* at 998–99. Although these encounters between the UC and the Respondent were recorded either via audio or video, the Government did not offer the recordings as evidentiary exhibits at the hearing, and opposing counsel did not have access to them.[28]

More troubling by far is the revelation during SA Burt's cross examination that in addition to UC Luis Lopez, a second UC went into American Pain during July 2009 and recorded his encounters with the Respondent. Those encounters by the second UC did not culminate with the Respondent prescribing controlled substances.[29] *Id.* at 1027, 1029.

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

SA Burt also provided testimony concerning three confidential sources (only one of whom was seen by the Respondent) and their contacts with doctors at American Pain. Relative to the Respondent, the first confidential source (CS1) discussed by Burt was arrested in Washington, DC after transporting upwards of 3,000 oxycodone pills from south Florida to Massachusetts, and at the time of his arrest, Burt testified that an empty prescription pill bottle from American Pain with the Respondent's name on it was found on his person. *Id.* at 829. Burt relayed that at the time CS1 was searched, he had the 3,000 pills secreted in a jock strap strapped to the inside of his leg, and they were not in any type of bottle with the Respondent's name on it. The individual told Burt during a July 2009 interview[30] that he was a member of a Boston-based drug trafficking organization that would obtain oxycodone in southern Florida and transport it back to Boston for resale. *Id.* at 831. CS1 told Burt that he did not have a legitimate medical need for drugs when he saw the Respondent at American Pain, and that during his office visit, the doctor did not physically touch him, but did tell him to bend over and touch his toes. *Id.* at 832–33. The Government did not submit evidence of, or provide opposing counsel access to, a patient file reflecting CS1's visit to the Respondent, a copy of the prescription allegedly issued, or the empty pill bottle described.[31] Burt's testimony divulged the fact that CS1's cooperation with authorities was being provided in relation to his July 2009 arrest and that a record check revealed CS1 had arrests prior to that incident, though Burt was unable to recall information of any detail concerning the nature and disposition of those arrests. *Id.* at 1018–20. Burt declined to disclose the name of CS1 when queried on cross-examination.[32] *Id.* at 1017.

SA Burt also testified regarding the drug overdose deaths of TY and SM after obtaining controlled substances from American Pain.[33] Burt's record testimony indicates that DEA Task Force Officer[34] (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.[35] 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

[28] In fact, as addressed *infra*, SA Burt did not review the recordings or read the history and physical examination form contained in the UC's patient file with an eye towards determining if the audio corroborated the information on the forms. Furthermore, Burt admitted these recordings were not provided to Dr. Kennedy for his use in formulating his expert testimony and reports. Tr. at 1007.

[29] As discussed in more detail anon, this development was particularly troubling in light of the Respondent's prehearing motion practice where he sought the disclosure of precisely this variety of evidence.

[30] Tr. at 1012.

[31] SA Burt testified that he has never actually seen the described pill bottle. Tr. at 830. Burt also revealed on cross-examination that he has never reviewed a patient file relative to CS1, and that said patient file was not reviewed by a doctor to determine the propriety of the controlled substance prescriptions purportedly issued by the Respondent. *Id.* at 1015.

[32] 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 him, no weight can be assigned to SA Burt's testimony concerning information provided by CS1, other than the fact that it may have informed 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).

[33] 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.

[34] 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.

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

testimony as noticed in the Government's prehearing statement.[36] 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.[37] Dr. Kennedy was offered by the Government and accepted as an expert in the field of pain medicine. *Id.* at 39. 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. *Id.* at 176–77, 365. Dr. Kennedy stated that

> there was no true doctor/patient relationship established for the prescription of controlled substances at the first or any visit, and [] it was grossly deficient and medically dangerous to prescribe in the fashion it was prescribed for the same reasons.

Id. Furthermore, Dr. Kennedy testified that after reviewing the charts, he concluded that the prescribing of controlled substances by the Respondent to the patients named in the charts was not for a legitimate medical purpose. *Id.* at 182.

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 files 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, during his testimony, Dr. Kennedy acknowledged that some level of standardization and utilization of forms is not, standing alone, improper,[38] Dr. Kennedy took issue with what he perceived as flaws in the forms utilized by the Respondent to document patient care. Dr. Kennedy even acknowledged that the Respondent's possession and use of stamps to affix prescription descriptions and doses on scripts, was not, standing alone, improper. *Id.* at 178. However, according to Dr. Kennedy, the forms employed by the Respondent were "grossly deficient in that [they] didn't really justify why the individual was given the high doses of narcotics or controlled substances that they were." *Id.* at 177.

