cease and desist orders against several respondents.

On November 1, 2012, the Commission instituted a proceeding for the enforcement of the Commission's remedial orders based on an enforcement complaint filed by Leviton. 77 FR 66080 (Nov. 1, 2012). The enforcement complaint alleged that respondents American Electric Depot Inc. (''AED''); Shanghai ELE Manufacturing Corp. (''Shanghai ELE''), and Shanghai Jia AO Electrical Co., Ltd. (''Shanghai Jia AO'') violated the general exclusion order. The enforcement complaint also alleged that other respondents violated cease and desist orders. On February 14, 2013, the presiding administrative law judge (''ALJ'') (Chief Judge Bullock) issued an initial determination finding AED, Shanghai ELE, and Shanghai Jia AO in default. All other respondents settled. On April 10, 2013, the Commission determined not to review the initial determination with respect to the defaulting respondents.

On April 16, 2013, complainant Leviton filed a motion requesting that the Commission issue (1) a cease and desist order against AED; and (2) seizure and forfeiture orders against ground fault circuit interrupters imported or sold by AED, Shanghai ELE, and Shanghai Jia AO. On April 26, 2013, the Commission investigative attorney (''IA'') filed a response supporting Leviton's motion. No respondent filed a response to Leviton's motion.

On May 22, 2013, the ALJ issued a recommended determination (''RD'') on remedy. The ALJ drew an inference from AED's refusal to participate in the enforcement proceeding that AED has commercially significant inventories of infringing articles. Accordingly, the ALJ recommended that the Commission issue a cease and desist order prohibiting AED from selling or distributing infringing articles in the United States. The ALJ declined to recommend seizure and forfeiture orders because he found Leviton failed to show evidence that infringing articles were previously denied entry, as required under Commission Rule 210.75(b)(6)(ii).

In connection with the final disposition of this enforcement proceeding, the Commission may issue or modify a cease and desist order and/or exclusion order in any manner necessary to prevent the unfair practices that were originally the basis for issuing the remedial orders in the original investigation. The Commission may also issue a seizure and forfeiture order upon satisfaction of the conditions in 19 CFR 210.75(b)(6).

Prior to effecting any remedy in this enforcement proceeding, the Commission must consider the effects of a potential remedy upon the public interest. The factors the Commission must consider include the effect that the remedy would have on (1) the public health and welfare; (2) competitive conditions in the U.S. economy; (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation; and (4) U.S. consumers.

Accordingly, the Commission is interested in receiving written submissions that address the public interest factors above and the form of remedy and bonding, if any, that should be ordered.

Written Submissions: Parties to the enforcement proceeding, interested government agencies, and any other interested members of the public are encouraged to file written submissions on the issues of remedy, bonding, and the public interest. Such submissions should address the ALJ's recommendation on remedy set forth in the RD. Complainant Leviton and the IA are also requested to submit proposed remedial orders for the Commission's consideration. Initial written submissions and proposed remedial orders must be filed no later than close of business on August 16, 2013. Reply submissions must be filed no later than the close of business on August 30, 2013. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–739 (Enforcement Proceeding)'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: July 31, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–18890 Filed 8–5–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–30]

Mireille Lalanne, M.D.; Denial of Application

On August 18, 2011, Chief Administrative Law Judge (ALJ) John J. Mulrooney, II, issued the attached decision, recommending that I deny the Respondent's application for a Certificate of Registration as a practitioner. Thereafter, the Government, but not Respondent, filed Exceptions to the decision.[1]

Having reviewed the entire record and the Government's Exceptions, I have decided to adopt the ALJ's recommended rulings, findings of fact, conclusions of law, and recommended order except as discussed below.[2] I will

[1] All citations to the ALJ's Decision are to the slip opinion as originally issued by him.

[2] I do not adopt the ALJ's discussion of Factor 2 (the applicant's experience in dispensing controlled substances) contained in the third paragraph of page 52 of his decision. Nor do I adopt the ALJ's reasoning that there is ''an arguable lack of at least readily- apparent ambiguity'' in the language of factor two. ALJ at 53 (citing *Chevron U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837 (1984)). In short, Congress only directed that the Agency ''consider'' evidence regarding an applicant's experience in dispensing controlled substances; nothing in the statute tells the Agency how much weight to give a practitioner's evidence of, in the ALJ's words, ''hav[ing] conducted a significant level of sustained activity within the scope of [her] registration for a sustained period.'' ALJ at 52.

As set forth in multiple cases, DEA can revoke based on a single act of intentional or knowing diversion, and an applicant's/registrant's evidence that she has otherwise complied with the CSA for a sustained period, does not, by itself, refute the Government's *prima facie* case. *See Dewey C. MacKay,* 75 FR 49956, 49977 (2010) (citing *Jayam*

therefore order that Respondent's application be denied.

The Government's Exception

The Government takes exception to the ALJ's conclusion that the unsworn hearsay statement of TG, purportedly one of Respondent's former patients, was entitled to no weight, because the Government did not establish that the statements contained therein are sufficiently reliable to constitute substantial evidence of a material fact.[3] Exceptions at 1 (citing ALJ at 7–9). Specifically, the Government elicited the testimony of a former Assistant Commonwealth's Attorney (hereinafter, prosecutor) regarding his interview of TG to show that Respondent had doubled TG's dose of Xanax for no medical reason. Exceptions at 2. Significantly, TG's unsworn statement comprised the entirety of the Government's proof of the allegation.

In declining to give weight to TG's statement, the ALJ applied the four factors for assessing the reliability of hearsay evidence set forth in *J.A. M. Builders, Inc.,* v. *Herman,* 233 F.3d 1350 (11th Cir. 2000). More specifically, the ALJ explained that:

> No foundation was laid by the Government regarding the absence of bias from . . . TG. The information provided in the interview[] could not be tested for consistency because such testimony was not corroborated by other evidence of record. Furthermore, there is no case law or other authority recognizing this variety of evidence as inherently reliable. Simply put, the Government, as a proponent of the evidence, did not lay a foundation sufficient to permit consideration of [TG's] interview[] to support [a finding that it constitutes] substantial evidence . . . .

ALJ at 8.

Notably, the Government does not take issue with the ALJ's reliance on *J.A. M. Builders,* even though that case is not binding on the Agency outside of a matter which falls within the jurisdiction of the Eleventh Circuit.[4] Instead, the Government argues that the ALJ improperly ''placed the burden on the Government to prove a stream of negatives as a prerequisite to giving the testimony any weight.'' Exceptions at 3.[5]

Regarding the first *J.A. M. Builders* factor—the issue of TG's potential bias—the Government argues that the former prosecutor testified about his interview and ''based on the testimony and cross-examination, no bias or inconsistencies were detected on TG's part.'' Exceptions at 4. As to the second factor—whether the statement was made known to Respondent prior to the hearing and whether the declarant could have been subpoenaed—the Government argues that TG's name and the details of his interview were ''disclosed to Respondent prior to the hearing, but Respondent declined to have [him] subpoenaed or take any steps to determine the veracity of [his] statement.'' *Id.* With respect to the third factor—whether the information was inconsistent on its face—the Government argues that ''there was nothing inconsistent on its face'' in the testimony of the former prosecutor regarding the interview, and that the ALJ improperly relied on inconsistencies in a transcript of the interview which the Government did not offer into evidence. *Id.*

Finally, addressing the fourth factor—whether the information has been recognized by the courts as inherently reliable—the Government contends that ''the truth of the facts alleged by TG could have been corroborated (or refuted) by an examination of TG's medical record,'' and that ''[p]resuming that Respondent made medical notes reflecting changes in TG's condition, she would have had access to the type of evidence needed to verify TG's statement that he received an amount of Xanax in excess of what was medically necessary.'' *Id.*[6] Thus, the Government contends that TG's statement ''was not unlike hearsay testimony from a laboratory report or laboratory technician which has been found to be inherently reliable because it can be verified with other scientific data, *i.e.,* TG's medical file.'' *Id.* at 4–5 (citing *United States* v. *Minnitt,* 617 F. 3d 327, 334–35 (5th Cir. 2010)).

Notwithstanding that the ALJ should have looked to the case law of the Sixth and DC Circuits in determining whether TG's statement constituted substantial evidence of the material fact for which it was offered, the Government's exception is still not well taken. As for its contention that the ALJ improperly ''placed the burden on the Government to prove a stream of negatives as a prerequisite to giving the testimony any weight,'' Exceptions at 3, apparently, in the Government's view, the mere admission of the evidence was sufficient to place on Respondent the burden of showing that the statement is not reliable.

The Government cites no authority for its position. Moreover, while it may be that the burden of producing evidence showing that some of the factors which counsel against giving weight to a hearsay statement is properly placed on the party against whom the statement is offered, the Government acknowledges no obligation to establish even a threshold level of reliability.[7] However, under the Administrative Procedure Act, ''the proponent of a rule or order has the burden of proof,'' 5 U.S.C. 556(d), and given the manner in which courts generally treat the admission of hearsay, it seems most unlikely that any

Krishna-Iyer, 74 FR 459,463 (2009)), *pet. for rev.* ≤ *denied* 664 F.3d 808 (10th Cir. 2011). Indeed, in *MacKay,* the Tenth Circuit expressly rejected the contention that a practitioner's so-called ''positive experience'' negates a *prima facie* showing of intentional diversion. *See* 664 F.3d at 819 (''Although Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to [two patients] is sufficient to support her determination that his continued registration is inconsistent with the public interest.''). So too, where, as here, the evidence supports a finding that an applicant/registrant acted with deliberate ignorance in prescribing controlled substances. As the ALJ correctly noted, in such cases, ''Agency precedent has firmly placed acknowledgment of [wrongdoing] and acceptance of responsibility as conditions precedent to merit the granting or continuation'' of a registration. ALJ at 44 (citing cases).

This is not to say that such evidence is never entitled to weight. Such evidence may persuade the Agency that an applicant/registrant has offered credible testimony that she accepts responsibility and will not engage in future misconduct. So too, where the Government's proof does not establish egregious violations, such evidence is given due consideration in setting the appropriate sanction. *See Gregg & Sons, Distributors,* 74 FR 17517, 17524 (2009).

[3] The Government agrees with the ALJ's ultimate conclusion that Respondent '''has committed acts that render [her] registration inconsistent with the public interest''' and his recommendation that her application be denied. Exceptions at 1.

[4] It is noted that the Government does not cite to any case law of either the Sixth Circuit or DC Circuit, the two courts of appeals which would have jurisdiction were Respondent to file a petition for review.

[5] The Government notes that ''there was no objection to [the former prosecutor's] testimony regarding TG's out of court statement.'' Exceptions at 3 & n.1. While Respondent's failure to object '''is a waiver upon appeal of any ground of complaint against its admission,''' TG's statement became '''part of the evidence in the case, and is usable as proof to the extent of whatever rational persuasive power it may have.''' *Passaic Daily News* v. *NLRB,* 736 F.2d 1543, 1554 (DC Cir. 1984) (quoting C. McCormick, *Handbook of the Law of Evidence* 113 (2d ed. 1972)). However, because as explained in this decision, I agree with the ALJ that TG's statement lacks sufficient indicia of reliability, it has no rational persuasive power. Accordingly, Respondent's failure to object to the testimony is of no consequence.

[6] Contrary to the Government's statement, it is obvious that Respondent would have no interest in verifying TG's statements that he received Xanax in an amount that exceeded what was medical necessary.

[7] For example, had TG given his statement under oath or provided an affidavit, some threshold level of reliability would have been established. Under such circumstances, the Government might have a point in arguing that Respondent should then have to show that TG was not disinterested. However, unsworn statements are notoriously unreliable and the Government put forward no evidence of corroborating circumstances which would support the conclusion that the statement was trustworthy.

court of appeals would sustain the Government's view.

For example, under the Federal Rules of Evidence, the proponent offering a hearsay statement ''bears the burden of showing the requirements are satisfied.'' Christopher B. Mueller & Laird C. Kirkpatrick, *Federal Evidence* § 8:140, at 271 (3d ed. 2007). Analogous to the statement at issue here, a hearsay statement, which is not otherwise admissible under one of the various exceptions contained in Rules 803 and 804 of the Federal Rules of Evidence, may nonetheless be admissible if ''the statement has equivalent circumstantial guarantees of trustworthiness''; in other words, if it is deemed to be sufficiently reliable. F.R. Evid. R. 807. Yet the courts have uniformly held that the proponent of the statement has the burden of establishing that it is trustworthy and admissible. *See United States* v. *Kim,* 595 F.2d 755, 766 (DC Cir. 1979) (''the burden is on the proponent to produce evidence of trustworthiness''); *see also United States* v. *York,* 852 F.2d 221, 225 (7th Cir. 1988) (''The government argues that it was [the defendant] who failed to make the notes of the interviewers a part of the record. However, it was the government . . . which bore the burden of demonstrating that the testimony it offered was trustworthy and entitled to an exception under the rule against hearsay testimony.''); *See also NLRB* v. *United Sanitation Serv.,* 737 F.2d 936, 941 (11th Cir. 1984) (''the burden is on the party seeking to invoke the residual exception to clearly demonstrate the existence of the requisite guarantees of trustworthiness''); *United States* v. *Colson,* 662 F.2d 1389, 1392 (11th Cir. 1981) (''having offered the transcript [of an interview by police of a third-party] under the residual hearsay exception . . . [defendant] bore the burden of establishing, *inter alia,* the trustworthiness and probative value of the transcript, a burden he failed to maintain'').

To be sure, the Federal Rules of Evidence do not apply in this proceeding and '''[p]rovided it is relevant and material, hearsay is admissible in [an] administrative proceeding,''' and may '''under certain circumstances . . . constitute substantial evidence.' '' *Bobo* v. *United States,* 52 F.3d 1406, 1414 (6th Cir. 1995) (quoting *Hoska* v. *United States Dep't of the Army,* 677 F.2d 131, 138 (DC Cir. 1982)). However, establishing that evidence is admissible requires crossing a lower threshold (whether in an administrative or judicial proceeding) than does showing that the evidence is sufficiently reliable to constitute substantial evidence (or, in a judicial proceeding, to satisfy a party's burden of proof). As a leading authority states:

> Admissibility . . . is a quality standing between relevancy, or probative value, on the one hand, and proof, or weight of the evidence, on the other hand. . . . Yet it does not signify that the particular fact has demonstrated or proved the proposition to be proved, but merely that it is received by the tribunal for the purpose of being weighed with other evidence.

I *Wigmore on Evidence* § 12, at 689 (Tillers rev. ed. 1983). As Wigmore further explains, ''[a]dmissibility falls short of proof or demonstration.'' *Id.* at 692.

With respect to the use of hearsay in administrative proceedings, both the Sixth and DC Circuits have explained that '''hearsay may be substantial evidence depending on its truthfulness, reasonableness, and credibility; hearsay statements are highly probative where declarants are disinterested witnesses, statements are essentially consistent, and counsel had access to the statements prior to agency hearing.''' *Bobo,* 56 F.3d at 1414 (quoting *Hoska,* 677 F.3d at 138–39). Moreover, '''hearsay may constitute substantial evidence depending upon its probative value and reliability, considering *inter alia,* possible bias of the declarant, whether [the] statements are signed and sworn to, whether they are contradicted by direct testimony, whether the declarant is available, and whether the hearsay is corroborated.''' *Bobo,* 56 F.3d at 1414 (quoting *Hoska,* 677 F.3d at 139) (other citation omitted).[8]

As to the potential bias of TG, the Government has not established that he was a disinterested witness. As the record establishes, TG was questioned during a law enforcement investigation into drug trafficking syndicates that were traveling from Harlan County, Kentucky to Nashville, Tennessee to obtain controlled substances which were then sold in Harlan County, and it appears that he offered the specific statement at issue here when the prosecutor needed evidence to respond to a motion by Respondent to dismiss the state court indictment. No evidence was offered as to whether, at the time of the interview, TG had been offered immunity or remained under jeopardy of criminal prosecution. Indeed, the Government argues that ''TG freely implicated himself in a scheme to obtain controlled substances from Respondent's practice for illegal purposes.'' Exceptions at 5. However, having implicated himself in such activity, TG would have had ample motivation to curry favor for himself (such as a reduction in likely criminal charges) by telling the authorities what they wanted to hear. *See United States* v. *McCleskey,* 228 F.3d 640, 644 (6th Cir. 2000) (''[W]here, as here, it is the government which seeks to introduce a statement, otherwise hearsay, which inculpates its declarant but which, in its detail, also inculpates the defendant by spreading or shifting onto him some, much, or all of the blame, the out-of-court statement lacks such indicia of reliability. It is garden variety hearsay as to the defendant and it does not lose that character merely because it in addition reliably inculpates the declarant.'').

Moreover, TG's statement was unsworn. While an unsworn hearsay statement may, in some circumstances, still constitute substantial evidence, *see J.A.M. Builders,* 233 F.3d at 1353 & 1355, courts are frequently skeptical of such statements, especially where the declarant cannot be viewed as a disinterested observer and the proponent of the evidence fails to put forward any evidence corroborating the statement or demonstrating its reliability. *See Hoska,* 677 F.2d at 288.

Here, the Government did not introduce TG's medical chart, which might well have shown that Respondent had doubled the dose of Xanax without documenting any reason for doing so. Indeed, the Government did not introduce any evidence (other than TG's statement) to show that Respondent had even prescribed controlled substances to him, let alone that she had doubled TG's purported Xanax dose for no medical reason. Contrary to its understanding, the ALJ properly placed the burden on the Government to corroborate TG's statement and not on Respondent to refute it.[9]

[8] While the ALJ relied on *J.A.M. Builders,* the same outcome is reached under the decisions of the Sixth Circuit in *Bobo* and DC Circuit in *Hoska.* I address the Government's exception under both the *J.A.M. Builders* factors and the *Bobo/Hoska* factors.

[9] As for the Government's contention that TG's statement is ''not unlike hearsay testimony from a laboratory report or a laboratory technician, which has been found to be inherently reliable,'' Exceptions at 4–5 (citing *Minnitt,* 617 F.3d at 334–35, the Government ignores that the *Minnitt* court expressly stated that such reports '''are not so inherently reliable as to be automatically admissible.' '' *Id.* at 334 (quoting *United States* v. *McCormick,* 54 F.3d 214, 223–24 (5th Cir. 1995)). Indeed, in neither *Minnitt* nor *McCormick* did the Government simply introduce the report of the failed drug test and nothing more to establish that the evidence was reliable. *See id.* (discussing other evidence supporting a finding that the evidence was reliable including that result had been confirmed by two different labs); *see also McCormick,* 54 F.3d at 224 (noting that ''the government proffered significant evidence demonstrating that the information reported in . . . urinalysis report [wa]s extremely reliable''). In addition, the evidence at issue in *Minnitt* (and *McCormick*) involved an issue

Nor does the purported consistency of TG's statement give any reason to reject the ALJ's finding that TG's statement does not constitute substantial evidence. Absent the complete statement, and thus the ability to determine whether there were inconsistencies in the statement (or potential inconsistencies which were not explored by the former prosecutor), the absence of inconsistencies in the snippets which were related by the former prosecutor is of considerably less consequence in determining whether TG's statement was reliable.[10] *See U.S.* v. *York,* 852 F.2d at 225–26.