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

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

Id. at 357.

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 49. 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 49–50. In other words, the diagnostic plan allows the treating doctor to eliminate or confirm items on the differential diagnosis. *Id.* at 50–52.

Dr. Kennedy testified that in his expert opinion, the Respondent's histories and physical examinations were "grossly deficient in that [the documentation] didn't really justify why the [patient] was given the high doses of narcotics or controlled substance that they were." *Id.* at 177. Kennedy stated that, in his view, the treatment plans evident in the charts were also defective because there was no individualized consideration apparent, that "[e]verybody got essentially the same thing," and that the treatment plans for all patients were invariably limited to a single option, *i.e.,* "the treatment plan was to give controlled substances, and that was essentially it."[39] *Id.* at 78.

[36] ALJ Ex. 6.

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

[38] Tr. at 74.

[39] At the consolidated hearing in this matter, the Government elicited testimony from Dr. Kennedy regarding additional aspects of practice that he found deficient regarding the prescribing practices of other respondents. For example, Dr. Kennedy opined that the prescribing of 30 mg of oxycodone to an opioid naïve patient would, in his opinion, be dangerous and improper. Similarly, Dr. Kennedy provided his opinion that the practice of ordering of an MRI prior to a physician meeting with a patient would be improper. However, regarding the charts that Dr. Kennedy reviewed relative to this Respondent, the government adduced no testimonial evidence regarding issues such as opioid naïveté or the timing of MRI scripts, and it would be unfair, improper and illogical for an Administrative Law Judge to extrapolate the

Although Dr. Kennedy had earlier conceded that it is the judgment of the examining physician that is generally relied upon in determining the necessity and appropriateness of diagnostic testing,[40] he also testified that, at least in his view, exclusive reliance on MRI procedures as the sole diagnostic tool is suboptimal, because they are not always required and not always appropriate. *Id.* at 75–77, 165–66. Kennedy characterized MRIs as the Respondent's principal diagnostic tool. *Id.* at 177.

Dr. Kennedy prepared two reports in connection with the Government's case against the Respondent, both of which are dated April 30, 2010, and both of which were admitted into evidence during his testimony. Govt. Exs. 28, 131; Tr. at 174, 194. One of the reports describes a general analysis of seventeen charts that the Respondent maintained on as many patients, that were (selected by and) provided to Dr. Kennedy by the Government from among patient files seized pursuant to a criminal search warrant executed at the Respondent's practice on March 3, 2010 (Patient Charts Analysis).[41] Govt. Ex. 28. Although this report purports to describe practices common to all seventeen files reviewed by Dr. Kennedy, much of the analysis is directed toward a chart prepared in connection with RZ,[42] one of the Respondent's patients. A second report (Supplemental Chart Analysis) prepared by Dr. Kennedy focuses on the chart maintained under the name Luis Lopez, which was the assumed name of a law enforcement officer who visited the Respondent's practice in an undercover capacity. Govt. Ex. 131; Tr. at 188, 335.

Many of the observations and conclusions contained within the two reports are remarkably similar. Dr. Kennedy's report makes it unambiguously clear that, at least in his opinion, all eighteen of the Respondent's charts that he reviewed suffered from the same shortcomings. The Patient Charts Analysis states that the Respondent's patient charts that Dr. Kennedy reviewed "are essentially the same with regard to review issues; as stated in the report of [RZ] referenced and discussed in this report in detail, [and that] there were no significant differences that affected [his] conclusions and summary." Govt. Ex. 28 at 2. A like-worded proviso accompanies Dr. Kennedy's analysis of the chart prepared in connection with the undercover officer's (Luis Lopez's) interaction in the Supplemental Chart Analysis. Govt. Ex. 131 at 1.

In Dr. Kennedy's opinion, the patient charts he reviewed that were prepared by the Respondent reflected care that fell below the applicable standard on multiple levels. In his report, Dr. Kennedy noted that the treatment notes in the charts: (1) contained no typewritten clinical notes and were "very brief, difficult to read (often impossible) and not within the standard of care due to their brevity and quality";[43] (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;[44] (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;"[45] (4) contained medication contracts that were "not always signed" and "listed criteria that was not followed by the doctors at American Pain;[46] (5) failed to document the efficacy of the prescribed medication; (6) did not set forth a "diagnostic plan, except to obtain an occasional MRI, the results of which made no difference in the 'treatment'";[47] (7) reflected "no therapeutic plan, except to use controlled substances to 'treat' the subjective complaint of 'pain' which was inadequately described;[48] (8) did not reflect "real therapeutic goals * * * for improvement of quality of life (activities of daily living, work, sleep, mood)";[49] (9) did not reflect "consultations with other physicians or specialists outside the American Pain group [which] could have and in some cases should have included orthopedics, neurology, neurosurgery, psychiatry, addiction medicine and psychology";[50] (10) reflected "a gross lack of past medical records in all charts reviewed and in some cases none at all";[51] and, (11) demonstrated controlled substance patient monitoring practices that were "not within the standard of care and outside the boundaries of professional practice."[52]

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.[53] Govt. Ex. 28 at 14; Tr. at

testimony elicited relative to the patients of other physician(s) to this Respondent. *See Gregg & Son Distribs.,* 74 FR 17517 n.1 (2009) (data should be provided while record is open, and "[t]o make clear, 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") citing *Southwood Pharms., Inc.,* 72 FR 36487, 36503 n.25 (2007). The absence of testimonial support by Dr. Kennedy on these issues relative to this Respondent does not adversely affect the weight to be attached to the conclusions set forth in the reports he prepared in connection with this Respondent which were received into evidence. Govt. Exs. 28, 131.

[40] Tr. at 63.

[41] During the prehearing proceedings, the Respondent moved for an order compelling production of, *inter alia,* all patient files seized from his office by the Government. The request (which was opposed by the Government) was denied in a separate order as *ultra vires.* ALJ Ex. 20; s*ee Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75961 (2000); *Roy E. Berkowitz, M.D.,* 74 FR 3678, 36760 (2009).

[42] 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. 17.

[43] Govt. Ex. 28 at 4.

[44] In Dr. Kennedy's opinion, the Respondent "prescribed, at the first visit, very high initial doses of controlled substance combinations despite not being within the standard of care for histories, physical examinations and/or absent past medical records [with] no apparent consideration given to patient safety with initial or subsequent prescription of controlled substance[s]." Govt. Ex. 28 at 7.

[45] Govt. Ex. 28 at 4.

[46] 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. Govt. Ex. 28 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.*

[47] Govt. Ex. 28 at 7. In Dr. Kennedy's opinion, Respondent in effect, acted as a "barrier" for [RZ] to receive appropriate medical evaluation and treatment. In other words, the very potent, high doses of opioids (oxycodone) and benzodiazepine (Xanax) may have masked or cover[ed] up [RZ'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.

[48] Govt. Ex. 28 at 7.

[49] Govt. Ex. 28 at 8.

[50] Govt. Ex. 28 at 7.

[51] Govt. Ex. 28 at 15. RZ's chart did not contain a request for past medical records. *Id.* at 8.

[52] Govt. Ex. 28 at 14.

[53] However, when pressed on the issue, Dr. Kennedy declined to identify any specific instance

Continued

179–80. It was Dr. Kennedy's observation that even a drug screen anomaly did not alter the seemingly inexorable continuation of controlled substance prescribing from the Respondent. *Id.* Dr. Kennedy also noted that the Respondent did not utilize out-of-office toxicology tests, or obtain out-of-state prescription monitoring program or outside pharmacy drug profiles. Furthermore, the charts contained only rare evidence of contact with primary care physicians, treating physicians, pharmacists, or other health care providers. *Id.*

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. In addition to providing incomplete information on his patient questionnaires, the undercover officer (a/k/a Luis Lopez) admitted to the Respondent that he had previously purchased oxycodone on the street. Govt. Exs. 46 at 9, 131 at 3. Other red flags noted by Dr. Kennedy in the reviewed charts included the relatively young age (in Kennedy's view) of the Respondent's chronic pain patients,[54] incomplete history information provided by the patients, periodically significant gaps between office visits,[55] referrals from friends, relatives, or advertising, but not other physicians,[56] 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.[57]

At the hearing, Dr. Kennedy testified that the entries in some of the charts that reflected that the patients were acquiring controlled substances "off the street," and urine drug screen results that were inconsistent with patient disclosures, were red flags that should have motivated a prudent physician to perform additional due-diligence steps, that, in addition to discussing the matter with the patient, could include reaching out to family members, previous treating physicians and pharmacists, obtaining past medical records, and additional testing. Tr. at 359–60, 362. Dr. Kennedy testified that his evaluation revealed that these red flags were present in the charts and precipitated no due-diligence actions on the Respondent's part. *Id.* at 360–64, 368–69.