The Government further argues that TG's name and the details of the statement were provided to Respondent in advance of the hearing, and that Respondent could have, but did not, subpoena him. While it true that the Government disclosed TG's name and that it intended to elicit testimony of his statement regarding the increase in his Xanax prescription, *see* ALJ Ex. 6, at 17, as for whether TG was available as a witness, the record is completely barren.[11]

Finally, it is acknowledged that Respondent did not contradict TG's statement in her testimony.[12] Putting aside whether Respondent had any obligation to contradict an unsworn and uncorroborated hearsay statement, this factor provides some support for concluding that TG's statement was reliable. However, even when it is coupled with the other factors which support the Government's position, on balance, the Government has still failed to overcome the other factors (*i.e.,* lack of proof that TG was disinterested, the unsworn nature of the statement, and lack of any corroboration) which strongly counsel against the conclusion that TG's statement possesses sufficient indicia of reliability to be deemed substantial evidence. Accordingly, I reject the exception.[13]

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Mireille Lalanne, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective September 5, 2013.

Dated: July 30, 2013.

Michele M. Leonhart,

Administrator.

Frank Mann, Esq., for the Government
Paul J. Bruno, Esq., for the Respondent

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

John J. Mulrooney, II, Chief Administrative Law Judge. On January 14, 2010, Dr. Mireille Lalanne, M.D., (Respondent) filed an application with the Drug Enforcement Administration (DEA) for a practitioner Certificate of Registration (COR), Control No. W10001926C. Gov't Ex. 2. On February 10, 2011, the DEA Deputy Assistant Administrator issued an Order to Show Cause (OSC) proposing to deny the Respondent's COR application on the grounds that the granting of her request for a COR would be inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f) (2006 & Supp. III 2010). On March 11, 2011, the Respondent timely requested a hearing, which was conducted in Nashville, Tennessee from June 7 through June 9, 2011.

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

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 of law below.

The Allegations

The OSC issued by the Government alleges that granting the Respondent's pending COR application would be inconsistent with the public interest based on the facts which, in its view, were related and contributed to the February 26, 2009, voluntary surrender of the COR that she held previously. Specifically, the OSC alleges: (1) that the Respondent was indicted and arrested for various state criminal violations, including facilitating the activities of a criminal syndicate trafficking in controlled substances,[1] second degree assault,[2] and wanton endangerment; [3] (2) that, consistent with a plea deal, she was ultimately convicted in a Kentucky state court of facilitating the trafficking of a controlled substance in the first degree; [4] and (3) that on March 22, 2010, the Tennessee Board of Medical Examiners (Tennessee Medical Board) concluded that she had committed misconduct sufficient to provide grounds for discipline, to wit: unprofessional, dishonorable, or unethical conduct [5] and a state drug law conviction.[6] ALJ Ex. 1 at 2. The Government's OSC further alleges that granting the pending COR application would be improvident because the Respondent prescribed controlled substances ''without a legitimate medical purpose and/or outside the

of scientific fact; as such, the credibility of the declarant (*i.e.,* the lab technician), stands on a dramatically different footing than that of TG, who was implicated in criminal activity. Likewise, in contrast to TG's statement, which involved the relation of historical facts several years after the incident, a lab report is typically a contemporaneously prepared record of the results and thus a record of a regularly conducted activity, which is admissible in Federal Court as a hearsay exception under Rule 803, in part because the preparer of the report has a duty to accurately report the results. Finally, there is absolutely no support for the contention that the courts have found statements, such as that given by TG, to be inherently reliable.

[10] The Government notes that the ALJ relied on the transcript of the interview TG gave to a deputy sheriff, which was not entered into evidence and faults the ALJ for relying on this interview to conclude that TG's statement contained inconsistencies. According to the Government, ''[l]ooking at the testimony of [the former prosecutor] regarding his interview with TG, there was nothing inconsistent on its face and the alleged inconsistencies pointed out by the ALJ (from Government Exhibit 21) [, a non-admitted exhibit,] were neither inconsistencies nor part of the official administrative record.'' Exceptions at 4. Even if the ALJ erred in reviewing a non-admitted exhibit to determine whether TG's statement was consistent, given that the weight of the factors counsels against the statement being deemed reliable, I conclude that any error is not prejudicial. *Cf.* 5 U.S.C. 706 (''due account shall be taken of the rule of prejudicial error''); *cf. also* F.R. Evid. R. 104 (''In making its determination'' as to whether evidence is admissible, a court is ''not bound by the rules of evidence except those with respect to privileges.'').

[11] It is acknowledged that the Government disclosed TG's actual name in a legend which listed the names of various patients. See ALJ Ex. 7; Ex. 1, at 2. However, it did not disclose TG's address and no other information establishes if his whereabouts are known. *Cf.* F.R. Evid. R. 807 (requiring party offering statement to ''make[] known to the adverse party . . . the particular of [the statement], including the name and address of the declarant'').

[12] The Government did not address this factor.

[13] While the Government took exception to the ALJ's declination to give weight to TG's statement, it did ''not take exception to the ALJ's failure to give weight to the out-of-court statements'' of three other persons, AW, TE, and CM. Exceptions at 5 n.4. Significantly, the Government moved into evidence an affidavit provided by AW, as well as a transcription of an interview she gave to the former prosecutor. AW's out-of-court statements presented a considerably stronger case than that of TG as to whether they were sufficiently reliable so as to constitute substantial evidence. However, because the Government does not challenge the ALJ's findings with respect to AW, I do not address whether her statements constitute substantial evidence.

[1] Ky. Rev. Stat. Ann. § 506.120 (West 2009).

[2] *Id.* § 508.020.

[3] *Id.* § 508.060.

[4] *Id.* § 218A.1412.

[5] Tenn. Code Ann. § 63–6–214(b)(1) (LexisNexis 2009).

[6] *Id.* § 63–6–214(b)(10).

usual course of professional practice'' on numerous occasions, in the face of evidence where such prescribing was contraindicated or heightened diversion risks were present. *Id.*

The Stipulations of Fact

The Government and the Respondent, through counsel, have entered into stipulations regarding the following matters:

Stipulation A: The Respondent was previously registered with DEA as a practitioner in Schedules II–V under DEA registration number AL1720588 at Tennessee Professional Associates, 3507 Charlotte Avenue, Nashville, Tennessee 37209–3936.

Stipulation B: On November 10, 2008, the Respondent was indicted by a grand jury in Harlan County, Kentucky (Harlan County Grand Jury) on five felony counts, including: (1) engaging in organized crime by providing controlled substances to three different ''syndicates'' (Counts I–III); (2) second degree assault by providing controlled substances to a pregnant patient whose child's health was damaged by the drugs (Count IV); and (3) wanton endangerment of an unborn child by providing controlled substances to the mother (Count V).[7]

Stipulation C: On February 4, 2009, the Respondent was arrested and charged with prescribing large quantities of OxyContin and methadone to approximately 350 residents of Harlan County with the knowledge that the patients were distributing these drugs to others.[8]

Stipulation D: On February 26, 2009, the Respondent surrendered her DEA registration as a condition of being released on bond.

Stipulation E: On September 8, 2009, the Respondent was indicted by the Harlan County Grand Jury on a single count of wanton murder, a capital offense. The Grand Jury charged that Respondent caused the death of a woman by providing her with addictive and dangerous drugs with the knowledge that the woman was addicted to the drugs and at a very high risk of death by overdose.[9]

Stipulation F: On January 11, 2010, the Respondent entered an *Alford*[10] plea to a misdemeanor count of facilitation of trafficking in a controlled substance in the first degree (Schedule I or II) in satisfaction of the pending criminal charges. By entering an *Alford* plea, Respondent did not admit guilt but acknowledged that the evidence against her strongly indicated guilt and that her best interests were served by a guilty plea. As a result of the *Alford* plea, all remaining charges were dismissed.

Stipulation G: The Respondent was sentenced to four months of unsupervised probation and agreed not to prescribe controlled substances to any resident of Harlan County, Kentucky. Respondent also agreed to forfeit $500,000 in bond money, with half going to fund youth drug prevention.

Stipulation H: On January 14, 2010, the Respondent submitted an online application for registration, control number W10001926C.

Stipulation I: On January 29, 2010, the Tennessee Board of Medical Examiners summarily suspended the Respondent's medical license, No. 14207.

Stipulation J: By Final Order effective March 23, 2010, the Tennessee Medical Board reinstated the Respondent's medical license and placed her license on probation for five years and until Respondent completed several conditions specified in the Order. The specified probation conditions include: (1) undergoing an evaluation by the Center for Personalized Education; (2) completing a 2-day course on medical ethics and a 3-day course of medical recordkeeping; and (3) obtaining practice monitoring for five years.[11] During the practice monitoring, at least ten percent of all Respondent's patient medical files must be reviewed each month and Respondent must receive training in the treatment of chronic or intractable pain. The practice monitor must also provide the Medical Board with reports every three months that include Respondent's: (1) compliance with the practice monitor's recommendations; (2) completion of education programs; (3) prescribing practices; (4) medical recordkeeping; and (5) treatment of chronic or intractable pain.

Stipulation K: Missing pages from the medical chart of Patient RW[12] contained in Respondent's Exhibit 32 were not available to the Government's medical expert witness, through no fault of his own, at the time of his review of the medical file and preparation of his report.

Stipulation L: Respondent's Exhibit 2 reflects an interview conducted of Patient RF by Carl Christiansen, a private investigator employed by the Respondent. The interview was conducted on a date between February 2009 and January 2010. Neither party warrants the veracity of RF's statements.

[7] Early during prehearing proceedings, the Government indicated that it did not intend to prove up acts set forth in the indictments or arrest warrants beyond the acts that were the subject of the misdemeanor plea disposition. *See* Stipulation F. Thus, although these criminal charges are the subject of a stipulation, and the procedural posture of the criminal case factored into the circumstances surrounding the Respondent's COR surrender, *see* Stipulation D, the underlying criminal allegations have played no role in this recommended decision and must play no role in the ultimate disposition of the pending application. *See Paul Weir Battershell, N.P.,* 76 Fed. Reg. 44359, 44364 n.17 (2011) (concluding that an indictment is an instrument containing accusations, not proof of the Respondent's actions).

[8] *See supra* note 7.

[9] *See supra* note 7.

[10] *See North Carolina v. Alford,* 400 U.S. 25 (1970).

[11] During the April 12, 2011 Prehearing Conference, the Respondent, through counsel, represented that because she has not been practicing medicine since the conviction, she has not been monitored.

[12] Pursuant to a Protective Order issued in this case on March 21, 2011, initials have been substituted for the names of patients. ALJ Ex. 9.

The Evidence

At the hearing conducted in this matter, the Government presented the testimony of: (1) a former state prosecutor and local police officer familiar with the criminal cases that comprise the genesis of the administrative investigation of the COR application that the Respondent filed in this case; (2) two diversion investigators relative to the investigation of the pending application; and (3) and an expert witness who reviewed selected patient charts from the Respondent's practice and provided expert opinions regarding the Respondent's prescribing practices.

In addition to presenting her case through her own testimony, the Respondent called her own expert witness.

The Kentucky Criminal Investigation and Conviction

The Government presented the testimony of Deputy John Teagle. At all times relevant to this case, Deputy Teagle was a narcotics detective at the Harlan County, Kentucky Sheriff's Department. Tr. 409. Deputy Teagle testified that the investigation that culminated ultimately in the Respondent's conviction commenced when law enforcement personnel noticed that controlled substance prescription bottles discovered during drug raids were issued by the Respondent's (then) partner at Tennessee Professional Associates (TPA), Dr. V. Vilvarajah. Tr. 410. While Teagle's testimony was sufficiently detailed, internally consistent, and plausible to be regarded as credible for these proceedings, this brief summary of its content circumscribes completely the entire boundaries of its acceptable use in these proceedings.

The Government elicited testimony from Deputy Teagle regarding an interview [13] he conducted with TE, a former patient at TPA.[14] A timely (and ultimately well-founded) objection was interposed by the Respondent's counsel in resistance to the Government's efforts to present this evidence in this manner. Tr. 412–14. While it is true that the evidence regarding Teagle's interview was received into the record as not patently inadmissible, that is a separate issue from the weight that can correctly be afforded to it. To be sure, hearsay testimony (as well as other forms of hearsay) is admissible evidence in administrative proceedings. *Richardson v. Perales,* 402 U.S. 389, 402 (1971) (signed reports prepared by licensed physicians admitted correctly at Social Security disability hearing); *Keller v. Sullivan,* 928 F.2d 227, 230 (7th Cir. 1991) (insurance company investigative reports admitted correctly in Social Security disability hearing where sufficient indicia of reliability established); *Calhoun v. Bailar,* 626 F.2d 145, 149 (9th Cir. 1980) (hearsay affidavits admitted correctly where indicia of reliability established). However, the weight afforded such testimony and, *a fortiori,* whether that testimony constitutes substantial evidence is an entirely different matter. As succinctly stated by the Eleventh Circuit:

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

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

Applying the *J.A.M. Builders* factors to this testimony, while true enough that the Respondent arguably could have secured TE's live testimony through process, the Government (the proponent of the evidence) has presented no predicate upon which a reasonable finding could be made that would justify consideration of this evidence in support of a finding of substantial evidence. Although there is no direct evidence of bias and TE was not then under investigation, the interview took place in a law enforcement setting where Teagle had suspicions that TE may have been dealing drugs. Tr. 416–17. There was insufficient other evidence to determine whether the information provided in the TE interview was consistent on its face, and not only has this form of information never been recognized by the courts as inherently reliable, but TE admitted that his memory of events during that time is less than stellar, or in his words, ''my mind's erased where I was on that junk.'' Without the live testimony of TE, there would not be a way to test meaningfully TE's residual memory capacity. The Government elected to offer TE's statements as hearsay at its own peril, and such testimony cannot be used to support a finding of substantial evidence in these proceedings.

The Government also presented the testimony of Sherif Guindi, Esq., a former Assistant Commonwealth Attorney (ACA) for the county of Harlan, Kentucky. Tr. 345, 399. Like Teagle, Guindi recalled that the attention of law enforcement was drawn to TPA because law enforcement officials had discovered prescription bottles authorized by the Respondent and her partner at the scene of narcotic enforcement activities (such as arrests, seizures, stings, and searches). Tr. 355. Mr. Guindi was involved in prosecuting the Respondent and negotiated, at least in part, her plea bargain. Tr. 345, 373–75, 379. Guindi, whose testimony was sufficiently detailed, consistent, and plausible to be credited, provided some level of background regarding the Respondent's procedural odyssey through the Harlan County state criminal case. Tr. 345–46, 371–81. As part of the plea agreement, the Respondent agreed to forfeit $250,000 that she had posted to secure her release on bond,[15] and she *donated* $250,000 to the Harlan Fiscal Court for use in drug eradication, rehabilitation, or prevention.[16] Tr. 345–46, 371–75; *see also* Stipulations B–C, E–G.

Not unlike its presentation of Deputy Teagle's testimony, the Government elicited information from former ACA Guindi relative to interviews that he

[13] A transcript of this interview, which had been taped by Teagle, was received into evidence. *See* Gov't Ex. 20.

[14] The sum and substance of TE's statement to Teagle portrayed him as an addict who successfully procured controlled substance prescriptions from the Respondent and her partner at TPA for no legitimate reason. Tr. 413–14; Gov't Ex. 20.

[15] This sum represented, at least in the state's theory, ill-gotten gains (85% of which went to the Harlan County Sheriff's Department, 15% of which went to the Harlan County Commonwealth Attorney's Office).

[16] The circumstances surrounding the Respondent's Harlan County guilty plea, including the Respondent's discomfiture regarding the propriety of the forfeitures, are well beyond the jurisdiction of this forum, have played no part in this recommended decision, and can play no part in the Agency decision in this matter.

conducted of AW [17] and TG,[18] who, like TE, were purportedly former patients of TPA while the Respondent was a partner there. An affidavit executed by AW was offered by the Government and received into evidence.[19] Gov't Ex. 17; Tr. 364–67. The Respondent, through counsel, registered timely, cogent (ultimately well-founded) objections to the Government's approach in this regard. Tr. 347, 360, 362–64, 367.

An application of the *J.A.M. Builders* factors to the interviews of AW and TG militate against affording it weight. Although the Respondent's counsel conceded that he neither made an attempt to subpoena AW, nor expended efforts to discover whether she still remained in jail, Tr. 347–48, (and while not on the record, the same circumstance may be assumed as true with regard to TG), each of the remaining factors favor exclusion of the evidence regarding Guindi's interviews. Regarding AW's possible bias, the transcript reveals that at the time of the interview AW was serving prison time after flunking a drug diversion rehabilitation program. Tr. 351–52. On the issue of whether AW could have been influenced by a desire to reduce her criminal liability based on her cooperation, Mr. Guindi was not particularly helpful. Guindi testified that he did not think AW was in a position to be placed back into the (rehab) program that she had washed out of, but that he did not know whether cooperation was a condition of the pretrial agreement that resulted in her diversion to Drug Court.[20] Tr. 353–54, 356. It is, likewise, not insignificant that during her interview, AW volunteered that she was inflicted with a back issue that conceivably could have justified the proper utilization of pain medications. Tr. 357.

No foundation was laid by the Government regarding the absence of bias from AW or TG. The information provided in the interviews could not be tested for consistency because such testimony was not corroborated by other evidence of record. Furthermore, there is no case law or other authority recognizing this variety of evidence as inherently reliable. Simply put, the Government, as the proponent of the evidence, did not lay a foundation sufficient to permit consideration of the AW/TG interviews to support substantial evidence, or even sufficient for this tribunal to make findings relevant to the issue that could be defended at any level of appeal. AW acknowledged her intoxication during the events that were the subject of the interview, and presented in this third-hand fashion, there is no way that her recollection could be meaningfully explored. TG, who at the tail end of his interview acknowledged that he saw the Respondent ninety percent of the time, overwhelmingly used the pronoun ''he'' throughout the transcript to describe the physician who treated him at TPA, referring to the Respondent's partner, Dr. Vilvarajah. Gov't Ex. 21 at 17. Regarding his state of mind during the events that he was recounting, TG revealed that ''[a]ll you think about is the medicine, you know, where your next little bit's going to come from.'' Gov't Ex. 21 at 17–18. As discussed, *supra,* the Government opted to elicit this information in this fashion rather than to produce the witnesses at the hearing or at least lay an adequate foundation for the meaningful reception of their testimony, and made this election at its own peril. Without more of a foundation, such as a way to gauge their degree of bias, potential interest, or the consistency of their recollections,[21] the reliability of the testimony regarding the AW/TG interviews falls short of a level where they can be considered gainfully, or contribute to a determination supported by substantial evidence.