On the issue of red flags, WA's patient file contains the Respondent's handwritten notation indicating the patient acquired oxycodone and Xanax "off [the] streets," yet the Respondent authorized prescriptions for Roxicodone, Xanax, and Percocet to WA during his initial and subsequent visits. Govt. Ex. 29 at 11, 23–33. Like scenarios were also apparent in the charts of numerous other patients who had informed the Respondent that they had previously acquired such substances in this illegal manner, including the undercover law enforcement officer (Luis Lopez). *See* Govt. Exs. 30 at 7; 33 at 4; 34 at 5; 37 at 1; 39 at 4; 40 at 1; 46 at 9 (notations indicating patients acquiring controlled substances "off the street"). Another patient file contained a similar note that the patient had received oxycodone "from [a] friend." Govt. Ex. 44 at 13.

KA's patient file contains a form indicating a positive UDS for opiates and oxycodone from 7/9/09, yet on the same date, the patient comfort assessment guide and medication contract signed by KA are both blank in the section where a patient is supposed to list any medications he or she is currently taking. Govt. Ex. 30 at 14–15, 33; *see also* Govt. Exs. 33 at 8–9, 23; 43 at 10–11, 27 (similar issues). Patient JR's 5/27/[09] UDS indicates a negative test for all listed substances, yet on her signed medication contract from the same date, she indicates she is currently taking three substances which, though misspelled, appear to refer to oxycodone, Percocet, and Xanax, a discrepancy which raises questions about the validity of the testing procedures and/or the patient's candor. Govt. Ex. 35 at 12, 26. Patient AZ's [58] UDS form, on the other hand, lists positive test results for oxycodone and opiates only on 11/12/09, yet the patient claims on two different documents from the same date that, in addition to two different strengths of Roxicodone, she is also currently taking clonazepam, a benzodiazepine that should have triggered a positive reading for that substance on her drug screen.[59] Govt. Ex. 45 at 9–10, 24. A prescribed controlled substance that is not reflected in a drug screen should have raised a sufficient suspicion of diversion to merit further inquiry by the registrant reflected in the patient file. At a minimum, these observations support the conclusion there was a general lack of vigilance on the part of the Respondent regarding his obligations as a registrant to minimize the risk of controlled substance diversion.

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. 28 at 3–4, 16. Dr. Kennedy's report set forth his opinion that this practice was designed to "effectively keep [the physicians at American Pain] 'off the radar' from monitoring by any private health care insurance company as well as all state and federal agencies (Medicaid and Medicare respectively). Govt. Ex. 28 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.

Notwithstanding the discomfiture that Dr. Kennedy expressed regarding non-physician referrals in his report, during his testimony at the hearing he clarified that it was not unusual for a physician to treat patients that have been referred by relatives and friends. *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 record-evidence way to measure the relative percentage of physician referrals in the Respondent's practice based on this limited sample of charts, the observations regarding referral sources are of limited value here.[60]

A review of the 18 patient files that informed the analysis, findings and

regarding any of Respondent's charts where he would have ordered an additional drug screen. Tr. at 180.

[54] Govt. Ex. 28 at 15.

[55] Govt. Ex. 28 at 13.

[56] Govt. Ex. 28 at 8, 15.

[57] Govt. Ex. 28 at 16.

[58] Given the testimony of SA Burt regarding the level of activity outside American Pain parking area as observed through the pole cam, it is remarkable that one patient actually indicated that one of the reasons she left the previous pain clinic she frequented was because of "people hanging outside place approaching patients for their medications." Govt. Ex. 45 at 20.

[59] Although a mathematically conceivable explanation for this discrepancy could be that the patient exhausted her prescribed clonazepam stock sufficiently in advance of the 11/12/09 testing so as to not register a positive reading, the chart should have reflected that the physician recognized, addressed, and documented this red flag regarding a potential abuse or diversion issue.

[60] 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.

conclusions offered in Dr. Kennedy's written report and testimony does reflect the presence of at least some of the red flag issues he identified therein, but there was not the unanimity among the files that he repeatedly urges. A review of the files reveals other treatment modalities beyond the exclusive regimen of controlled substances reflected in the selected patient charts urged by Kennedy in his report.[61] Govt. Exs. 30 at 1; 34 at 1; 35 at 1; 36 at 7; 38 at 3; 43 at 2; 44 at 2; 36 at 6, 27.

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. 28 at 16.

On cross examination at the hearing, Dr. Kennedy's attention was directed to what would seem, at least to a lay person, to present as including a significant level of detail set forth in the charts he reviewed relative to the Respondent's patient documentation, including both subjective complaints of discomfort and objective signs of medical anomalies. Tr. at 214–27, 230, 233–38, 243–44, 246–56, 262–66, 269–70, 273–87, 289–98, 305–08, 311–18, 320–29, 332–47, 366. Even the file prepared in connection with the undercover officer's interaction with the Respondent reflects recorded subjective complaints coupled with a remarkable MRI and other objective signs indicating some medical pathology. *Id.* at 335–47. Undaunted, Dr. Kennedy (the sole expert to testify at the hearing), remained committed to his position that the manner in which the documentation was completed was fundamentally insufficient for a physician to adequately proceed to treat the patients with controlled substances. *Id.* at 226–29, 231–32, 238–41, 258, 262, 264, 267–68, 286, 290, 299–301, 309–11, 342–43, 366–67. Dr. Kennedy, more than once, succinctly stated that "[i]t's not even close." *Id.* at 268, 310.

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,[62] he was unable to identify the documentation standard in the Florida Administrative code with any degree of particularity, and he also acknowledged that he was not aware of what the standard is in Florida Medical Board administrative decisions regarding the overprescribing of medication or what constitutes an adequate medical history. *Id.* at 149–51, 233, 304. While, overall, Kennedy presented testimony that appeared candid and knowledgeable, there were areas in his written report that rang of hyperbole and over-embellishment. The reasoning behind some of the seemingly critical observations in the written report, such as the "cash basis" of the Respondent's practice and the absence of doctor referrals among the reviewed patient files, did not well survive the crucible of cross examination at the hearing. However, overall, Dr. Kennedy's testimony was sufficiently detailed, plausible, and internally consistent to be considered credible, and, consistent with his qualifications, he spoke persuasively and with authority on some relevant issues within his expertise, and notwithstanding the Respondent's objections relative to his Florida-related experience, he is currently an assistant professor teaching at a Florida Medical School. It may well be that the greatest and most significant aspect of Dr. Kennedy's opinion is that on the current record, it stands unrefuted. Thus, his opinion is the only expert opinion available for reliance in this action.[63] Consistent with his written report, Dr. Kennedy testified that from what he could glean in the charts he examined, the physical examinations were "grossly deficient in that [the physical examination] didn't really justify why the individual was given the high doses of narcotics or controlled substances that they were," that MRIs were the primary diagnostic tools and they should not have been, that the treatment plans were improperly "rubber stamped" with few modifications, and "there was no true doctor/patient relationship established for the prescription of controlled substances at the first of any visit, and that it was grossly deficient and medically dangerous to prescribe in the fashion it was prescribed for the same reasons." *Id.* at 177–79. 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[64] 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.

[61] 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.

[62] Tr. at 628.

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

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

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

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Deputy Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945 (1988); *England Pharmacy,* 52 FR 1674 (1987); *see also David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993); *Joy's Ideas,* 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16422 (1989). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors * * * " *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). The Deputy Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * * " *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

In an action to revoke a registrant's DEA COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e). Once DEA has made its *prima facie* case for revocation of the registrant's DEA Certificate of Registration, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall,* 412 F.3d at 174; *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72, 311 (1980). Further, "to rebut the Government's *prima facie* case, [the Respondent] is required not only to 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 can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 FR 10077 (2009); *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, that are attendant upon the lack of registration are not a relevant consideration. *Abbadessa,* 74 FR at 10078; *see also Gregory D. Owens, D.D.S.,* 74 FR 36751, 36757 (2009).

The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *George C. Aycock, M.D.,* 74 FR 17529, 17543 (2009); *Abbadessa,* 74 FR at 10078; *Krishna-Iyer,* 74 FR at 463; *Medicine Shoppe,* 73 FR at 387.

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

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm. Co., Inc.,* 411 U.S. 182, 188 (1973)), *cert. denied,* __ U.S. __, 129 S.Ct. 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Deputy Administrator's decision, *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Deputy Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

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

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by any cognizant state licensing board or professional disciplinary authority. However, that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer,* 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie,* 68 FR at 15230; *John H. Kennedy, M.D.,* 71 FR 35705, 35708 (2006). Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to

determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 FR 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008), *cert. denied,* __U.S.__, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not state officials. *Stodola,* 74 FR at 20375. Thus, on these facts, the fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.