Consistent with Mr. Guindi's testimony (as well as mutually-stipulated facts), the Government submitted into evidence documents reflecting the transactions of the Respondent's conviction and sentencing in Harlan County, Kentucky. Among the documents was the Commonwealth's Offer on a Plea of Guilty, which indicated that Count I of the indictment for engaging in organized crime, a felony, was amended to facilitation to trafficking in a controlled substance, a misdemeanor. Gov't Ex. 7 at 1; *see* Stipulation B. The state's offer of a reduced charge was conditioned on the Respondent's agreement to refrain from prescribing any medications to residents of Harlan County, and was based, at least in part, on the Respondent's having excluded at least 251 patients from her pain management practice for ''misusing prescription drugs,'' and the state's conclusion that the Respondent was ''instrumental'' in prosecuting 16 patients for ''misusing printed prescription pads and forging signatures.'' Gov't Ex. 7 at 2. The recommended sentence part of the plea offer, which was ultimately ratified by the state district court,[22] proposed that the court dismiss Counts II through V; that the court dismiss the subsequent indictment for wanton murder, *see* Stipulation E; [23] that the Respondent receive eleven months imprisonment in the county jail, probated to four months; and that the Respondent forfeit $500,000 [24] to the state. Gov't Ex. 7 at 2. The Government also introduced into evidence the Order of Probation, dated January 11, 2010, pursuant to the plea agreement and conviction, that ordered, *inter alia,* the unsupervised probation of the Respondent and the proscription from prescribing controlled substances

[17] In the transcript prepared in connection with her statements to Mr. Guindi, it was clear that at the time she made her statements to him, AW was incarcerated based on charges related to the investigation of TPA. Gov't Ex. 19 at 1. AW admitted that she was addicted to drugs during the time she was being seen at TPA and ''was under the influence most of the time [she] was in [at the practice].'' *Id.* at 6. AW's interview provided information that, if credited, could arguably have established that the Respondent knew or should have known that AW always had fresh needle marks on her arms from intravenously injecting her pain medications before office visits, had prior scarring from same, and wore sleeveless shirts during warm weather so that these obvious signs of drug abuse were clearly displayed. Furthermore, her interview also could have supported the proposition that AW was not physically examined by the Respondent prior to receiving controlled substance prescriptions, and that she was never questioned by the Respondent about selling her controlled prescriptions or her reasons for travelling such a long distance each month for medical care. Additionally, the interview results would have arguably shown that AW recognized other patients at TPA as residents of her home town in Harlan County, and that some of her neighbors/fellow patients exhibited signs and behaviors of intoxication that also should have been apparent to the Respondent and other TPA staff. Tr. 358–60, 364, 385; Gov't Ex. 19.

[18] If credited, TG's interview could have provided evidence that he and other Harlan County residents travelled a long distance together to obtain controlled substances from the Respondent to abuse or sell back in Harlan, that the Respondent prescribed controlled substances to TG for three years, that she increased his dosage at least once for no reason, and that the practice habits at TPA allowed TG to abuse the controlled substances that he obtained there. Tr. 368–71.

[19] The affidavit was generated by the prosecution in the state criminal case in opposition to a defense motion to dismiss. Tr. 378–83

[20] Although Mr. Guindi represented that this sort of information was easily obtainable at the time through his mobile smart phone or by quick telephone request made to the Harlan County Clerk's Office to fax over AW's plea sheet, neither the Government nor the Respondent entreated him to make such an inquiry. Tr. 354, 356–57.

[21] Further confounding the usefulness of AW's statements, Guindi testified that AW told him that she was impaired by the effects of the narcotic pain drugs most of the time that she visited the Respondent's practice and that the drugs interfered with her recollection abilities. Tr. 384–85. The same was reflected in the transcript of AW's interview. Gov't Ex. 19 at 6.

[22] Gov't Ex. 10 (Judgment and Sentence on Plea of Guilty); *see* Gov't Ex. 9 (Guilty Plea).

[23] The indictment was ordered dismissed by the Harlan Circuit Court on February 2, 2010. Gov't Ex. 12.

[24] Half of the $500,000 sum was forfeited to the state as illegal drug trafficking proceeds, and the remaining half was donated to the Harlan Fiscal Court for use in youth activities and facilities aimed at preventing drug abuse. Gov't Ex. 10 at 5.

to residents of Harlan County. Gov't Ex. 11 at 2.

During her testimony at her DEA administrative hearing, the Respondent made it clear that even though she entered a guilty plea on the criminal charge, she has always maintained, and still does unwaveringly maintain, her innocence on the charges, and believes her acts were ''unintentional.'' Tr. 922–24, 1038; *see also* Stipulation F.

State Medical Board Proceedings

The evidence of record unequivocally establishes that the Tennessee Medical Board adjudicated a disciplinary case based on the Respondent's Kentucky state court criminal conviction. Following an initial summary suspension effected on January 29, 2010, a hearing was conducted by the Board. A final order issued by the Board on March 22, 2010, acknowledged the Respondent's state court misdemeanor conviction for facilitation to trafficking in a controlled substance in the first degree, but afforded her the benefit of retaining her medical privileges, subject to several conditions.[25] Gov't Exs. 14, 15; Stipulations I, J.

The Respondent's Prescribing Practices

The Government's investigation regarding the COR application [26] at the center of these administrative proceedings was presented primarily through the testimony of Rhonda Phillips and James Stevens, DEA Diversion Investigators (DIs) stationed in Nashville, Tennessee.

The Diversion Investigators

Notwithstanding the parties' stipulations regarding the procedural milestones associated with the Respondent's state criminal case, DI Phillips, a veteran of over twenty-three years as a DI, outlined numerous court-related documents associated with the misdemeanor conviction. Gov't Exs. 3–7, 9–12; Resp't Ex. 31. DI Phillips also testified that the Respondent surrendered a previous COR [27] through the execution of a Form DEA–104 (Form 104) signed by the Respondent and conveyed to Phillips by facsimile through her counsel. Tr. 672–74; Gov't Ex. 13. DI Phillips recalled that she prepared the surrender form upon telephonic consultation with the Respondent's counsel, explained that the surrender would be designated as ''for cause,'' and received an executed facsimile copy the same day. Tr. 672–74. Above the Respondent's signature, the Form 104 has a checked box adjacent to boilerplate language in the form reading, in pertinent part:

> In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part[,] I hereby voluntarily surrender my [COR], unused order forms, and all my controlled substances . . . as evidence of my agreement to relinquish my privilege to handle controlled substances . . . . Further, I agree and consent that this document shall be authority for the Administrator of the Drug Enforcement Administration to terminate and revoke my registration without an order to show cause, a hearing, or any other proceedings . . . .

Gov't Ex. 13. Immediately above the afore-quoted standard surrender language appear the words: ''I am surrendering this privilege only as a condition of bond, and I am not making any admissions as to any wrongdoing.'' *Id.* The Respondent's counsel and Phillips had discussions surrounding the execution of the Form 104 wherein the former explained to the latter that the Respondent needed to effect a COR surrender as a condition of her bond release on the state criminal court matter. Tr. 810–11. Phillips explained unequivocally that a new application and administrative show cause process must precede the Respondent's reacquisition of her registration privileges. Tr. 811–12

DI Phillips also testified that, as part of her investigation into the current application, she obtained [28] and reviewed some charts from TPA [29] that were identified to her as relating to the Respondent's patients from the custody of the Tennessee Medical Board's Office of General Counsel (OGC),[30] and three additional charts [31] from the Harlan County, Kentucky Commonwealth's Attorney's Office (KCA). Tr. 688–94, 700. Ten files from the universe of files retrieved from OGC [32] and KCA were selected at random and provided to a medical consultant, Dr. Stephen Loyd, M.D., for analysis. Tr. 825.

Additionally, over a well-reasoned, timely objection interposed by the Respondent's counsel, Tr. 793–99, DI Phillips testified concerning her interview of CM,[33] a former patient of TPA that was treated by the Respondent,[34] Tr. 799–808. Applying the *J.A.M. Builders* [35] factors to this evidence, CM's hearsay statements, conveyed through DI Phillips, cannot be considered for any purpose in these proceedings. While the Respondent's counsel arguably could have subpoenaed the witness, the Government has tendered no information as to how lack of bias could be assessed or how to gauge the consistency of the information, and this is not the type of information that has been recognized by the courts as inherently reliable. Thus, DI Phillips' account of CM's statements have not been considered for any purpose in this recommended decision and should not be used in support of any finding in the adjudication of the present application.

DI Stevens testified that while he has been a DI for approximately three years, he is also a retired police lieutenant with over thirty years of experience, twenty-four of which were spent assigned to cases involving narcotics, pharmaceutical drugs, and illegal

[25] The specified probation conditions include: (1) undergoing an evaluation by the Center for Personalized Education; (2) completing a two-day course on medical ethics and a three-day course of medical recordkeeping; and (3) obtaining practice monitoring for five years. During the practice monitoring, at least ten percent of all Respondent's patient medical files must be reviewed each month and Respondent must receive training in the treatment of chronic or intractable pain. The practice monitor must also provide the Medical Board with reports every three months that include the Respondent's: (1) compliance with the practice monitor's recommendations; (2) completion of education programs; (3) prescribing practices; (4) medical recordkeeping; and (5) treatment of chronic or intractable pain. Stipulation J.

[26] A copy of the current application, which was submitted online, was received into evidence. *See* Gov't Ex. 2.

[27] A copy of the Respondent's prior COR was received into the record. *See* Gov't Ex. 1.

[28] Phillips utilized an administrative subpoena to acquire the patient charts. Tr. 424.

[29] Phillips credibly testified that, through differences in handwriting, she was able to distinguish the Respondent's notes from those of her partner at TPA, Dr. Vilvarajah. Tr. 704–05. The Respondent, who heard DI Phillips' testimony in which she distinguished the Respondent's hand from Dr. Vilvarajah's, testified that Phillips' interpretations were accurate. Tr. 982–83.

[30] According to DI Phillips, all but two of the charts selected bore a certification of accuracy from the Respondent. Tr. 690–92, 826–28.

[31] Gov't Exs. 26, 45, 51.

[32] DI Stevens testified that while two boxes of charts were retrieved from OGC, the two DIs reviewed only one box of charts, and that one box was chosen at whim. Tr. 514–15.

[33] DI Phillips testified that the interview was not recorded by video or audiotape. Tr. 831. However, Phillips testified that she did prepare written notes regarding the interview, and at the hearing the Government acquiesced to a request made by Respondent's counsel for access to those notes. Tr. 833.

[34] Had CM's statements to Phillips been deemed sufficiently reliable to have been considered, they would have indicated that she was treated by TPA for four years, and that the Respondent and Dr. Vilvarajah did not take her off controlled substances even after she informed them that she was pregnant. Tr. 802–07. Ironically, in light of the fact that neither of the two experts who testified at the hearing was asked to render an opinion on the relative merits of prescribing controlled substances to pregnant patients (or continuing to do so), on the present record, the usefulness of CM's statements to Phillips regarding this issue (even if they had been sufficiently reliable to be considered) would have been dubious.

[35] 233 F.3d 1350, 1354 (2000).

controlled substances. Tr. 418–19. Like DI Phillips, Stevens testified to reviewing patient charts in connection with the Respondent's case to detect indicators of abuse or diversion.[36] Tr. 421. The testimonies presented by DI Stevens and DI Phillips were sufficiently detailed, consistent, and plausible to be deemed credible in these proceedings.

The Government's Expert

The Government presented testimony from, and a written report[37] prepared by, Dr. Stephen Loyd, M.D.[38] Dr. Loyd testified that: (1) he holds a board certification in general internal medicine; (2) he serves as the Associate Chief of Staff for Education at the Veterans Affairs Medical Center (VAMC) in Johnson City, Tennessee; and (3) he is an associate professor of internal medicine at the James H. Quillen College of Medicine at East Tennessee State University.[39] Tr. 11, 13. Dr. Loyd testified that he practices medicine at VAMC in both in-patient and out-patient capacities, teaches medical school courses at all levels, trains medical residents, and has been recognized as an expert in other litigation forums. Tr. 14–16, 231–32. He testified that although he handles chronic pain patients, those cases comprise less than ten percent of his patient-base.[40] Tr. 16. Without objection, Dr. Loyd was received as an expert in the field of internal medicine with an emphasis on proper controlled substance prescribing practices.[41] Tr. 14–16.

Dr. Loyd testified that, when treating patients afflicted with chronic pain, physicians follow a protocol, the first step of which is to identify the chief complaint, or in other words, the patient's own understanding of why they are seeking medical intervention. Tr. 17–19. The second step of the protocol is to ascertain the patient's history regarding the genesis of the chief complaint. Tr. 19–20. A differential diagnosis, that is a list of possible etiologies for the pain symptom(s), comes next, with a review of bodily systems and physical examination, followed by an assessment and treatment plan prepared based on the information acquired by the foregoing process. Tr. 20–24. According to Dr. Loyd, the nature and extent of the physical exam can be affected by the nature of the chief complaint and can be of a more limited nature on subsequent visits. Tr. 23–24.

According to Dr. Loyd, in treating chronic pain, consistent with the guidance set forth in the Pain Control Ladder (PCL) developed by the World Health Organization (WHO), he commences chronic pain treatment with the least addictive medication, which is generally a non-controlled, non-steroidal, anti-inflammatory drug (NSAID). Tr. 25–28. If that level of medication has not proven effective, Dr. Loyd testified that he would ''take it up a notch'' to the second rung of the PCL, a low-potency opioid analgesic, reserving ''the very powerful narcotics, such as oxycodone, OxyContin, [or] Duragesic'' for ''severe chronic pain.'' Tr. 27.

Dr. Loyd also testified that a physician prescribing controlled substances has an obligation to probe for signs of patient addiction, and that this is a process that normally commences with questions deployed while eliciting the patient's history and are designed to flesh out areas of potential concern. Tr. 28–31. Dr. Loyd opined that the questioning becomes more in depth when he is treating a chronic pain case where the utilization of controlled-substance medication may be of longer duration, and that there are identifiable ''red flags'' of diversion risk that a treating physician should look for. Tr. 31.

A ''crescendo pattern of drug use,'' defined in his testimony as an increase ''in the frequency and strength of the drug over time,'' is a phenomenon that Loyd identified as a diversion red flag. Tr. 31–32. Dramatic, overstated, but vague pain complaints, as well as a patient seeking a specific medication by name[42] are other red flags described by Dr. Loyd. Tr. 33–34. Likewise, patient reports of lost or stolen prescriptions and early requests for refills were also characterized by Loyd as red flags, Tr. 49, as was evidence that a patient has declined to avail himself of treatment recommendations that are not related to controlled substances (e.g., a patient who ignores a recommendation to obtain an MRI or participate in physical therapy), Tr. 59–60. In Dr. Loyd's opinion, monitoring to ensure that patients are not procuring controlled substances from multiple physicians and/or pharmacies, or as Dr. Loyd characterized it, ''doctor shopping'' and ''pharmacy shopping,'' is also an important feature of controlled substance prescribing. Tr. 35–36. In that regard, Dr. Loyd testified that Tennessee has had an online prescription monitoring program available for practitioner query since 2008. Tr. 49.

Dr. Loyd testified that the practice of directing random urine drug screens (UDS) is a tool that should be utilized when prescribing controlled substances. Tr. 34–35. According to Loyd, through the use of UDSs, practitioners can evaluate whether pain patients are taking the medication that has been prescribed to them, which serves the dual purposes of assisting the physician in determining how effective a given drug regimen is in addressing pain symptoms and monitoring for diversion. Tr. 35. Patients who screen positive for illicit substances were described by Dr. Loyd as ''very much at risk for suffering from addiction'' and need careful monitoring. Tr. 36. Dr. Loyd testified that although a physician could prescribe to a patient who initially presents with positive UDS results for illicit substances (e.g., marijuana or cocaine), evidence of continued use would be grounds to discontinue controlled substance pain medication. *Id.* Dr. Loyd testified that he would be reluctant to prescribe a controlled substance before receiving results from an initial UDS administered to a patient upon intake, but that he would possibly go ahead and issue controlled substances in a case where a patient presented with a cancer diagnosis. Tr. 37.

Loyd testified that, in his opinion, the accepted medical practice is always to address a UDS anomaly with what he characterized as a ''confrontation'' with the patient to investigate the basis. Tr. 42–44. While Dr. Loyd agreed that a single UDS anomaly was not universally a reason to summarily discharge a patient from his practice, even a single

[36] Stevens credibly testified that, through differences in handwriting, he was able to distinguish the Respondent's notes from those of her partner at TPA, Dr. Vilvarajah. Tr. 428. The Respondent confirmed that DI Stevens' interpretations were able. Tr. 982–83.

[37] Dr. Loyd's written report was received into evidence. *See* Gov't Ex. 57.

[38] Dr. Loyd testified that the Government was compensating him at a rate of $300.00 per hour for his expertise and testimony. Tr. 232.

[39] Dr. Loyd testified that his duties include both direct patient care and teaching responsibilities. Tr. 218–19, 223–24.

[40] Interestingly, although Dr. Loyd testified that while he treats chronic pain patients, his practice group also refers patients requiring more specialized care out to a medical group that specializes in pain management. Tr. 220–23. In response to a question seeking clarification about his qualifications, Dr. Loyd stated ''If you're talking about the medical specialty of pain management, no, I did not practice that. Did I take care of pain patients? Absolutely.'' Tr. 221.

[41] Dr. Loyd's CV was received into evidence. *See* Gov't Ex. 55.

[42] Dr. Loyd acknowledged that his utilization of this phenomenon as a red flag is tempered by the reality that some patients, through experience, can legitimately apprise a treating physician regarding the success of particular medications used in the past in a way that can appropriately inform the doctor's prescribing decisions. Tr. 253.

inconsistent UDS requires exploration of the issue. Tr. 251. In describing the standards at his own practice, Dr. Loyd stated that ''at the very least, when you had [a UDS] that was inconsistent, you would investigate.'' *Id.* Thus, a suspicious UDS requires a patient confrontation. Furthermore, such a confrontation and its results must be documented in the patient chart. Dr. Loyd put it this way:

> *If you didn't document it, you didn't do it. That's the standard.* So I may have had a long discussion with my patient and [he] may have told me [he] didn't take [his] medication because [he was] hospitalized and [he] didn't take it for two weeks while [he was] on a ventilator. Very well may have been the case. *If I didn't document it in my chart, then it didn't happen. That is the standard.*

Tr. 44 (emphasis supplied); *see also id.* at 50.

Interestingly, Dr. Loyd testified that he is unaware of any recognized standard regarding the frequency with which UDSs should be administered, but in his practice, he directs one at intake, and another upon his perception of a red flag that emerges during the course of treatment. Tr. 48–49.

Dr. Loyd's presentation regarding the accepted standard set within the state of Tennessee for controlled substance prescribing was not without rough spots. The witness initially indicated that there was no acceptable medical practice within the state that he knew of that would provide guidance on how to handle a UDS anomaly. Tr. 39–40. He then retreated from this (otherwise seemingly unequivocal) position by indicating that there was an ''[a]ccepted medical practice,'' for that issue and others, as described above. Tr. 42. Loyd also acknowledged that he was not aware of any state standard for the definition of chronic pain, Tr. 17, 319–20, and conceded that he was unaware that any standards for prescribing within the state were memorialized in any formal way, Tr. 28. As discussed in some detail, *infra,* there is guidance in Tennessee regarding the utilization and monitoring of pain medication that the Government's expert was unaware of and woefully unprepared to address. In a similar vein, Dr. Loyd conceded that he had no familiarity with the Federation of State Medical Boards' *Model Policy for the Use of Controlled Substances for the Treatment of Pain,* 2004 (*Model Policy*), a widely recognized guidance tool utilized by physicians and legislatures nationwide. Tr. 137.