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

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

In this case, the gravamen of the allegations in the OSC, 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, notwithstanding the Respondent's *Krishna-Iyer*-based [65] protestation in his brief that he has been somehow denied the ability to present "positive experience in dispensing controlled substances,"[66] 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. The Government, on the other hand did elect to present evidence on the subject.

Regarding the Government's presentation, Agency precedent has long held that in DEA administrative proceedings that "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.,* 74 FR 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.,* 61 FR 728, 730 (1996); *see also Roy E. Berkowitz, M.D.,* 74 FR 36758, 36759–60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). That being said, however, the marked difference between the amount of evidence that the Government noticed in its OSC/ISO and the amount that it ultimately 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," 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;

[65] The Respondent cites the Agency's decision in *Krishna-Iyer,* 74 FR at 459–01 and the unpublished 11th Circuit remand related to that case. *Krishna-Iyer* v. *DEA,* No. 06–15034 (11th Cir. 2007), Slip Op. at 3.

[66] Respt's Br. at 3.

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] [t]here are signs within American Pain warning individuals not to have their prescriptions filed at Walgreens pharmacies [is] because Walgreens refuses to dispense the prescriptions;

Walgreens has flagged all American Pain doctors and will not fill any of their prescriptions;

[Physical exams at American Pain are] usually no more than a blood pressure check and some bending and stretching;

Dismissed patients would be routed to other doctors within the clinic;

[There was] co-mingling of [American Pain] physician's drugs;

[American Pain maintained] no inventories of drugs dispensed;

[Details surrounding] the death of [American Pain] patient OB [where] [t]he cause of death was determined to be drug intoxication—opiate and benzodiazepine;

[Information] from a confidential source [who indicated] that she traveled to American Pain in order to obtain controlled substances that were later sold in Kentucky for $25 per pill[,] [that] [the American Pain physician she encountered] did not spend any significant time conducting a physical examination of [her] [,] [that she would simply ask questions regarding [her] well being and would then "stamp" a prescription for [controlled substances][,] * * * that on one visit [during a power failure a] security guard working for the clinic instructed everyone to be patient and that the doctors would be with them shortly to "get your fix."

ALJ Ex. 6 at 3–9.

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

The evidence the Government did present raises issues regarding not only Factor 2 (experience dispensing[67] 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 5th largest practitioner purchaser of oxycodone in the United States."[68] No evidence to support that allegation (or its relevance) was ever brought forth at the hearing. To the extent that fact may have been true or relevant, it was never developed. What's more, the Florida Administrative Code specifically eschews pain medication prescribing analysis rooted only in evaluation of medication quantity. Fla. Admin. Code r. 64B8–9.013(g). Lastly, there was no indication that despite Langston's obvious qualifications to do so, that she or anyone else ever conducted an audit of the controlled-substance-inventory-related recordkeeping practices at American Pain.

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

Likewise, without additional details or at least some context, Burt's testimony that individuals with "staff" written on their shirts appeared to be directing patients into the clinic reveals virtually nothing about the Respondent's prescribing practices. Tr. 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,[69] or advising them to comply with vehicle and traffic laws,[70] does not shed illumination on the Respondent's prescribing practices. There was neither evidence that the Respondent knew that these isolated incidents occurred, nor was there contextual evidence from which the relevance to these proceedings could be gleaned. Even if this tribunal was inclined to engage in the unsupported assignment of motives to the actions of these employees, under these circumstances, such an exercise could not constitute substantial evidence that could be sustained at any level of appeal.

Burt's testimony regarding his conversations with Dr. Sollie, who was formerly employed by American Pain, was also not received in a manner that could meaningfully assist in the

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

[68] ALJ Ex. 6 at 11–12.

[69] Tr. at 825.

[70] Tr. at 826.

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,[71] and that some patients were intentionally evading the American Pain urinalysis process. Sollie 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 evidence connected with Burt's testimony concerning the undercover operations focused on the Respondent unfolded in a somewhat disquieting manner when viewed in context with the prior motion practice in this case. As a preliminary matter, it must be acknowledged that Burt's testimony regarding the details of the Luis Lopez evolution, because it lacked detail, was of negligible import. Burt related that the UC told him that American Pain employees made statements and Burt viewed some statements on videotape, but there is no indication as to who the employees were, why Burt or the UC believed them to be employees, or what the basis for the directions to the patients were. For example, American Pain employees advising patients to avoid a particular pharmacy would doubtless have more relevance to these proceedings if the Government had presented any evidence that the pharmacy to be avoided (Walgreens) had some aversion to filling American Pain prescriptions. There was no such evidence. To the extent the Government was seeking to introduce the UC interaction evidence with a view toward reflecting on the Respondent's prescribing practices, evidence regarding the details of the interaction between the Respondent and the UC would seem to have been imperative.[72] This is particularly true here, where an MRI actually showed that the UC had a back impairment that could be treated by the use of the controlled substances prescribed by the Respondent. Thus, other than to provide contextual evidence concerning one of the patient charts reviewed by Dr. Kennedy, Burt's testimony regarding the UC interaction does not advance the Government's case for revocation.

Of somewhat more concern is the procedural context of the UC-related portions of the Government's case. During pre-hearing procedures, the Respondent sought discovery in the form of, *inter alia*, "[a]ll audio and video recordings pertaining to visits to American Pain during which the undercover officer was seen by [the Respondent]." ALJ Ex. 18 at 1. The Government correctly pointed out that, under the Administrative Procedure Act (APA) and Agency precedent, a discovery order is beyond the authority of this tribunal, but went on to argue that under Agency precedent "the only formal discovery required in DEA hearings is the exchange of documents and summarized testimony,"[73] and that the

"Respondent in this matter will be provided the documents and testimony to be used against him, and will be permitted to confront and cross examine witnesses and evidence presented by the Government at hearing."

Id. at 3. In a separate order (Discovery Denial Order),[74] the discovery request was denied as *ultra vires,* and the Respondent's attention was invited to explore other available procedural mechanisms, such as specific subpoena requests (none were submitted), applications to the United States District Court under Fed. R. Crim. P. 41(g), and, if warranted, the pursuit of the application of an evidentiary adverse inference before this tribunal. The Discovery Denial Order contained the following language:

"While discovery beyond the regulations is not a viable option available to the parties in this action, the position taken by the Government, if taken to its natural analytical conclusion, would allow it to intentionally seize exculpatory evidence, render it unavailable, and prevail in an administrative enforcement action that requires a due process hearing [with a footnote that added that] [t]here is no indication that such a scenario has taken place or would take place here. [The Order went on to state that] [w]hile the analytical simplicity of the Government's position is facially appealing, it is unlikely that Congress, in enacting the APA and the Controlled Substances Act, intended such a result."

ALJ Ex. 20 at 7. Ironically, the precise scenario that this tribunal expressed confidence would not likely occur, is exactly the scenario that unfolded at the hearing. The Government seized the Respondent's patient charts and proceeded under a theory that the Respondent inexorably prescribed controlled substances to essentially anyone posing as a patient who made a request. Through an agent who was ill-equipped to provide interaction details, the Government presented testimony that a UC who (at least by its theory) was not a legitimate candidate for a controlled substance prescription, received one from the registrant. It was only through the cross-examination performed by a co-Respondent's counsel present at the consolidated hearing that it was revealed that another UC who attempted to procure controlled substances from this Respondent was refused. The Respondent (and this tribunal) have never been apprised of the details of the interaction or been given access to the patient chart regarding the rebuffed UC.

In *International Union (UAW)* v. *NLRB,*[75] the United States Court of Appeals for the District of Columbia Circuit held that the National Labor Relations Board committed reversible error by declining to apply the "adverse inference rule" where one of the parties had "relevant evidence within his control which he fail[ed] to produce."[76] This precedent was embraced by the Eleventh Circuit in *Callahan* v. *Schultz,* 783 F.2d 1543, 1545 (11th Cir. 1986). The judicious utilization of the adverse inference rule allows an administrative tribunal to use the tools available to it and "permits vindication of the tribunal's authority in situations where vindication might, as a practical matter, be impossible otherwise." *Int'l Union,* 459 F.2d at 1339. Such an inference is appropriate under the circumstances of this case where the evidence of the unsuccessful UC was clearly within the Government's control and should, to maintain the integrity of the proceedings, have been disclosed if not produced. Accordingly, an adverse interference will be applied here to the extent that is will be assumed in this recommended decision that, regarding the unsuccessful UC, his encounter with the Respondent reflected a correct and professional interaction memorialized by documentation that met with the standards set by the Florida Medical Board. Thus, the evidence regarding this unsuccessful UC, even if it had been provided to the Respondent, could have

[71] Tr. at 898.

[72] In fact, the Government actually interposed an objection that exploration of this issue was beyond the scope of the direct examination. Tr. at 986.

[73] ALJ Ex. 19 at 6.

[74] ALJ Ex. 20.

[75] 459 F.2d 1329, 1336 (D.C. Cir. 1972).