It was also interesting that Dr. Loyd did not outline pain management standards existent within the state of Tennessee, but instead styled the parameters of his critical analysis as ''accepted medical practice'' that he learned ''in [his] training.'' Tr. 42. While undoubtedly true that there is an established requirement in legal precedent to tailor analysis of medical practice to standards existent within a state law, *Volkman v. DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales v. Oregon,* 546 U.S. 243, 272, 274 (2006)), the Agency has recently accepted the propriety of ''measur[ing] the usual course of professional practice under [the CSA and the regulations] with reference to generally recognized and accepted medical practices.'' *Jacobo Dreszer, M.D.,* 76 Fed. Reg. 19386 (2011) (quoting *United States v. Smith,* 573 F.3d 639, 647–48 (8th Cir. 2009) (internal quotation marks omitted) (citing *United States v. Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008)).

A written report of sorts that was prepared by Dr. Loyd in connection with his review of selected patient charts from the Respondent's practice was also received into evidence. Gov't Ex. 57. As a preliminary matter, it is worthy of note that the format of Dr. Loyd's report was confusing and singularly unhelpful. While a critical objective of securing expert assistance is to aid the trier of fact in analyzing and processing material beyond the ken of the ordinary citizen, Dr. Loyd's report is untitled, unsigned, disorganized, unfocused, and written in a manner that bespeaks a free association narration of documents and other items provided to him by the Government in no particular order. A principal reason for the difficulty in the structure (or lack of it) employed by the report undoubtedly comes from the manner of its genesis. During his testimony, Dr. Loyd explained that the document that was characterized as his ''report'' was actually a collection of patient chart review summaries that he provided to the lead diversion investigator (DI) on the case ''to see what [DEA] thought of my work.'' Tr. 53–54. Loyd acknowledged that clerical mistakes are present in the report, owing in his estimation, to his own limited typing skills and misunderstanding of the purpose to which the pages he provided to DEA would be utilized. *Id.* Although undoubtedly true that enhanced communication between expert and proponent could likely have yielded a more refined written product, the submitted pages demonstrated a significant level of analysis regarding the reviewed patient charts.

Its weaknesses notwithstanding, Dr. Loyd's overall presentation as an expert was sufficiently clear, cogent, and well-reasoned to be relied upon in this recommended decision.

The Respondent's Expert

The Respondent presented the testimony of Dr. Thomas Miller, M.D.,[43] a board-certified anesthesiologist who is also a diplomate of the American Academy of Pain Management.[44] Tr. 541–41. Dr. Miller, who specializes in pain management and has practiced in that area since 1978, was accepted without objection as an expert in the fields of anesthesiology and pain management. Tr. 543.

While, in contrast to Dr. Loyd, Dr. Miller expressed some level of awareness that the Federation of State Medical Boards had adopted a *Model Policy,* he like Dr. Loyd, had no awareness of any pain medication guidance set forth in state statutes. Tr. 591. In some contrast to Dr. Loyd, however, Dr. Miller testified that pain management is the principal focus of his practice. Tr. 544–46. In the course of his testimony, Dr. Miller outlined the steps ordinarily taken regarding chronic pain patient care at intake. During the intake process, Dr. Miller, who does not accept walk-in patients, has each new patient complete pain symptom forms, directs that the patient bring in any current medication(s), explains the parameters and significance of the pain medication contract between doctor and patient, takes vital signs, directs a UDS, conducts a full physical examination, and outlines a treatment plan. Tr. 545–48. Regarding the appropriate use of an intake UDS report that reflects the presence of illicit drugs, Dr. Miller indicated that while he would not automatically refuse to treat every patient who registers positive for illegal drugs, there would be much discussion with such a patient on the issue and that he would schedule an additional urinalysis and explain to the prospective patient that he or she must be clean from illicit drugs prior to treatment. Tr. 549–52. According to Miller, ''[T]here's a lot of interaction going on with that patient, but *I simply don't write controlled substances for somebody who has an illicit substance in their urine.''* Tr. 552 (emphasis supplied). When pressed on the issue later in his testimony, Dr. Miller was emphatic that he would not continue to treat a patient who demonstrated illicit drug use on more than one occasion, and indicated that doing so would be

[43] Dr. Miller testified that he was being compensated by the Respondent at a rate of $500 per hour for his expertise and testimony. Tr. 544.

[44] Dr. Miller's CV was received in evidence. *See* Resp't Ex. 30.

problematic. Tr. 613–14. Dr. Miller testified that he believes that he tests for drugs more often than other pain management specialists because, in his words, ''I'm very, very keyed in on trying to identify diverters.'' Tr. 556. It is Dr. Miller's practice to inquire of the last time the patient took a dose of his or her prescribed medication prior to the administration of a UDS. Tr. 563. Inasmuch as Dr. Miller is aware of the expected length of time medications will remain in the body and the patient has advised him of the most recent dose taken, there is little room for ambiguity in this evolution regarding the implications of his patients' UDS results. Tr. 563. When a UDS report in Dr. Miller's practice reflects the absence of a controlled substance that his pre-test conversation reveals should have been in the patient's system, his reaction is unequivocal; he stated: ''[T]hat's a drug diverter, and I will then alert law enforcement.'' *Id.* Miller also explained that where a patient takes medicine in a way that is inconsistent with the terms of the pain medication contract (even with an excuse), that patient is directly told that such a deviation will not be tolerated in the future. Tr. 566. Dr. Miller also endorsed the importance of documenting UDS results, stating as unequivocally as Dr. Loyd, that ''*if there's no documentation, then I assume it wasn't done.''* Tr. 593 (emphasis supplied). Furthermore, according to Dr. Miller, ''[i]gnoring [UDS] results would be a problem.'' Tr. 616. Much as the two experts agreed on the issue of the importance of documentation, Miller's testimony concerning the handling of a UDS anomaly revealed a consonant viewpoint with that of Dr. Loyd. While not referring to the evolution as a ''confrontation,'' Dr. Miller indicated that upon a UDS irregularity, he would invariably discuss the discrepancy with the patient and document the results of that discussion. Tr. 623–25.

Dr. Miller also testified that, in his practice, reviewing a new patient's prior medical records is a condition precedent to rendering opioid pain management treatment, and that he has insisted on the expeditious acquisition of such records even where the patient's former doctor is hundreds of miles away. Tr. 587–88. Miller observed that, although the charts he reviewed for the Respondent reflected that while the pain management contracts employed at TPA included a provision requiring that past medical records be obtained, ''they just didn't follow through with it all the time.'' Tr. 588. Miller was clear in stating that he would not rely only on the word of his patient regarding the pain medications and dosages prescribed by former physicians. Tr. 604.

Dr. Miller testified that, at the Respondent's request, he reviewed and evaluated thirty-two of her patient files that were provided to DEA through the Tennessee Medical Board and the Commonwealth's Attorney's Office.[45] Tr. 567–70. In that regard, Miller testified that in his expert opinion there were both positive and negative features about the Respondent's patient files. Tr. 570. On the positive side, the records reflected histories and physical examinations on intake, as well as indicators that UDS testing was being performed at the practice. Tr. 571. On the negative side, when asked about the presence of prior medical records and imaging reports, Miller could say only that these were ''sometimes'' present in the charts. *Id.* Dr. Miller indicated that the type of UDS that TPA employed to test for opiates did not measure the presence of oxycodone. Tr. 575–76. Additionally, Miller faulted the Respondent's practice for unevenness in obtaining referral information from the patients, and for ''poor documentation'' on follow up visits regarding areas such as activities of daily living and aberrant behavior with respect to medication compliance. Tr. 576–78. Furthermore, Dr. Miller criticized the Respondent's practice regarding how well the doctors and staff followed up on diversion red flags once they were enountered. Miller put it this way:

> Sometimes they had a problem that they recognized some substance abuser or that a person had a substance abuse problem, and they recognized that they needed to send [the patient] to rehab, but there's no evidence that the patient actually went to rehab, and they continued prescribing.

Tr. 578.

Based upon his review of the Respondent's patient charts, Dr. Miller also concluded that that one or two patients among those he analyzed were prescribed methadone and OxyContin together, a combination of medications that in Miller's view is unwise. Tr. 584–85, 610–11.

However, Dr. Miller was also of the view that the deficiencies that the Respondent demonstrated regarding her pain management practice were correctable with proper training. Tr. 579–80. Although Dr. Miller testified that the Respondent advised him that she no longer intended to practice pain management,[46] he also testified that the Respondent visited him for two days at his office and they spent that time reviewing correct controlled medication prescribing practices and monitoring. Tr. 581–83. Miller indicated his willingness to serve as a ''practice monitor'' for the Respondent in the same manner as he has performed this function in the past for nurse practitioners. Tr. 590–91.

Dr. Miller's testimony, while not without its weaknesses, was sufficiently consistent, comprehensive, and founded on material in the evidence of record to be relied upon in the adjudication of this application. Although there were no dramatic differences of significant consequence between his expert opinions and those of Dr. Loyd that impact on consequential issues here, to the extent that conflicts exist, Dr. Miller's depth and breadth of experience in the area of pain management were clearly more comprehensive than that of Dr. Loyd.

The Respondent's Testimony

The Respondent testified that she graduated medical school in Haiti in 1977, acquired subspecialties of pain medicine and anesthesiology, and amassed what can fairly be characterized as an impressive level of experience in those fields. The Respondent apparently practiced medicine for twenty-seven (presumably uneventful)[47] years prior to her regrettable foray into the Kentucky criminal justice system. Tr. 862, 867. A year after graduation she began residing regularly in the United States and moved to the District of Columbia where she completed her first year of residency at a hospital concentrating in surgery. Tr. 862–63. In 1979, she embarked on three additional years of medical training at Howard University Hospital, the first two of which were focused in the area of anesthesia satisfying her second and third year residency requirements, and the last year which was a fellowship in the dual areas of anesthesiology and obstetrics. Tr. 873. The Respondent testified that she accepted a job offer following her formal

[45] The patient charts that were offered and received into evidence represent a subset of this group.

[46] Tr. 615. However, this view is in some conflict with the Respondent's own testimony, wherein she seemed to convey a potential interest to resume practice in the field of pain management when explaining reasons why she wished that DEA would grant her COR application. Tr. 993–94.

[47] The Respondent testified that although the Kentucky Medical Board had asked to review patient charts in 2003, no charges resulted from that inquiry. Tr. 929–32. In fact, she stated that she has never been disciplined by any medical board prior to the evolution by the Tennessee Medical Board that caused her license there to be placed on probation. Tr. 866–67.

medical training at the formerly-known Meharry-Hubbard Hospital in Nashville, Tennessee, serving a thirteen-year post as the head of the anesthesia department within the division of surgery, from 1982 until 1995. Tr. 863–64. She also had the additional responsibility of teaching classes to medical and dental students as an assistant professor in surgery. Tr. 864. The Respondent explained that she was laid off due to a hospital merger in 1995. *Id.* Brief stints practicing bariatric medicine and anesthesiology at the Orofacial Institute followed, until 1997 when she and Dr. V. Vilvarajah formed TPA,[48] a practice focused primarily in pain management and secondarily in bariatrics. Tr. 864–65; 882. The Respondent testified to holding medical licenses in three states: an inactive license in Kentucky,[49] a probated license in Tennessee, and an active license in Florida. Tr. 866–67. She also testified that throughout the time that she practiced pain management, she kept current and abreast of the specialty's progress and evolution by investing considerable time each year into continuing medical education (CME) courses and networking, and that she incorporated the improvements and advances to the field that she learned about into her own practice. Tr. 892–93. By the Respondent's own reckoning, she accumulated twice the minimum CME credits required to maintain her license every three years. Tr. 893.

As discussed in more detail elsewhere in this recommended decision, her plea of guilty notwithstanding, the Respondent is now and has consistently been resolute in her conviction that she has committed no crime. Tr. 922–24, 1038.

Regarding her medical practice, the Respondent testified that each prospective patient who penetrated the doors of TPA, whether by referral or as a walk-in,[50] was subjected to a screening process by which their appropriateness for pain management was evaluated and their medical complaint was verified. Tr. 876–80. The medical assistant who scheduled the initial appointment was tasked with notifying the prospective patient that he or she must bring identification to their first visit (*e.g.,* a driver's license), a medical record, past imaging reports, pharmacy profiles, and bottles that held previously-prescribed medications (if any) to their first visit. Tr. 877. The Respondent stated that patients were not automatically accepted into the practice, even with the required documentation, and medical assistants were directed to inform the patients of that policy when arranging the first appointment. *Id.* The Respondent also stated that once the patient arrived at the office for an initial visit, the medical assistant would ensure that he or she was in compliance with the documentation production policy, to wit: ''[T]he medical assistant verifie[d] that they ha[d] whatever she asked them to bring.'' Tr. 879. It was the Respondent's recollection (at least initially) that seventy percent of all patients coming into TPA were based on referrals from other doctors. Tr. 898–90. The Respondent testified that some patients were screened by the TPA staff and rejected as patients for various reasons,[51] and sometimes patients were discharged with reports made to law enforcement authorities. Tr. 905–06, 913–14. According to the Respondent, TPA stopped accepting medical insurance and became a cash-only practice in 2006. Tr. 890.

As assertive as her testimony began, the Respondent progressively became more equivocal in how she continued to describe the office's new patient evaluation procedure. The next phase of the protocol that she explained included a face-to-face conversation between the patient and either Dr. Vilvarajah or herself, to allow the physician to observe, among other things, dress, demeanor, and manner of speech. *Id.* The Respondent's portrayal of the protocol shifted from the doctor routinely verifying the authentication of the patient-supplied documents, to ''*if* we see a report of an x-ray, we *may* call that x-ray lab and verify that this x-ray lab is correct.'' *Id.* (emphasis added). The Respondent later stated that if she or her partner decided to accept the person as a patient, and caused the initial workup procedures to commence (including taking vital signs, blood work, and a urine screen), that she would ''go again over their medical record and *if they [brought] a medical record,* we [would] take from that medical record whatever is pertinent to the patient's problem and have the medical assistant make a copy of [these] document reports.'' Tr. 885. (emphasis supplied). When pressed on the issue of why she would ever prescribe controlled substances at an initial visit in a case where the patient declined to furnish his or her prior medical records, the Respondent's equivocation diminished and she asserted that such a practice was ''[n]ot [done] without prior medical records [and that] [t]hey ha[d] to have some type of problem, some medical reason why [she] would prescribe to them.'' Tr. 898. Such medical justification might be established to the satisfaction of the Respondent with just an MRI (in addition to the patient's complaint and her exam). *Id.* When pressed on the issue of why she did not forbear prescribing until a full medical record was obtained rather than just an x-ray or pharmacy report, the Respondent stated that ''some [of her patients did] not have a medical record[, s]o, all they bring is that x-ray,'' and testified that she believed that there was not a patient chart in evidence reflecting that the patient lacked a prior medical record or x-ray but yet still received prescriptions for opiates on the first visit. Tr. 899; *see* Tr. 1004 (confirming her policy of not prescribing controlled substances without some form of prior medical record). However, even a perfunctory glance at the charts received into the record reflects that the Respondent's statements in this regard are inaccurate. *See, e.g.,* Gov't Ex. 22 (controlled substance prescriptions issued first visit, MRI report dated same as initial visit and initialed by TPA the *day after* initial visit, no prior medical record); Gov't Ex. 23 (controlled substance prescriptions issued at first visit, two MRI reports for knee and lumbar spine, no prior medical chart); Gov't Ex. 24 (controlled substance prescription issued at first visit, only MRI submitted with sole impression of ''[n]o acute osseous abnormality,'' no prior medical chart); Gov't Ex. 28 (controlled substance prescriptions issued at first visit, only MRI report dated four years prior, no prior medical chart); Gov't Ex. 31 (controlled substance prescriptions issued at first visit, only prescription label for OxyContin 40 mg and MRI with ''[m]ild degenerative changes'' as sole impression submitted at first visit, no prior patient chart); Gov't Ex. 32 (controlled substance prescriptions issued at first visit, MRI report dated almost five years prior, single progress

[48] While the Respondent and Dr. Vilvarajah were married for a brief period, their marriage had dissolved prior to the formation of their business relationship. Tr. 1041–42.

[49] According to the Respondent's testimony, she let her license lapse without renewing it, and it has not been the subject of any disciplinary action. Tr. 866.

[50] The Respondent testified that while TPA used to advertise in the telephone directory and accepted walk-in patients (who arranged for an appointment by their own devices beforehand) starting in 1997, this was a practice that ceased in 2006. Tr. 876–78.

[51] The Respondent testified that TPA maintained a log book with photocopies of the driver's licenses of prospective patients who were rejected in the course of the intake process. Tr. 905–06. An exhibit that was purported to be photocopies of the contents of the log book was excluded based on foundational and relevance grounds. Tr. 906–13; Resp't Ex. 1 (ID). The evidence does not contradict the Respondent's assertion that some patients were rejected from TPA at intake, and the Government has not contested this premise.

note by former physician over nine months prior, no prior patient chart); Gov't Ex. 33 (controlled substance prescriptions first visit, incomplete record of an initial evaluation by former physician four and a half years prior, no prior patient chart); Gov't Ex. 34 (controlled substance prescriptions issued by Respondent at first visit, chief complaint regarding ribs and knees, one follow up chart note regarding elbow x-ray by previous physician less than two years prior, no prior medical chart); Gov't Ex. 38 (controlled substance prescriptions issued at first visit, no prior medical records); Gov't Ex. 43 (controlled substance prescriptions issued by Respondent at first visit, prior MRI report dated over eight years prior and office visit note by a prior neurosurgeon over eight years prior, no prior medical chart); Gov't Ex. 48 (controlled substance prescriptions issued by Respondent at first visit, no prior medical records); Gov't Ex. 49 (controlled substance prescriptions issued by Respondent at first visit, no prior medical records). Even the Respondent's own expert, Dr. Miller, indicated that past medical records and imaging reports were only ''sometimes'' in the patient charts. Tr. 571.

This area saw some additional level of exploration during the Respondent's cross-examination. Regarding Patient FH (Gov't Ex. 39), the Respondent recounted that the patient's chief compliant was pain emanating from a broken rib and his knees, and that she prescribed him Lortab, OxyContin, and Xanax at his first visit. Tr. 1004–06.[52] When confronted that the only prior objective medical evidence furnished by the patient was a record pertaining to an elbow fracture, the Respondent was moved to concede on reflection that ''looking at it back, I *probably* gave it to him, this prescription, based on my findings from his broken ribs and his knees.'' Tr. 1006 (emphasis supplied). She then further admitted that she failed to follow up, and prescribed controlled substances to FH for four years, grounded almost exclusively based upon a subjective patient complaint. The chart reflects no x-ray or MRI that could have confirmed, refuted, or explained the patient's alleged conditions. The Respondent agreed that upon reflection, her controlled substance prescribing lacked a medical justification. Tr. 1006–07.

During her testimony, the Respondent addressed the manner in which she reacted to UDS anomalies, including how she responded to new patients whose UDS failed to reflect medications they attested to being on, or who subsequently tested negative for drugs prescribed at TPA. According to the Respondent's testimony, it was not uncommon for patients to test negative for substances prescribed, but in those cases she would speak to the patient and document the reason why that was the case. Tr. 894–95. The Respondent recounted numerous justifications she encountered that were connected with UDS result irregularities. Examples included TPA's determination to commence opioid treatment on a new patient at a lesser dose than the patient's former practice, a phenomenon that sometimes resulted in the patient consuming the medications prescribed at TPA at a more rapid pace; another patient who experienced vomiting before providing a urine sample, an event that could result in a reduction of the drug in the system; a patient who was prescribed antibiotics by his or her primary care physician, and was therefore directed by that physican to suspend the taking of TPA's pain medications; a patient who suspended taking controlled prescriptions temporarily on his or her own judgment out of safety concerns associated with impaired driving ability. Tr. 894–96. The Respondent recollected that the TPA's tolerance for prescribing to patients who demonstrated potential drug addiction became more restrictive near the end of 2007. Tr. 1013. However, unlike the more stringent policy of her expert witness, Dr. Miller, the Respondent indicated that TPA would tolerate two UDS stumbles which reflected illicit drug hits. Tr. 1013–15.

The Respondent's assertions to the contrary notwithstanding, the record is replete with instances where the Respondent remained willing to continue to prescribe controlled substances in the face of negative UDS results that should have been positive, with associated charts that were devoid of documentation that might explain the discrepancies. *See, e.g.,* Gov't Ex. 27 (Patient CE); Gov't Ex. 28 (Patient DF); Gov't Ex. 33 (Patient TH); Gov't Ex. 34 (Patient FH); Gov't Ex. 38 (Patient MM); Gov't Ex. 48 (Patient HGW).

The Respondent's handling of this issue during the course of her testimony was not altogether consistent. Upon a representation made by Government counsel that Patient HGW's chart (Gov't Ex. 48) contained twenty instances of individual substances found in drug screen reports that reflected results inconsistent with what was legal or prescribed by TPA (at which point the Respondent admitted that there were at least some inconsistent drug results that she noticed), the Respondent initially disclaimed that her care and prescribing did not fall below the standard of care in Tennessee by responding this way, ''For that particular patient, it depends on how you see it.'' Tr. 1002–03. But when directed to a page reflecting that she prescribed four separate controlled substances at HGW's next to last visit of four years of treatment, the Respondent agreed that issuing that set of controlled prescriptions after so many red flags did fall below the state standard of care. Tr. 1003.

The Respondent provided detail about additional policies she employed to stem diversion. She testified that when she suspected a patient was engaged in doctor shopping, she would confront the patient, where appropriate verify the treatment with the another treating physician, and in cases where the patient's explanation for a discrepancy panned out, the Respondent testified that it was her custom to offer the patient the option of continuing treatment with her partner. Tr. 1010–11. However, the Respondent later admitted that although Patient RN's chart[53] reflected exactly this scenario, no such notes were to be found in the file. Tr. 1011–12. The Respondent explained that prospective patients who were unable to produce a pharmacy profile were afforded the option providing prescription bottles, the labels of which would be removed and affixed to the TPA patient chart. Tr. 1009–10. When asked if the patient charts produced at the hearing contained such indicia, she clarified that those patients who lacked profiles in reality only sometimes brought in their bottles. According to the Respondent, she knew that it occurred at least on occasion, inasmuch as she observed bottle labels affixed in several ''other charts'' not submitted into evidence (of the thirty that were). *Id.*

The Respondent stated that TPA switched drug screen analysis methods from immunoassay (IA) to gas chromatography (GC) midway through 2007, because the GC has a more sensitive cutoff and is able to discriminate among naturally-occurring or synthetically-engineered opioid

[52] The chart reflects that the Respondent failed to take down a patient history reflective of what opioid drugs Patient FH had received in the past, if any, when she prescribed Lortab and OxyContin for the first time. *See* Gov't Ex. 39 at 23, 85–86, 89. This was apparently in spite of FH reporting on his intake form that while he was not currently on any pain medications, *see id.* at 89 (blank line under prompt regarding treatments and medications presently received for pain); *see also id.* at 86 (new patient notes filled in by Respondent), he experienced ninety percent relief in the last day from the pain medications or treatments he was experiencing, *id.* at 89.

[53] Gov't Ex. 39.

substances. *See* Tr. 899–902. However, in light of TPA's history of chronic inaction in the face of problematic testing results, enhancements regarding UDS testing bear little relevance on the Respondent's suitability for a registration. Put another way, unreliable results are as easily ignored as reliable ones.

During the course of her testimony, the Respondent conceded that the recordkeeping entries she employed in her patient charts ''were not completely adequate,'' but ascribed at least some of the blame to the nature of her early training during the 70's and 80's. Tr. 903. The Respondent testified that she now understood how the field had changed over time. *Id.* There was no direct link made by the Respondent between recent developments in examination protocol and her history of seeming indifference to diversion red flags (principally the unresolved UDS result anomalies) that appear throughout the examined patient charts. In the Respondent's estimation, she may have been ''duped'' by some of her patients in the midst of her endeavors ''to take care of these patients with all [her] heart.'' Tr. 993–94, 1041.

The Respondent, through her own testimony, submitted into evidence numerous certificates demonstrating the successful participation in CME seminars. Some courses were completed pursuant to the probation status imposed on her by the Medical Board as obligatory terms, while others were undertaken over-and-above the probationary conditions. Tr. 986–87; *see* Tr. 987–92; Resp't Ex. 3 (''Intensive Course in Medical Record Keeping,'' June 3–4, 2010) (certificate of attendance only, no credit value indicated); Resp't Ex. 4 (''Prescribing Controlled Drugs,'' July 21–23, 2010) (20.75 credits);[54] Resp't Ex. 7 (''Intensive course in Medical Ethics, Boundaries & Professionalism,'' Sept. 2–3, 2010) (22.50 credits); Resp't Ex. 8 (''Topics in Pain Management, Volume 26, Issue 1,'' Sept. 20, 2010) (1.50 credits); Resp't Ex. 9 (''Topics in Pain Management, Volume 26, Issue 2,'' Sept. 20, 2010) (1.50 credits); Resp't Ex. 10 (''Risk Management Essentials for Physicians, Second Edition, Part I,'' October 15, 2010) (5.0 credits); Resp't Ex. 12 (''Controversies in Pain Management, Pain, Dependency, and Addiction,'' Nov. 12, 2010) (7.00 credits); Resp't Ex. 13 (''Topics in Pain Management, Volume 26, Issue 3,'' Nov. 24, 2010) (1.50 credits); Resp't Ex. 14 (''CME.COM Principles and Practice of Pain Medicine,'' Dec. 30, 2010) (27.00 credits).[55] She also provided a letter, dated August 23, 2010, from Winston C.V. Parris, M.D., a professor of anesthesiology and the Division Chief of Pain Management at Duke Medicine. Resp't Ex. 5. Dr. Parris certified that the Respondent was with him for two weeks in August of 2010, at the Pain and Palliative Care Clinic at Duke University Medical Center. *Id.* During that time, the Respondent observed Dr. Parris's new patient interactions and evaluations, follow-up patient assessments, and performance of interventional procedures. *Id.* In addition to her observations, Dr. Parris verified that the Respondent also ''attended all Grand Round lectures and Journal Club'' and participated in discussions regarding chronic pain management patients. *Id.; see* Tr. 988–89.

During the Respondent's testimony, there was no acknowledgement of her own culpability. Consistent with her guilty plea and the surrender of her COR, the Respondent maintained a relatively calm demeanor that lent itself more to one patiently enduring a required procedural evolution than one who has truly acknowledged any measure of wrongdoing or desired to signal acceptance of any measure of responsibility. On the issue of credibility, the Respondent repeatedly acknowledged clear conflicts with admitted documentary evidence of record, and was forced, on multiple occasions, to withdraw from positions she had previously presented without discernible ambiguity. Her position that much of the deficiencies outlined in discharging her obligations were explainable by the time period during which she attended medical residency[56] flies directly in the face of her extensive and impressive training and experience in the fields of pain management and anesthesiology, and simply stated, is patently implausible. She was also frequently ambiguous in outlining details associated with her patient care. In short, beyond some biographical data and a handful of uncontested topics, the Respondent's testimony was not sufficiently detailed, consistent, or plausible to be deemed fully credible on contested issues in these proceedings.

Patient Chart Reviews

DIs Phillips and Stevens both reviewed patient charts that the former had procured from the Tennessee Medical Board and the Commonwealth's Attorney's Office. A subset of ten of the acquired charts were provided to and reviewed by the Government's medical consultant, Dr. Loyd, and the entire group was eventually provided to and reviewed by the Respondent's medical expert, Dr. Miller. By a preponderance, the evidence of record supports the following observations and findings relative to the reviewed patient records.

Patient LC

The LC patient chart[57] was reviewed by DI Stevens, was received in evidence for review by this tribunal, and was analyzed by Dr. Loyd. Dr. Loyd testified that although his review of LC's chart revealed numerous urinalysis anomalies, there was no evidence of any of the sort of patient confrontations about those anomalies that he indicated were required by his understanding of accepted medical practice.[58] Tr. 60–61. Loyd also testified that there were other red flags of diversion in the chart, including requests for specific drugs, signs of doctor shopping (to the tune of ''eight different providers, utilizing five different pharmacies in a three-month period''),[59] and a crescendo pattern of controlled substance use that was unsupported by history, physical examination, or imaging. Tr. 63, 65–66. According to Dr. Loyd, these red flags, that were present in the chart, did not receive the required patient confrontation. *Id.* Additionally, a chart note references a possible addiction issue, recommends a formal addiction treatment regimen at an identified facility, but sets forth no measure of documented follow up on the issue. Tr. 66–67. Significantly, Dr. Loyd found that the Respondent continued to prescribe controlled substances to LC even after the UDS anomalies became apparent. Tr. 72. Loyd testified he concluded that the controlled substances prescribed by the

[54] Where indicated, all credits submitted reflect that they are awarded as something counting toward ''American Medical Association (AMA) PRA Category 1,'' a term that regrettably does not have the benefit of further explanation in the record.

[55] Although unclear as to any relevant purpose it has toward the disposition of her COR application, the Respondent also provided proof as to her attendance in a course on ''Domestic Violence: Care and Intervention,'' completed as mandatory CME credit for her continued licensure on November 1, 2010. Resp't Ex. 11; Tr. 990.

[56] Tr. 903.

[57] *See* Gov't Ex. 24.

[58] Although Dr. Loyd initially testified that he perceived that the patient's failure to follow up on a physical therapy recommendation also constituted a red flag that did not benefit from a required confrontation, his subsequent acknowledgement that he was unable to ascertain the mechanics of how the recommendation was made or followed up on, sufficiently eviscerated the strength of this observation to deprive it of any appreciable weight. Tr. 58–62.

[59] Tr. 66.

Respondent to LC ''were outside the scope of accepted medical practice and not for legitimate medical reasons.'' *Id.* In his report, Dr. Loyd summarized his conclusions regarding the Respondent's controlled substance prescribing practices relative to LC as follows:

> [LC] was prescribed scheduled drugs in quantities and frequency [sic] inappropriate for his complaint or illness. He had dramatic and compelling but vague complaint (10/10 pain) not substantiated by physical exam findings or imaging. He was clearly ''doctor shopping.'' He had five inconsistent drug screens, several of which were suspicious for diversion. He had a crescendo pattern of drug use with progression to multiple drugs. He requested drugs by name. . . . The controlled substances prescribed in [LC's] case were outside the scope of accepted medical practice and not for a legitimate medical purpose.

Gov't Ex. 57 at 2.

Through his testimony, DI Stevens identified what he believed to be six red flags [60] of abuse or diversion, five of which were purportedly inconsistent UDS results and one that was a letter reporting suspicion of doctor shopping by a health insurance company. DI Stevens addressed these areas in the LC patient chart chronologically.

The first UDS addressed by DI Stevens' testimony was conducted on August 20, 2003. Tr. 425–26; Gov't Ex. 24 at 64. The results of this UDS reflected values below the cutoff thresholds (negative results) for each of the controlled substance classes tested, including amphetamines, barbiturates, benzodiazepines, cocaine, marijuana, methadone, methaqualone, opiates, phencyclidine (PCP), and propoxyphene. Gov't Ex. 24 at 64; see Tr. 425–26. DI Stevens, who is not a medical professional, testified that he found a prescription in the chart issued by the Respondent on July 23, 2003 (less than a month prior to the UDS) for Percocet, a Schedule II controlled substance that contains oxycodone. Tr. 426; Gov't Ex. 24 at 50 (script photocopy); *see* 21 C.F.R. § 1308.12(b)(1)(xiii) (2011). Percocet is a drug that DI Stevens expected to cause a positive result on Patient LC's UDS for opiates.[61] Notwithstanding this alleged anomaly, which would have been received by the Respondent's clinic some days after the screen, DI Stevens pointed out that Patient LC continued to receive controlled substances in ascending quantities and additional varieties at subsequent office visits, including the first visit after the UDS on October 15, 2003, Gov't Ex. 49 (script photocopy for #84 Percocet 10/325 mg), and another visit on January 6, 2004 by the Respondent, *id.* at 47 (script photocopies for #112 Percocet 10/325 mg and the benzodiazepine #30 Valium 5 mg), without any notation regarding the anomaly to the patient chart, Tr. 427–31; *see also* Gov't Ex. 24 at 17–18 (chart entries dated October 15, 2003 and January 6, 2004 reflecting issuance of same prescriptions as the script photocopies).[62] DI Stevens testified that the chart note for the October visit, rather than expressing concern over the anomaly, instead observed (counter intuitively) that ''patient has no side effects or evidence of addiction.'' Tr. 430; Gov't Ex. 24 at 18 (chart entry dated October 15, 2003, ''Patient has no side effects or evidence of addiction''); *see also id.* at 17 (chart entry dated January 6, 2004, ''No side effects or evidence of addiction'').

DI Stevens testified that a drug screen collected March 3, 2004 indicated Patient LC was negative for all controlled substances including opiates and benzodiazepines, notwithstanding a chart entry reflecting prescriptions issued on February 3, 2004 for Percocet and Valium signed by the Respondent. Tr. 431–33; Gov't Ex. 24 at 17. Again, this information inspired the Respondent to enter a note that there were ''[n]o side effects or evidence of addiction.'' Tr. 433; Gov't Ex. 24 at 17. However, DI Stevens testified to finding photocopies of additional scripts issued and signed by the Respondent following the March 2004 UDS results. Tr. 433–34; Gov't Ex. 24 at 44; *see also id.* at 16 (chart entry with Respondent's signature dated May 26, 2004 documenting ''No side effects or evidence of addiction'' and prescriptions for Percocet and Valium).

DI Stevens also noted a September 15, 2004 discrepant UDS report that signaled positive results for the presence of opiates, benzodiazepines, and methadone. Tr. 434; Gov't Ex. 24 at 60. Stevens review of the chart revealed controlled prescriptions only for Percocet and Valium (no methadone) at documented visits occurring before the test, Tr. 435–36; Gov't Ex. 24 at 16 (chart entry dated May 26, 2004 signed by Respondent), and that Patient LC received his first prescription for methadone from the Respondent's practice on the same visit that he first tested positive for the drug, Tr. 436; Gov't Ex. 24 at 15 (chart note), 43 (script photocopy). The chart also shows no controlled substance prescription for the month before the September UDS, and no explanation as to why the patient was not coming in, or whether during his absence from the practice he was receiving controlled prescriptions elsewhere. *See* Tr. 438. According to DI Stevens, this is another example of a drug screen anomaly. *See* Tr. 437–38. A progress note dated September 15, 2004 (a time concurrent with the UDS but before methadone was prescribed) and signed by the Respondent reads, ''[Patient] feels that the methadone gives him more profound relief. No side effects or evidence of addiction.'' Gov't Ex. 24 at 15. The chart sets forth neither a basis for the patient's knowledge of the advantages of methadone, nor a comment regarding whether and under what conditions (legal or otherwise) LC obtained and tried methadone, nor is any detail provided as to what dosages of methadone were taken by LC and how often. Despite these possible causes for concern (or at the very least grounds for further documentation), DI Stevens testified that he observed evidence within LC's patient chart of controlled substances being prescribed by the Respondent at his next two office visits, on October 13, 2004, for Valium and Percocet, and on November 10, 2004, for Valium and methadone. Tr. 436–37; Gov't Ex. 24 at 15 (chart notes).

The next red flag that DI Stevens identified in his testimony was a report generated by, and accompanied with a

[60] A single anomalous UDS may contain multiple anomalies.

[61] During the course of DI Stevens' testimony, it quickly became apparent that he was operating under the assumption that a substance containing oxycodone, like Percocet, should cause a positive on the UDS for opiates if taken as prescribed the month preceding it. *See, e.g.,* Tr. 434–38 (noting the significance that Patient LC tested positive in a later UDS for opiates even though he was not issued a prescription for Percocet a month immediately prior), 460 (commenting the significance of Patient HGW's UDS negative result for opiates even though he obtained prescriptions for Percocet and OxyContin a month prior).

[62] Both parties to this proceeding submitted proposed evidence in the form of photocopies contained in exhibits in advance of hearing that, due presumably to poor or multi-generational photocopying, were found profoundly unintelligible. Prior to hearing, this tribunal issued an advisal to the parties taking notice of this issue, ALJ Ex. 19, and the parties were further advised on the record before the first witness was sworn that these pages would be returned to its respective proponent at the time the balance of the exhibit was offered into evidence, Tr. 5–6, as these pages could not constitute substantial evidence in any shape or form. Throughout the course of the hearing, to cure this problem, the parties identified some problematic portions of their respective proposed exhibits and were afforded the relief of substituting better-quality reproductions. Insofar as proving that prescriptions for controlled substances emanated from the Respondent, the Government also employed the alternative method of relying solely on progress and treatment plan notes entered in the patient chart appearing to have been written by the Respondent's hand when the photocopies of scripts were indiscernible or only partially depicted. This alternative process proceeded without objection by the Respondent, and the Respondent confirmed, through her own testimony, the reliability of prescription notes that Government witnesses claimed were made by her, Tr. 982–83.

cover letter dated November 19, 2004, from, the insurance company United Health Care, which was found in the LC patient chart and addressed to the Respondent.[63] Tr. 438–39; Gov't Ex. 24 at 70–71. The report advised that during the third quarter of 2004, eight prescribers individually prescribed an assortment of controlled substances to Patient LC that he filled at five different pharmacies. *Id.* at 70. In its letter, the insurance company ''encourage[d]'' Respondent to, ''if appropriate, use [the report] to modify [Patient LC's] use of narcotic analgesics.'' *Id.* at 71. Based upon his experience as a diversion investigator, Stevens believed this information to be demonstrative of doctor shopping on the part of Patient LC. Tr. 439. A chart note reflective of this information was identified by DI Stevens to have been made by Dr. Vilvarajah on December 7, 2004, to wit: ''According to UHC [Patient LC] visited 8 MD's, 5 Pharmacies [sic] and obtained 215 days [sic] supply during 7/9/04 through 9/30/04.''[64] Tr. 439; Gov't Ex. 24 at 13. A hand-scrawled annotation was also identified as the phrase ''Correct immediately!'' with an arrow pointing to the total number of unique pharmacies reported. Gov't Ex. 24 at 82. Still, DI Stevens identified prescriptions issued by the Respondent approximately one month later on January 5, 2005, for methadone and Valium, notwithstanding the presence of the entries and insurance letter in the chart. Tr. 440; Gov't Ex. 24 at 40. A chart note reflecting these prescriptions was entered by the Respondent immediately below (on the same page as) Dr. Vilvarajah's chart note documenting his doctor shopping reservations. Gov't Ex. 24 at 40.