[76] The applicability of the adverse inference rule is not dependent upon the issuance of a subpoena seeking to compel production. *Int'l Union* v. *NLRB,* 459 F.2d at 1338.

logically established no greater benefit to his litigation position.

Furthermore, in this case, because SA Burt's testimony regarding the UC's interaction with the Respondent has been afforded no weight, the non-availability of the details regarding the unsuccessful UC has resulted in no adverse impact regarding the Respondent's case. This is ever so much more true where an adverse inference has resulted in the assumption that the only such credited interaction in the record was in all ways appropriate. Put another way, the Government's attempt to show that the Respondent's interaction with the successful UC demonstrated his proclivity to dole out controlled substances for insufficient reasons was not persuasive.[77] However, if the testimonial vessel had delivered the testimony in a more effective fashion and the testimony regarding the successful UC had been credited, it seems that there was at least the potential for a significant compromise to the fairness of the adjudication. To the extent that a strained interpretation of the APA and existing DEA regulations have empowered the Government in espousing the position that it should rightfully be permitted to seize all potential evidence and dole back only those portions that adversely implicate the Respondent, that course is likely to result in precedent on judicial review that could impose unintended appellate consequences that could (and perhaps should) severely curtail its options in future enforcement actions. The point raised in the Respondent's brief that "[t]he Due Process Clause forbids an agency from using evidence in a way that forecloses an opportunity for a party to offer a contrary presentation," Respt's Br. at 3 (citing *Volkman* v. *DEA,* 567 F.3d 215, 220 (6th Cir. 2009), is well taken. The APA guarantees that "[a] party is entitled to present his case or defense." 5 U.S.C. 556(d). Irrespective of the number of assurances provided by the Government that a respondent will be afforded all the rights to which he is entitled, the practice of seizing all evidence from a Respondent, presenting a selective compilation of that which tends to disparage his case, while denying access to information from which he could meaningfully defend against the allegations, does not have a strong likelihood of ratification on appeal. More importantly, when brought to its logical end, it could tend to undermine the integrity of the adjudication in the eyes of the public. That no cognizable prejudice was realized to this Respondent's ability to present his case here does not enhance the wisdom of the procedural course embarked upon. That being said, no prejudice resulted to the Respondent here.

The Government's evidence at the hearing targeted not only the Respondent's experience practicing under Factor 2, but also his compliance with applicable state and federal laws relating to controlled substances under Factor 4. To effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). Consistent with the maintenance of that closed regulatory system, subject to limited exceptions not relevant here, a controlled substance may only be dispensed upon a prescription issued by a practitioner, and such a prescription is unlawful unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 U.S.C. 829; 21 CFR 1306.04(a). Furthermore, "an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly * * * issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances." *Id.*

A registered practitioner is authorized to dispense,[78] which the CSA defines as "to deliver a controlled substance to an ultimate user[79] * * * 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,* 567 F.3d at 223 (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

[77] As evidenced by the ultimate disposition of this recommended decision, other evidence of record relating to the chart analysis by Dr. Kennedy was more successful in this regard.

[78] 21 U.S.C. 823(f).

[79] "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).

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,[80] 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,[81] provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances. Fla. Stat. § 458.326 (2009). Moreover, the Florida Board has adopted,[82] 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," [83] 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

[80] 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).

[81] 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).

[82] 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).

[83] 21 CFR 306.04(a).

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

Id. at 9.013(3)(a).

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

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

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

Id. at 9.003(3)(c).

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

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

Id.

Under the subheading "Consultation," the Florida Board promulgated the instruction that

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

Id. at 9.003(3)(e).

It is abundantly clear from the plain language of the Florida Standards that the Florida Board places critical emphasis on physician implementation of adequate safeguards in their practice to minimize diversion and the need to document the objective signs and rationale employed in the course of pain treatment utilizing the prescription of controlled substances. Conscientious documentation is repeatedly emphasized as not just a ministerial act, but a key treatment tool and a vital indicator to evaluate whether the 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).

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

[84] 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.

(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, even applying an adverse inference that permits the assumption that the Respondent was approached by an undercover agent and acted appropriately, the evidence establishes, by a preponderance, that the prescriptions the Respondent issued in Florida were not issued within "the usual course of [the Respondent's] professional practice." 21 CFR 1306.04(a). Consideration of the evidence under the second and fourth factors support the COR revocation sought by the Government in this case.

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

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

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

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

Recommendation

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

Dated: August 10, 2010.

John J. Mulrooney II,

U.S. Administrative Law Judge.

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