Another anomalous UDS, taken May 25, 2005, was also addressed by DI Stevens' testimony. *See* Tr. 440–42; Gov't Ex. 24 at 59. The results, reminiscent of others discussed *supra,* were negative for all controlled substances tested. Tr. 441–42; Gov't Ex. 24 at 59. Because Patient LC received prescriptions for Valium and methadone at an office visit the month before the test on April 27, 2005, a UDS report that was devoid of these substances would presumably come as a surprise to the treating physician confronting such results. Tr. 441; Gov't Ex. 24 at 12 (chart note). DI Stevens testified that because he expected, based on the controlled substances prescribed the month before the UDS, to see positive showings for benzodiazepines and methadone, this was another example of a red flag of diversion that earned no mention in the progress notes written into the patient chart by the Respondent. Tr. 442–43. Nevertheless, Patient LC received controlled substances issued by the Respondent at the next two office visits for Valium and methadone on June 22 and July 22, 2005, respectively. Tr. 443–45; Gov't Ex. 24 at 11 (chart note), 37 (June 22, 2005 script photocopy for methadone), 36 (July 20, 2005 script photocopies for methadone and Valium).

An UDS that was collected on March 1, 2005 reflected a positive response only for methadone should have raised some level of concern, in view of the fact that the Respondent has prescribed methadone plus Percocet and Valium to LC twenty-eight days prior (February 1, 2006) to the date the urine sample was provided. Tr. 445–46; Gov't Ex. 24 at 56, 32 (script photocopies); *id.* at 12 (chart note). As perceived by DI Stevens, not even passing concern over the apparent inconsistency appears anywhere in the patient chart. Tr. 446–47; Gov't Ex. 24 at 8–9. In spite of the drug screen, the Respondent blithely continued to provide Patient LC with a steady flow of Percocet, methadone, and Valium prescriptions during the course of the next three office visits that followed the UDS results. Tr. 447–48; Gov't Ex. 24 at 30 (script photocopies dated April 26, 2006), 29 (script photocopies dated May 24, 2006), 28 (script photocopies dated June 21, 2006); *see id.* at 7–8 (chart entries reflecting same prescriptions issued by Respondent).

Patient RN

The patient chart[65] maintained on Patient RN was reviewed by DI Phillips, was received in evidence for review by this tribunal, and was evaluated by Dr. Loyd. Dr. Loyd's report and testimony discussed the controlled substance prescribing practices evident in the patient chart maintained on RN. Loyd noted that although this chart reflected an effective pain assessment history, no alcohol or substance abuse history was taken, and although controlled substances were ostensibly prescribed to address complaints of chronic knee pain, the chart failed to show any physical examination of the knee during the patient's monthly office visits. Gov't Ex. 57 at 7. It was Loyd's view that the upward titrations of controlled pain drugs were implemented ''without a history, physical exam or imaging to support the increase in medications.'' *Id.* In fact, Loyd testified that he ''didn't feel like there was enough [in the chart] to indicate the use of opiate narcotics.'' Tr. 163.

More fundamentally, Loyd observed that three UDS reports recorded in the chart reflect the absence of controlled substances that had been prescribed to RN and should have been in his system.[66] Gov't Ex. 57 at 7. The chart reflects that RN eventually was expelled from the practice upon a fourth UDS which showed the presence of cocaine. Gov't Ex. 39 at 4; Gov't Ex. 57 at 7.

At the conclusion of his assessment regarding the RN patient chart, Dr. Loyd summarized his conclusions as follows:

> [RN] was prescribed scheduled drugs in quantities and frequency [sic] inappropriate for his complaint(s)—left knee and low back pain. These complaints were not supported with physical exam findings or imaging. He had no substance abuse history taken. He requested medication by name—Percocet. He had a total of four failed drug tests. He had findings that were consistent with drug diversion that were not followed up on. He had a crescendo pattern of drug use with progression to multiple drugs. . . . The controlled substances prescribed for left knee pain and low back pain in [RN's] case were outside the scope of accepted medical practice and not for a legitimate medical purpose.

Id. at 7–8.[67]

In her testimony, DI Phillips presented what she believed to have been five anomalous UDS results evident in RN's patient chart. Among them was a drug screen reporting negative results for all controlled substances a month after opiates and benzodiazepines were prescribed to RN, Tr. 703–06; Gov't Ex. 39 at 14 (chart entry dated August 27, 2005 noting prescriptions for Percocet, OxyContin, and Xanax), 37 (photocopies of same), 50 (UDS report dated September 6, 2005 negative for all substances), and another reflected a positive result for cocaine, Tr. 715–16; Gov't Ex. 39 at 44 (UDS report dated March 24, 2007); *see* Gov't Ex. 39 at 4 (March 31, 2007 chart note by Dr. Vilvarajah reflecting RN positive for cocaine).[68] Regarding a UDS that popped positive for methadone and opiates, neither of which were ever prescribed by Dr. Vilvarajah, and had not been prescribed for the month prior to the screen by the Respondent, the presence of methadone was addressed by the Respondent as reflected in

[63] For reasons non-apparent, the report was dated after the cover letter, November 30, 2004.

[64] Therefore, Patient LC was able to fill enough prescriptions to supply him with 215 days worth of controlled substances in only an 83-day period.

[65] *See* Gov't Ex. 39.

[66] Yet Dr. Loyd felt that regarding a positive methadone UDS result, the chart reflected a sufficient inquiry. Tr. 300.

[67] The Government also elicited some testimony regarding Dr. Loyd's estimation of the relative distance between RN's home and the Respondent's practice, Tr. 159–61, but the issue was not sufficiently developed to merit consideration on any issue to be decided in this case, and like other testimony relative to such distances, played no part in this recommended decision.

[68] The patient record shows that Dr. Vilvarajah terminated Patient RN from the practice as a consequence for testing positive for cocaine. Gov't Ex. 39 at 3–4.

a chart note. Tr. 707–08, 710–11, 845–49. The handwritten entry by the Respondent indicated that Patient RN had been admitted to the VA hospital and that the VA administered methadone to RN. Tr. 846–47; Gov't Ex. 39 at 11–12; *see* 710–11. Records within Patient RN's file to verify the veracity of her account, or documented efforts to procure them, were absent from the chart. During her testimony, the Respondent acknowledged that RN's chart did not reflect any efforts by anyone at TPA to reach out to the VA hospital to inquire about the alleged methadone prescription. Tr. 1012.

DI Phillips also pointed to chart indications that Patient RN tested negative for opiates despite prescriptions for oxycodone 40 mg and oxycodone 15 mg a month before the test. Tr. 711–12; Gov't Ex. 39 at 10 (chart entry of prescriptions issued August 12, 2006), 47 (UDS dated September 9, 2006 negative for opiates). DI Phillips' testimony demonstrated that the Respondent's seemingly inexorable response to each anomaly was to provide Patient RN with additional prescriptions for controlled substances.[69] *See, e.g.,* Tr. 707–09, 713–15.

Patient BR

The BR patient chart [70] was reviewed by DI Phillips, was received in evidence for review by this tribunal,[71] and was evaluated by Dr. Loyd. In his report and testimony, Dr. Loyd noted that pain medications trended upwards, and that the chart contained indications of three UDS reports where BR failed to test positive for controlled substance pain medications that should have been in his system, with no indication that the matter was raised between doctor and patient. Gov't Ex. 57 at 10; Tr. 186–87. The chart also contained a remark that BR was visibly drowsy while standing by for his appointment in the office waiting room, as well as a phone call notation that a pharmacy employee had telephoned to report that on the same day he was nodding off in the waiting room, he had fallen down at the pharmacy. Gov't Ex. 57 at 10; Tr. 188–89. Loyd testified that respiratory suppression is a potential side effect of the controlled substance medications prescribed to BR, Tr. 187, 190, and that, in his expert opinion, simply jotting a note that memorialized these events and conducting no confrontation or follow up is not within the usual course of professional practice, Tr. at 189–91.

Loyd also found a red flag that, although BR's intake paperwork indicated that he was currently taking no medication,[72] a UDS [73] performed registered positive for marijuana metabolite and opiates. Tr. 191–93. There was no chart indication that an appropriate confrontation about this issue between physician and patient ever occurred.

Dr. Loyd's report set forth the essence of his analysis as follows:

> [BR] was prescribed narcotics inappropriately. He had a trauma injury that may have required a controlled substance. However, his urine drug screens were negative for medication that he was being prescribed for his pain. He had a crescendo pattern of drug use with a progression to multiple drugs. . . .[74]

Gov't Ex. 57 at 10.

Patient MC

The MC chart [75] was reviewed by DI Phillips, was received in evidence for review by this tribunal,[76] and was evaluated by Dr. Loyd. Dr. Loyd testified that although chart indicators supported the utilization of controlled substance pain agents, Tr. 83–85, the Respondent incorrectly continued to prescribe controlled substances to MC, even after encountering multiple UDS anomalies with no documentation supporting any evidence that an appropriate patient confrontation took place.[77] Tr. 78–80. Even though MC's patient chart shows three UDS reports which were negative for opiates that were prescribed, according to Loyd's report, ''[t]here were no questions raised as to why the screens were negative and the possibility of diversion was not mentioned.'' Gov't Ex. 57 at 3. Based on the uninterrupted controlled substance prescribing without probing confrontation, Dr. Loyd opined that the Respondent's controlled substance prescribing regarding Patient MC was not within the usual course of a professional practice. Tr. 86.

Patient MF

The MF patient chart [78] was reviewed by DI Phillips, was received in evidence for review by this tribunal,[79] and was evaluated by Dr. Loyd. Dr. Loyd testified that the chart maintained on Patient MF demonstrated both a crescendo pattern

[69] One purported UDS irregularity suggested by DI Phillips relative to the RN chart does not withstand objective analysis. A UDS conducted in connection with RN's initial visit on March 11, 2005 reflects the presence of opiates in RN's system on that date. Tr. 717; Gov't Ex. 39 at 52. DI Phillips concluded that this was problematic based upon the form for new patient notes wherein it signified that RN was not currently on any medications. Tr. 716; Gov't Ex. 39 at 67. While, after it was brought to her attention, DI Phillips conceded that on the same form under ''History of Present Illness'' prescriptions for OxyContin and Lortab were written, it was her theory that these drugs were presumably taken by Patient RN at some point, but not necessarily contemporary with the initial visit. Tr. 851–53. It was further revealed on cross-examination that Patient RN indicated on one of his intake forms that he was currently receiving oxycodone and Lortab for his pain. Tr. 853–54, Gov't Ex. 39 at 74. Thus, on the current record, the March 11, 2005 UDS report cannot be conclusively found to support a true anomaly requiring additional investigation or confrontation.

[70] *See* Gov't Ex. 42.

[71] *Compare* Gov't 42 at 54 (Patient BR denies on patient history intake form ''nervous breakdown/depression/anxiety''), *with id.* at 52 (patient anxiety documented on new patient notes); *compare id.* at 44 (UDS anomalies positive for marijuana and non-prescribed opiates, *and id.* at 43 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 11, 30 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax), *and id.* at 11, 29 (same); *compare id.* at 42 (UDS anomaly negative for prescribed opioids), *with id.* at 10, 28 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax), *and id.* at 10, 27 (same but substituting methadone for Percocet), *and id.* at 9, 26 (same), *and id.* at 8–9, 25 (same), *and id.* at 8, 24 (same); *compare id.* at 39 (UDS anomalies negative for prescribed methadone and opioids), *and id.* at 7 (chart note by Dr. Vilvarajah that BR tripped and fell in pharmacy day of UDS and that BR was negative for opiates and methadone), *and id.* (chart entry at next visit by Dr. Vilvarajah that BR was notified about the pharmacist call), *with id.* at 6, 21 (prescriptions afterward by Respondent for methadone and Xanax), *and id.* at 6, 20 (same), *and id.* at 5, 18 (same), *and id.* at 4, 17 (same), *and id.* at 3, 16 (same). For reasons discussed elsewhere in this decision, DI Phillips' observations regarding the possible commuting distance for Patient BR that she apparently gleaned from the Internet, Tr. 792–93, has not been sufficiently developed on the present record to be utilized for any purpose in this recommended decision.

[72] Gov't Ex. 42 at 55.

[73] Gov't Ex. 42 at 44.

[74] Although Dr. Loyd also mentioned that he attached some level of significance to his observation that BR did not participate in recommended physical therapy, Tr. 185–86, as discussed elsewhere in this decision, *see supra* note 42, this aspect of his review is critically diminished by Loyd's acknowledgement that he is unfamiliar with the office protocol regarding referrals and follow-up. Tr. 58–62. Similarly, although in his report and initial testimony Dr. Loyd felt that the patient's continued ability to pursue physically arduous employment while simultaneously registering complaints of significant pain constituted a red flag, he subsequently retreated from that position. Tr. 195–97.

[75] *See* Gov't Ex. 25.

[76] *Compare* Gov't Ex. 25 at 50 (UDS anomaly negative for prescribed opioids), *with id.* at 13, 37 (prescriptions afterward by Respondent for OxyContin and Percocet with note authored by her ''no evidence of addiction''), *and id.* 13 (same); *compare id.* at 48 (UDS anomalies positive for PCP and negative for prescribed opioids), *with id.* at 9, 28 (prescriptions afterward by Respondent for OxyContin and Percocet), *and id.* at 9, 27 (same), *and id.* at 8, 26 (same), *and id.* at 7–8 (same); *compare id.* at 47 (UDS anomaly negative for prescribed opioids and note on report by Dr. Vilvarajah remarking same), *with id.* at 6, 22 (prescriptions afterward by Respondent for OxyContin and Percocet and chart entry to ''[c]ontinue present pain regime''), *and id.* at 4, 18 (prescriptions same).

[77] While Dr. Loyd testified that he would have preferred to see additional evidence of development of a potential psychological issue stemming from a traumatic event raised by MC's history, Tr. 82–83, 85–86, there was insufficient development of this issue to put it to useful purpose in a disposition of the issues relevant to this case.

[78] *See* Gov't Ex. 29.

[79] *Compare* Gov't Ex. 29 at 48 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 9, 29 (prescriptions afterward by Respondent for OxyContin 20mg, OxyContin 40mg, and Xanax); *compare id.* at 46 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 5 (chart entry by Respondent ''Lab results discussed with patient and copy given. P[atien]t's mother died a w[ee]k ago and the next day after the funeral, her father fell and got a head concussion [illegible] was released yesterday. P[atien]t feel (sic) overwhelmed [with] all these problems.''), *and id.* at 4–5, 21 (prescriptions by Respondent after UDS and concurrent with chart entry for OxyContin, Percocet, and Xanax), *and id.* at 4, 19 (same prescriptions), *and id.* at 3, 17 (same prescriptions).

of controlled substance use and multiple UDS anomalies, neither of which received the benefit of an appropriate confrontation conference with the patient.[80] Tr. 89–94. According to Dr. Loyd's report, the chart showed three UDS reports that were negative for prescribed controlled substances that had been prescribed to [MF] and should have registered positive, and that ''[n]o questioning took place as to why these screens didn't show the drugs [MF] was supposed to be taking[,] and the possibility of diversion was not raised.'' Gov't Ex. 57 at 4. Regarding a subsequent UDS that reflected a positive result for methadone, a drug that had not been prescribed to Patient MF, the report noted that the patient's explanation that she had fallen out of bed and taken her husband's medication was an unacceptable explanation which only showed a violation of the law and her medication pain agreement. *Id.*

Regarding the Respondent's controlled substance prescribing to MF, Dr. Loyd acknowledged that narcotics were appropriate for this patient based on the chart,[81] but opined that ''[t]he controlled substances prescribed in th[is] case were inappropriate in strength and frequency while obvious signs of misuse of controlled substances were ignored,'' Tr. 101.

DI Phillips' testimony identified a drug screen report that reflected positive results for methadone and propoxyphene, two substances that were not prescribed to Patient MF by either the Respondent or Dr. Vilvarajah, and a negative result for benzodiazepines, which had been prescribed to MF in the form of Xanax a month prior to the test. Tr. 756–57; Gov't Ex. 29 at 14 (chart entry noting prescriptions issued September 14, 2005), 51 (UDS report dated October 12, 2005). As acknowledged by DI Phillips, in a chart note, the Respondent recorded that she confronted and admonished MF about her unauthorized methadone use. Tr. 841; *see* Gov't Ex. 29 at 13. It was also DI Phillips' testimony that other than reading on to check for patient compliance with the Respondent's warning, she declined to make a judgment call on the sufficiency of the Respondent's actions here,[82] Tr. 845–46, but did note that there was nothing to indicate that the positive propoxyphene elicited any documented reaction from the Respondent. Tr. 841. Regarding MF's explanation that she took her husband's methadone after a spill out of bed, Phillips opined that beyond Dr. Loyd's estimation that the excuse was wanting, the scenario was not merely indicative of a red flag, but constituted an admission of actual diversion. Tr. 89–90. What is more, as highlighted in the Government's brief and similar to the unexplained presence of propoxyphene, no effort was documented to confront Patient MF regarding the absence of Xanax (which had been prescribed) from her system. *See* Gov't Br. at 17. Later drug screens in the record support the continued practice of the Respondent to prescribe controlled substances to Patient MF in the face of red flags and without raising them with the patient.

Patient TH

The TH chart[83] was reviewed by DI Phillips, was received in evidence for review by this tribunal,[84] and was evaluated by Dr. Loyd. In his testimony and in his report, Dr. Loyd observed that the chart maintained on Patient TH reflected several red flags. A UDS administered at the time of intake showed positive for cocaine. Gov't Ex. 57 at 5; Gov't Ex. 33 at 13, 49. The chart does record a confrontation of sorts on this issue, wherein TH apparently explained his use as a method to ''deal with the pain.'' Gov't Ex. 33 at 13. However, during his testimony, Dr. Loyd explained that while direct application of cocaine could cause some level of local, topical numbing, the ingestion of cocaine has no pain relieving feature. Tr. 289–90. Inasmuch as the offered explanation (that the patient was using cocaine to ameliorate pain symptoms) has no medically reasonable basis, the note documenting the patient's statement in the chart can hardly be reasonably perceived as a valid explanation of a UDS anomaly produced by the investigation of a serious registrant.

Dr. Loyd also described a subsequent positive marijuana UDS result, Gov't Ex. 33 at 45, as well as negative drug screens that failed to show the presence of controlled substances the patient had been prescribed, Gov't Ex. 57 at 5; Tr. 104–06. Loyd opined that the chart reflected inadequate follow up measures,[85] that there was no sign of the required patient confrontation on the issues, and that the prescribing of controlled substances should have been abated upon the second UDS that reflected an illicit substance. Tr. 107. In his report, Dr. Loyd noted a two-year period of treatment that was devoid of physical exams and imaging reports, and noted that

> [d]uring this same two[-]year period [TH] had two other [UDSs] that were inappropriate for the medications that he was being prescribed [one that was][86] negative for [benzodiazepines] and opiates—he was supposed to be taking both and [another that was] negative for opiates [that] he was supposed to be taking. No questioning took place as to why these were negative and about the possibility of diversion.
> Gov't Ex. 57 at 5.

Dr. Loyd testified that while he takes no professional issue with the decision to prescribe controlled substances based on the chart findings, the prescriptions were not within the usual course of a professional practice in that ''[t]he strengths and frequency were inappropriate given the history, physical examination and imaging findings and the [UDSs] being inconsistent [was] ignored. Tr. 102. In his report, Dr. Loyd stated that TH

> was prescribed scheduled drugs in quantities and frequency [sic] inappropriate for his complaint or illness. He lacked physical exam findings or imaging results to support the use of chronic narcotics. [TH] had a crescendo pattern of drug use with progression to multiple drugs. He had a history of active illicit drug use—cocaine and marijuana. He had multiple, inconsistent drug screens that were not questioned. The controlled substances prescribed in [TH's] case were outside the scope of accepted

[80] Dr. Loyd also discussed a letter in the patient chart from MF's attorney detailing an interaction with police wherein her medication was seized, and asking that her medication be replaced. Tr. 95–99; Gov't Ex. 57 at 4. There was some level of confusion regarding the date of the letter, Tr. 280–82, 314–15, and insufficient development of the issue to reliably divine an appropriate utilization of this incident for a relevant issue in the case.

[81] Tr. 102.

[82] Undoubtedly a prudent course in view of her lack of medical training.

[83] *See* Gov't Ex. 33.

[84] *Compare* Gov't Ex. 33 at 49–50 (UDS anomaly positive for cocaine), *and id.* at 48 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 13 (prescriptions afterward by Respondent for OxyContin 20 mg, OxyContin 40 mg, Tylox, and Xanax and chart note by Respondent noting Patient TH took cocaine to try to ''deal'' with the pain but absence of explanation for negative prescribed opioids and benzodiazepines result), *and id.* at 12 (same), *and id.* at 12, 40 (same), *and id.* at 11, 39 (same); *compare id.* at 45 (UDS anomaly positive for marijuana), *with id.* at 7, 42 (chart entry by Dr. Vilvarajah to repeat UDS because of possible false positive due to TH's denial of marijuana use and claim of taking several antacids, but no verification of claim and drug test not repeated until eight months later; entry also notes that TH should attend substance abuse classes and proof of attendance and completion is expected, but no follow up indicated in chart), *and id.* at 5, 20 (prescriptions afterward by Respondent for OxyContin, Tylox, and Xanax), *and id.* at 4, 19 (same), *and id.* at 3–4, 18 (same), *and id.* at 15 (same).

[85] Although a chart entry concerning the positive marijuana result reads, ''Takes several antacids possible false (+) will repeat [drug screen],'' Gov't Ex. 33 at 7, Dr. Loyd testified that TH's chart did not reflect any prescription for the antacids that could cause false results for the marijuana metabolite. Tr. 107–08. Furthermore, although Dr. Loyd testified that a UDS should have been conducted a month after the positive UDS was discussed with TH, the patient was not retested for marijuana for another seven months. Tr. 110–12; Gov't Ex. 33 at 42.

[86] Dr. Loyd corrected a UDS date in his testimony. Tr. 113.

medical practice and not for a legitimate medical purpose.

Gov't Ex. 57 at 5.

Patient RW

The RW chart [87] was reviewed by DI Phillips, was placed in evidence for review by this tribunal,[88] and was evaluated by Dr. Loyd. Dr. Loyd's report and testimony addressed his analysis of the chart maintained on Patient RW. Dr. Loyd observed that the intake processes for this patient contained an insufficient history and physical examination and that there was no indication that a substance abuse history was elicited. Gov't Ex. 57 at 12. Loyd noted three UDS results that failed to reflect the presence of controlled substances that had been prescribed and should have been in RW's system. *Id.;* Tr. 210–12.

The report written by Dr. Loyd summarized his review of RW's chart as follows:

[RW] was prescribed scheduled drugs in quantities and frequency [sic] inappropriate for her complaint or illness. She was prescribed narcotics on the first office visit without alternatives being tried and without a physical exam or imaging to support her complaint. No alcohol or drug history was taken. She requested drugs by name—Oxycodone, Hydrocodone. She had urine drug screens that were inconsistent with the medication that she was being prescribed multiple times per day. The controlled substances prescribed in [RW's] case were outside the scope of accepted medical practice and not for a legitimate purpose.

Govt' Ex. 57 at 12; *see also* Tr. 212–13.

Patient LS

The chart [89] maintained on Patient LS was also reviewed by DI Stevens, was received in evidence for review by this tribunal,[90] and was analyzed by Dr. Loyd in his report and in his testimony. Dr. Loyd noted that the LS patient chart evidenced three UDS reports reflecting negative results for controlled substance medications that had been prescribed, which should have been in the patient's system, and which did not inspire any manner of confrontation or inquiry. Gov't Ex. 57 at 11; Tr. 202–05. Loyd also found it significant that the level of controlled substance medication remained stagnant for three years without benefit of further physical examination or imaging.[91] *Id.*

In his report, Dr. Loyd set forth his view on the controlled substance prescribing as follows:

[LS] was prescribed scheduled drugs in quantities and frequency [sic] inappropriate for her illness. She had no physical exam findings or imaging to support the use of chronic narcotics. She was started on controlled substances, multiple, [sic] on the first office visit without alternatives being tried. . . . Her complaint was dramatic and compelling, 9/10 pain, and was not supported with history, physical exam findings or imaging. She had three separate urine drug screens that were inappropriate for the medications that she was being prescribed indicating that she was not taking them as prescribed and raising the possibility of diversion. The controlled substances prescribed in this case were outside the scope of accepted medical practice and were not for a legitimate medical purpose.

Gov't Ex. 57 at 11; *see* Tr. 207.

Patient FH

The patient chart [92] maintained on Patient FH was reviewed by DI Stevens, was placed in evidence for review by this tribunal,[93] and was analyzed by Dr. Loyd. In his report and testimony, Dr. Loyd noted that FH's chart reflects seven UDS reports that did not contain the controlled substance opioids and benzodiazepines that the patient had been prescribed, and no sign of the appropriate doctor-patient confrontation that should have occurred based on those incidents. Gov't Ex. 57 at 6; Tr. 134–37. Although a potentially painful rib fracture was among the possible etiologies of the pain symptoms, FH declined to obtain the chest x-ray directed by the Respondent. Tr. 129. Furthermore, Dr. Loyd testified that his review of the chart did not reveal ''anything from the history, the physical examination or imaging to support . . . a narcotic analgesic at any dose.'' Tr. 129.

In his report, Dr. Loyd provides the following summary regarding his chart analysis:

[FH] was prescribed controlled substances in quantities and frequency [sic] inappropriate for his illness. He was prescribed narcotics on the first office visit. He lacked physical exam findings or imaging to support the indication of controlled substances.[94] He had a crescendo pattern of

[87] *See Gov't* Ex. 50.

[88] *Compare* Gov't Ex. 50 at 34 (UDS anomaly negative for prescribed opioids), *and id.* at 9 (note by Dr. Vilvarajah following that Patient RW tested negative for prescribed medications), *with id.* at 9 (note immediately underneath by Respondent that RW has ''[n]o side effects or evidence of addiction [and that RW] takes her medications regularly [and] feels better''), *and id.* at 8, 23 (prescription afterward by Respondent for Percocet), *and id.* at 7, 21 (same with increased dosage units).

[89] *See* Gov't Ex. 44.

[90] *Compare* Gov't Ex. 44 at 69 (UDS anomaly negative for prescribed opioids), *with id.* at 13, 39 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax), *and id.* at 12 (same); *compare id.* at 66 (UDS anomaly negative for prescribed opioids), *with id.* at 11, 36 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax and chart entry documenting that drug screen results were discussed and a copy of the report was given to LS), *and id.* at 9, 31 (prescriptions same), *and id.* at 8, 30 (same), *and id.* at 7–8, 29 (same); *compare id.* at 65 (UDS anomaly negative for prescribed opioids), *with id.* at 7, 28 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax), *and id.* at 5, 26 (same), *and id.* at 5, 25 (same), *and id.* at 4, 23–24 (same), *and id.* at 3–4, 22 (same).

[91] Although Dr. Loyd testified that in his view the level of the patient's complaints seemed inconsistent with his perceived severity of the MRI results, Tr. 199–200, it would be difficult (and in this case unnecessary) to tease out where his testimony in this regard constitutes a potential good-faith professional difference of medical opinions, from a departure from a registrant-related duty to minimilegitimate prescriptions. The latter concern is a proper focus of ze diversion by issuing only these proceedings, while the former presents an issue for a different venue. 21 C.F.R. § 1306.04(a); *see Gonzales v. Oregon,* 546 U.S. 243, 270 (2006) (explaining that the CSA grants the Attorney General authority to regulate the practice of medicine ''insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood [not the power] to regulate the practice of medicine generally''). Dr. Loyd's testimony that he would have commenced treatment of LS with an NSAID, Tr. 201–02, warrants like consideration.

[92] *See* Gov't Ex. 34.

[93] *Compare* Gov't Ex. 34 at 78 (UDS anomalies negative for prescribed opioids and benzodiazepines and positive for non-prescribed propoxyphene), *and id.* at 76 (UDS anomalies negative for prescribed opioids and benzodiazepines, *and id.* at 75 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 14, 47 (prescriptions afterward by Respondent for OxyContin, Lortab, and Xanax), *and id.* at 14, 46 (same); *compare id.* at 73 (UDS anomalies negative for prescribed opioids and benzodiazepines), *and id.* at 72 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 10, 38 (prescriptions after by Respondent for OxyContin, Lortab, and Xanax), *and id.* at 10 (same), *and id.* at 9 (same), *and id.* at 9, 36 (same); *compare id.* at 70 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 8, 34 (prescriptions afterward by Respondent for OxyContin, Lortab, Xanax), *and id.* at 32 (same), *and id.* at 30 (same), *and id.* at 6 (same with chart entry by Respondent ''Lab results discussed [with patient] and copy given. [Patient] states that he takes [*sic*] ''runs out'' his medications every [month]. . . . No side effects. [Patient] aware that he must take his medication of to [*sic*] his visit to TPA. Will reject random [drug screen].''), *and id.* at 6, 29 (same prescriptions), *and id.* at 5, 28 (same), *and id.* at 5, 27 (same), *and id.* at 4, 25 (same).

[94] Although Dr. Loyd testified that, consistent with the guidance provided in the WHO Ladder, he would have initiated a course of NSAIDs, Tr. 118–21, there is no basis on the current record upon which this apparent difference of medical opinion can be construed to reflect positively or negatively on whether the Respondent failed in some way to discharge her duties as a DEA registrant to minimize the risk of diversion and issue controlled substance prescriptions for a legitimate medical purpose and within the course of a professional practice. *See* 21 C.F.R. § 1306.04(a); *Gonzales v. Oregon,* 546 U.S. 243, 270 (2006) (explaining that the CSA grants the Attorney General authority to regulate the practice of medicine ''insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood [not the power] to regulate the practice of medicine generally''). This is a difference, albeit a nuanced one, from Dr. Loyd's conclusion that the objective imaging, information, and documented observations

drug use with progression to multiple drugs. He seemed to have no interest in his diagnosis as he didn't follow up and obtain a chest x-ray. He had seven inconsistent urine drug screens. The controlled substances prescribed in [FH's] case were outside the scope of accepted medical practice and not for a legitimate medical purpose.

Gov't Ex. 57 at 6. During his testimony, Dr. Loyd affirmed his view that the controlled substance prescribing practices demonstrated in LC's chart were outside the scope of accepted medical practice, were not for a legitimate medical purpose, and were not within the usual course of a professional practice. Tr. 141–42.

Patient DP

Dr. Loyd's report and testimony also outlined his review of the patient chart[95] maintained on DP. Loyd's assessment was that DP's medical history, which included a right-leg crush injury (from a 500-pound boulder), multiple resultant surgeries, and reflex sympathetic dystrophy (described by Loyd as ''very painful and debilitating''), Tr. 171, justified the utilization of controlled pain medication. In fact, Dr. Loyd's report contains his conclusion that ''[t]he narcotics prescribed in [DP's] case were for a legitimate medical condition and [] were used within the scope of accepted medical practice.'' Gov't Ex. 57 at 9.

That said, Dr. Loyd also noted that the chart contained three UDS reports which reflected that prescribed controlled pain medications that should have been present in DP's system were not, and that the chart is devoid of any indication that the patient was confronted about a single one.[96] *Id.;* Tr. 172–73, 176.

Patient ES

DI Phillips also presented testimony regarding her review of the patient chart[97] maintained on Patient ES. Phillips testified that she identified six anomalies connected to UDSs reports in the ES chart. Among those anomalies were testing positive for marijuana while testing negative for all other substances, including benzodiazepines and opiates following prescriptions for Xanax and two strengths of OxyContin, Tr. 722–23; testing negative for all substances, including those prescribed (twice), Tr. 725, 733–34;[98] testing positive for methadone without a prescription from the Respondent's practice, Tr. 728–29; testing negative for benzodiazepines following a prescription for Xanax, Tr. 731–33; and testing negative for opiates after being prescribed two forms of oxycodone, Tr. 739–40.[99] Consistent with the aforementioned anomalies, Patient ES was supplied with prescriptions for controlled substances following them. *See* Tr. 724–30, 733, 735–45.

Patient HGW

DI Stevens reviewed the patient chart[100] of HGW. DI Stevens identified nine UDS that contained anomalies, Gov't Ex. 48 at 161 (dated February 14, 2003), 160 (dated March 14, 2003), 159 (dated April 11, 2003), 157 (dated October 28, 2003), 148 (dated May 19, 2004), 147 (dated March 29, 2005), 146 (dated May 24, 2005), 145 (dated November 10, 2005), 142 (dated May 25, 2006), and one phone message dated December 21, 2005 from another pain management clinic seeking verification of information pertaining to Patient HGW as a new patient (indicating that HGW was doctor shopping on the Respondent's practice),[101] *id.* at 15; *see generally* Tr. 449–75. Anomalies were identified by DI Stevens within each drug screen, yet the Respondent, undeterred, continued to supply the patient with increasing quantities and varieties of controlled substances. For instance, at the first visit, Patient HGW represented that he was not on any medications at all, Tr. 452; Gov't Ex. 48 at 181, yet his drug test came back with positive results for cocaine, marijuana, opiates, and benzodiazepines, Tr. 450; Gov't Ex. 48 at 161–62. HGW was tested again the next month (March 14, 2003) and a second positive marijuana result appeared on the drug screen report. Tr. 453; Gov't Ex. 48 at 160. The Respondent, despite both of these red flags, prescribed Percocet and Xanax on July 31, 2003. Tr. 458; Gov't Ex. 48 at 130. In all, Patient HGW tested positive for marijuana four times while at the Respondent's practice. *See* Tr. 461; Gov't Ex. 48 at 148 (May 19, 2004 UDS), 147 (March 29, 2005 UDS). There were even times identified in the HGW patient chart by DI Stevens that the Respondent continued to prescribe controlled substances following UDS results that were negative for all substances tested. *See, e.g.,* Tr. 467, 469–70. *Compare,* Gov't Ex. 48 at 100–01 (prescriptions dated October 8, 2004 for OxyContin, Xanax, and Percocet), *and* 145 (UDS dated November 10, 2005 reporting negative results for all substances examined), *with* 71 (controlled prescriptions issued December 8, 2005 by Respondent for OxyContin, Percocet, Xanax, and Halcion), *and* 15 (chart note dated December 8, 2005 reflecting issuance of controlled prescriptions, but silent regarding UDS anomaly). Even though each of these anomalous drug screens were noted in the patient chart, the Respondent doled out prescriptions for controlled substances to HGW after almost every one.

Additional Patient Charts

Other medical files were addressed by DI Phillips' testimony in an expedited fashion and were subjected to this tribunal's examination. According to Phillips, her review of each of these charts revealed that the Respondent continued to prescribe controlled substances without resolving UDS irregularities that presented red flags in need of further investigation or inquiry. This list of additional charts reviewed incorporated patients CE (Gov't Ex. 27),[102] DF (Gov't Ex. 28),[103] EJ (Gov't Ex.

in the chart do not support the utilization of controlled substances.

[95] *See* Gov't Ex. 41.

[96] The Government also elicited some testimony regarding Dr. Loyd's estimation of the relative distance between DP's home and the Respondent's practice, Tr. 181–82, but the issue was not sufficiently developed to merit consideration on any issue to be decided in this case, and like other testimony relative to such distances, played no part in this recommended decision.

[97] *See* Gov't Ex. 43.

[98] At the visit following an all-negative drug screen on July 21, 2004, the Respondent entered the following concurrent observations in the patient chart, dated August 18, 2004, that Patient ES is ''very anxious'' due to a divorce evolution and '''runs out' of [medication] 3–4 days before visit,'' but that he also evidences ''[n]o side effects or evidence of addiction.'' Gov't Ex. 43 at 23. These assertions along with the negative drug screen, coexisting in somewhat of a tension with the Respondent's duties as a registrant charged with detecting addiction to those she prescribes controlled substances and verifying red flags, was noticed by the Government in its brief. *See* Gov't Br. at 11 n.13.

[99] Patient ES's medical chart reflects numerous prescriptions for the drug Adipex, which is a brand of phentermine, a Schedule IV controlled substance, prescribed to ES for weight loss. 21 C.F.R. § 1308.14(e)(9) (2011); *see, e.g.,* Gov't Ex. 43 at 20. For reasons that were not established at hearing or otherwise, the Government did not address these prescriptions in its case. Accordingly, they will play no role in the determination that must be made through this recommended decision.

[100] *See* Gov't Ex. 48.

[101] Receiving prescriptions for controlled substances from other physicians was a violation of HGW's pain management contract with the Respondent. Gov't Ex. 48 at 178, para. 9.

[102] *Compare* Gov't Ex. 27 at 24 (UDS anomalies negative for prescribed opioids and benzodiazepines and initialed by Respondent), *and id.* at 7 (chart entry by Respondent noting CE tested negative for her prescribed medications), *with id.* at 6, 14 (prescriptions afterward by Respondent for Lortab and Xanax), *and id.* at 6 (same), *and id.* at 5, 13 (same), *and id.* at 5, 12 (same), *and id.* at 4 (same), *and id.* at 4 (same).

[103] *Compare* Gov't Ex. 28 at 37 (UDS anomaly negative for prescribed opioids), *with id.* at 8, 26 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax and chart entry by Respondent ''no evidence of addiction''), *and id.* at

Continued

35),[104] TK (Gov't Ex. 36),[105] TP (Gov't Ex. 40),[106] DP (Gov't Ex. 41),[107] and SY (Gov't Ex. 52).[108]

During his testimony, DI Stevens in like, summary fashion identified additional medical charts in which he found continued controlled substance prescribing in the face of at least one unresolved UDS anomaly. *See* Tr. 475–508. These additional charts, which were similarly parsed by this tribunal, corresponded to Patients LB (Gov't Ex. 22),[109] RB (Gov't Ex. 23),[110] JE (Gov't Ex. 26),[111] PG (Gov't Ex. 30),[112] BG (Gov't Ex. 31),[113] EG (Gov't Ex. 32),[114] SM (Gov't Ex. 37),[115] MM (Gov't Ex. 38),[116] WS (Gov't Ex. 45),[117] AT (Gov't

9, 25 (same), *and id.* at 10, 21 (same), *and id.* at 11, 20 (same).

[104] *Compare* Gov't Ex. 35 at 54 (pharmacy report supplied by Patient EJ, OxyContin 80 mg absent), *with id.* at 57 (new patient notes documenting purported prescription by prior practitioner for OxyContin 80 mg); *compare id.* at 59 (patient history intake form indicating Patient EJ denied ''nervous breakdown/depression/anxiety''), *with id.* at 57 (new patient notes documenting complaints of anxiety and insomnia); *compare id.* at 46–47 (UDS anomalies positive for purportedly non-prescribed benzodiazepines and propoxyphene), *with id.* at 13, 36 (prescriptions afterward by Respondent for OxyContin, Oxy IR, and Xanax), *and id.* at 12, 35 (same); *compare id.* at 44 (UDS anomaly negative for prescribed opioids and positive for non-prescribed propoxyphene), *with id.* at 11, 33 (prescriptions afterward by Respondent for OxyContin 40 mg, OxyContin 5 mg, and Xanax), *and id.* at 10, 30 (same), and *id.* at 9, 28 (same), *and id.* at 8 (same).

[105] *Compare* Gov't Ex. 36 at 34 (UDS anomalies positive for non-prescribed methadone), *with id.* at 9, 22 (prescriptions afterward by Respondent for OxyContin 40 mg, OxyContin 20 mg, and Xanax), *and id.* at 8, 21 (same), *and id.* at 7, 18 (same); *compare id.* at 32 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 5, 15 (prescriptions afterward by Respondent for OxyContin 20 mg, OxyContin 40 mg, and Ativan (brand name for lorazepam, a Schedule IV substance pursuant to 21 C.F.R. § 1308.14(c)(28) (2011))).

[106] *Compare* Gov't Ex. 40 at 42 (UDS anomaly negative for prescribed opioids), *with id.* at 10, 22 (prescriptions afterward by Respondent for OxyContin and Percocet), *and id.* at 10, 23 (same), *and id.* at 9, 25 (same), *and id.* at 8, 27 (same); *compare id.* at 40 (UDS anomaly negative for prescribed opioids and note written on report by Dr. Vilvarajah that Patient TP is ''negative for prescribed meds''), *with id.* at 7, 29 (prescriptions afterward by Respondent for OxyContin and Percocet), *and id.* at 6, 30 (same), *and id.* at 6, 31 (same).

[107] *Compare* Gov't Ex. 41 at 65 (UDS anomalies negative for prescribed methadone, opioids, and benzodiazepines), *with id.* at 15, 53 (prescriptions afterward by Respondent for methadone, OxyContin 40 mg, and Xanax), *and id.* at 14, 50 (same), *and id.* at 14, 49 (same with increase in dosage units for methadone), *and id.* at 13, 47 (same); *compare id.* at 62 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 11, 42 (prescriptions afterward by Respondent for methadone, OxyContin 40 mg, OxyContin 80 mg, and Xanax), *and id.* at 10, 39–40 (same), *and id.* at 9, 37 (same), *and id.* at 7, 32 (prescriptions by Respondent for methadone, OxyContin 40 mg, Fioricet, and Xanax); *compare id.* at 60 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 6–7, 30–31 (prescriptions afterward by Respondent for methadone, OxyContin 40 mg, Fioricet, and Xanax), *and id.* at 5, 26 (same), *and id.* at 4–5, 24 (same), *and id.* at 4, 22 (same).

[108] *Compare* Gov't Ex. 52 at 24–25 (UDS anomaly positive for non-prescribed propoxyphene), *with id.* at 4, 11 (prescriptions afterward by Respondent for MS Contin ER, Percocet, and Xanax). For reasons stated elsewhere in this recommended decision, DI Phillips' observations regarding patient commuter distances that she gleaned from the Internet, Tr. 788–90, were generally disputed in principle by Dr. Miller, Tr. 571, and have not been the subject of sufficient development in this record to be considered for any purpose.

[109] *Compare* Gov't Ex. 22 at 35 (UDS anomalies negative for prescribed opioids and benzodiazepines and positive for non-prescribed propoxyphene), *with id.* at 5 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax), *and id.* at 5, 16 (same), *and id.* at 4, 14 (same), *and id.* at 3, 13 (same with increased dosage units).

[110] *Compare* Gov't Ex. 23 at 45 (UDS anomaly negative for opiates and benzodiazepines), *with id.* at 13, 37 (prescriptions afterward by Respondent for Xanax and Lortab); *compare id.* at 43 (UDS anomaly negative for prescribed opioids and benzodiazepines), *with id.* at 8, 31 (prescriptions afterward by Respondent for Lortab and Xanax), *and id.* (same), *and id.* (same).

[111] It was revealed on cross-examination that the chart for Patient JE did not possess a true drug screen anomaly. DI Stevens misidentified a prescription for Xanax that he believed was issued before the UDS (and therefore should have caused a positive result for benzodiazepines), but due to an administrative error on the part of the Respondent, the wrong date was transcribed onto the prescription. *See* Tr. 480, 530–38. *Compare* Gov't Ex. 26 at 8 (UDS at initial office visit with collection date November 19, 2004), *with* 10 (photocopy of prescription for Xanax dated November 9, 2004 depicted next to prescription for OxyContin dated November 19, 2004). Still, this oversight, due in part by an error made by the Respondent, is not so significant as to outweigh the assertions made by DI Stevens in his testimony that the other patient files contained one or more drug screen anomalies that were trailed by additional quantities of controlled substances being supplied to each patient.

[112] *Compare* Gov't Ex. 30 at 55 (January 28, 2006 UDS anomalies negative for prescribed opioids and positive for non-prescribed methadone), *and id.* at 11 (February 11, 2006 chart entry by Respondent that drug screen was positive for methadone and PG is on Roxicodone), *and id.* (February 25, 2006 chart entry by Dr. Vilvarajah noting that PG had unused methadone from a prescription he received back in April 2005 and that PG is against surgical measures), *with id.* at 9, 32–33 (prescriptions afterward by Respondent five months after UDS for MS Contin, Xanax, and Roxicodone), *and id.* at 8, 30 (same for the month subsequent); *compare id.* at 54 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 7–8, 29 (prescriptions afterward by Respondent for MS Contin, Roxicodone, and Xanax), *and id.* at 7, 27–28 (same plus Ambien), *and id.* at 6, 25–26 (same).

[113] *Compare* Gov't Ex. 31 at 44 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 10, 28 (prescriptions afterward by Respondent for OxyContin, hydrocodone, and Xanax), *and id.* at 10, 27 (same), *and id.* at 9, 26 (same), *and id.* at 9, 25 (same), *and id.* at 8, 24 (same); *compare id.* at 41 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 8, 23 (prescriptions afterward by Respondent for OxyContin, hydrocodone, and Xanax), *and id.* at 7, 22 (same), *and id.* at 7, 21 (same), *and id.* at 6, 20 (same), *and id.* at 6, 19 (same); *compare id.* at 42 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 4, 16 (prescriptions afterward by Respondent for OxyContin, hydrocodone, and Xanax).

[114] *Compare* Gov't Ex. 32 at 78 (UDS anomaly negative result for prescribed benzodiazepines), *with id.* at 18–19, 58 (prescriptions by Respondent afterward for OxyContin, Lortab, and Xanax and chart note ''[n]o side effects or evidence of addiction''), *and id.* at 18 (same); *compare id.* at 17 (chart entry noting pharmacy informed Respondent's practice that Patient EG filled prescription by another doctor for Xanax indicating doctor shopping and violation of pain management contract), *with id.* at 17, 55 (prescriptions afterward by Respondent for OxyContin and Lortab); *compare id.* at 76 (UDS anomaly negative result for prescribed opioids), *with id.* at 16, 54 (prescriptions afterward by Respondent for OxyContin and Lortab), *and id.* at 16, 53 (same), *and id.* at 15, 50 (same), *and id.* at 15, 49 (same); *compare id.* at 75 (UDS anomaly positive for non-prescribed benzodiazepines), *with id.* at 13, 46 (prescriptions by Respondent afterward for OxyContin and Lortab), *and id.* at 13, 45 (same), *and id.* at 12 (same), *and id.* (same), *and id.* at 10, 41 (same); *compare id.* at 72 (UDS anomaly positive for non-prescribed benzodiazepines), *with id.* at 6–7, 34 (prescriptions afterward by Respondent for OxyContin and Lortab), *and id.* at 5, 32 (same).

[115] *Compare* Gov't Ex. 37 at 45 (UDS anomaly negative for prescribed opioids and benzodiazepines), *with id.* at 6, 15 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax), *and id.* at 5, 14 (same); *compare id.* at 43 (UDS anomalies negative for prescribed opioids and benzodiazepines), *with id.* at 4–5, 13 (prescriptions afterward by Respondent for OxyContin, Percocet, and Xanax).

[116] *Compare* Gov't Ex. 38 at 106 (patient history intake form indicating Patient MM denied ''nervous breakdown/depression/anxiety''), *with id.* at 105 (new patient notes documenting complaints of anxiety and insomnia); *compare id.* at 97 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 20, 77 (prescriptions afterward by Respondent for OxyContin, Lortab, and Xanax), *and id.* at 19, 76 (same), *and id.* at 18, 73 (same), *and id.* at 18, 72 (same), *and id.* at 17–18, 71 (same); *compare id.* at 94 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 17, 69 (prescriptions afterward by Respondent for OxyContin, Lortab, and Xanax), *and id.* at 16, 65–66 (same), *and id.* at 16, 63 (same), *and id.* at 15 (same), *and id.* at 14, 56–57 (same); *compare id.* at 93 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 14, 54 (prescriptions afterward by Respondent for OxyContin, Lortab, and Xanax), *and id.* at 13, 53 (same), *and id.* at 11, 45–46 (same); *compare id.* at 91 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 8, 37 (prescriptions afterward by Respondent for OxyContin, Lortab, and Xanax), *and id.* at 8, 36 (same), *and id.* at 7, 34 (same); *compare id.* at 90 (UDS anomaly negative for prescribed benzodiazepines), *with id.* at 6–7, 32–33 (prescriptions afterward by Respondent for OxyContin, Lortab, and Xanax and chart entry, ''Lab results discussed [with patient and] copy given. . . . No side effects, no evidence of addiction.''), *and id.* at 6, 30 (same prescriptions), *and id.* at 4 (same prescriptions), *and id.* at 3–4, 23 (same prescriptions).

[117] *Compare* Gov't Ex. 45 at 36 (UDS anomalies negative for oxycodone despite purported prescription from prior practitioner for OxyContin and positive for hydromorphone despite absence of claim for prior prescription of same), *with id.* at 35, 36 (prescriptions afterward by Respondent for OxyContin and Roxicodone). Hydromorphone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(vii) (2011).

Ex. 46),[118] TW (Gov't Ex. 49),[119] and AW (Gov't Ex. 51).[120]

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

The Analysis

The Administrator[121] is authorized to deny a COR application when convinced that the registrant has been convicted of a felony under the CSA or any state law relating to a controlled substance. 21 U.S.C. § 824(a)(2) (2006). It is undisputed in this case that the Respondent has been convicted of a Kentucky state crime relating to controlled substances.

Pursuant to 21 U.S.C. § 823(f) (2006 & Supp. III 2010), the Administrator may deny an application for a DEA COR if persuaded that the issuance of such a registration would be inconsistent with the public interest. The following factors have been provided by Congress in determining ''the public interest:''

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f).

''[T]hese factors are considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application for a registration should be denied. *Id.; David H. Gillis, M.D.,* 58 Fed. Reg. 37507, 37508 (1993); *see Morall v. DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *Joy's Ideas,* 70 Fed. Reg. 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.,* 54 Fed. Reg. 16422, 16424 (1989). Moreover, the Administrator is ''not required to make findings as to all of the factors.'' *Hoxie v. DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall,* 412 F.3d at 173–74. The Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick v. DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (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,* 74 Fed. Reg. 459, 462 (2009).

In the adjudication of an application for a COR, the DEA has the burden of proving that the requirements for registration are not satisfied. 21 C.F.R. § 1301.44(d) (2011). Where the Government has sustained its burden and established that an applicant has committed acts inconsistent with the public interest, that applicant must present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008); *Samuel S. Jackson, D.D.S.,* 72 Fed. Reg. 23848, 23853 (2007). Normal hardships to the practitioner, and even the surrounding community, which are attendant upon the denial of a registration are not a relevant consideration. *Abbadessa,* 74 Fed. Reg. at 10078; *see also, Gregory D. Owens, D.D.S.,* 74 Fed. Reg. 36751, 36757 (2009). The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs. v. DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 483; *see also Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (2010) (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Abbadessa,* 74 Fed. Reg. at 10078; *Krishna-Iyer,* 74 Fed. Reg. at 463; *Medicine Shoppe,* 73 Fed. Reg. at 387.

While the burden of proof at this administrative hearing is a preponderance-of-the-evidence standard, *see Steadman v. SEC,* 450 U.S. 91, 100–01 (1981), the Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. And while ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz v. U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989); *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

[118] *Compare* Gov't Ex. 46 at 59 (UDS anomalies positive for non-prescribed barbiturates and negative for prescribed opioids and benzodiazepines), *and id.* at 57 (UDS anomalies positive for cocaine and marijuana), *with id.* at 7, 32 (prescriptions afterward by Respondent for OxyContin 40 mg, Lortab, and Xanax); *compare id.* at 55 (UDS anomaly negative for prescribed opioids), *with id.* at 6, 29–30 (prescriptions afterward by Respondent for OxyContin 20 mg, OxyContin 40 mg, Lortab, and Xanax), *and id.* at 5, 28 (same less OxyContin 20 mg), *and id.* at 5, 27 (same).

[119] *Compare* Gov't Ex. 49 at 111 (UDS anomaly positive for cocaine), *and id.* at 110 (UDS anomaly negative for prescribed benzodiazepines), *and id.* at 106 (UDS anomaly positive for cocaine, negative for prescribed opioids), *and id.* at 104 (UDS anomaly negative for prescribed opioids), *and id.* at 11 (chart entry by Respondent that Patient TW admitted she was taking some of her husband's medications ''to 'function''' after not visiting the practice for seven months due to birth of baby), *with id.* at 11, 52 (prescriptions afterward by Respondent for Percocet and Xanax contemporaneous with her chart entry about taking husband's medications). Evidence of record further demonstrates that the Respondent prescribed additional controlled substances at later office visits; however, those prescriptions followed drugs screens that were either consistent with the period of absence from the clinic (i.e., negative for all substances tested) or were consistent with prescribed opioids and benzodiazepines. While there were also two other drug screens that lacked anomalies, they were scattered among the string of anomalous UDS reports, and the Respondent's (one) cited prescription set was in the face of at least two red flags that were not addressed (a UDS with negative result for prescribed opioids and an admission of taking husband's medications without confrontation, admonishment, or inquiry into whether they were controlled).

[120] Patient AW is the individual that was interviewed by former ACA Guindi. Regarding her chart, compare Gov't Ex. 51 at 14 (UDS anomaly negative for benzodiazepines despite purported prescription by prior practitioner for Xanax), with *id.* at 12–13 (prescriptions afterward by Respondent for methadone and OxyContin), and *id.* at 10–11 (same with doubled dosage units for methadone), and *id.* at 6, 8 (same with doubled dosage units again for methadone), and *id.* at 6–7 (same), and *id.* at 2, 4 (prescriptions by Respondent for OxyContin, Percocet, and Xanax).

[121] This authority has been delegated pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2011).

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'n Co.,* 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 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 Administrator and do not limit the exercise of that discretion. 5 U.S.C. § 557(b) (2006); *River Forest Pharmacy, Inc. v. DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factor 1: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority

In this case, it is undisputed that the Respondent holds a valid and current state license, albeit subject to the terms and conditions of a five-year probationary period, to practice medicine. Action taken by a state medical board is an important, though not dispositive, factor in determining whether the continuation of a DEA COR is consistent with the public interest. *Patrick W. Stodola, M.D.,* 74 Fed. Reg. 20727, 20730 (2009); *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 461 (2009). It is well-established Agency precedent that a ''state license is a necessary, but not a sufficient condition for registration.'' *Robert A. Leslie, M.D.,* 68 Fed. Reg. 15227, 15230 (2003); *John H. Kennedy, M.D.,* 71 Fed. Reg. 35705, 35708 (2006). The considerations employed by, and the public responsibilities of, a state medical board in determining whether a practitioner may continue to practice within its borders are not coextensive with those attendant upon the determination that must be made by DEA relative to continuing a registrant's authority to handle controlled substances. Even the reinstatement of a state medical license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.,* 55 Fed. Reg. 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6590 (2007), *aff'd, Chein v. DEA,* 533 F.3d 828 (DC Cir. 2008), *cert. denied,* ____ U.S. ____, 129 S. Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not state officials. *Stodola,* 74 Fed. Reg. at 20375. As stated in *Paul Weir Battershell, N.P.,* 76 Fed. Reg. 44359, 44365–66 (2011):

> [Precedent within the Agency] has repeatedly [recognized] that a practitioner's possession of state authority ''is not dispositive of the public interest inquiry.'' *George Mathew,* 75 Fed. Reg. 66138, 66145 (2010) (citing *Stodola,* 74 Fed. Reg. at 20730 n.16; *Leslie,* 68 Fed. Reg. at 15230). ''[T]''he [CSA] requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Levin,* 57 Fed. Reg. at 8681.

Here, after a contested hearing on the merits, the Tennessee Medical Board found that the Respondent, in light of her criminal guilty plea, committed ''[u]nprofessional, dishonorable or unethical conduct,'' [122] and was ''[c]onvict[ed] of an[] offense of state or federal drug laws . . . .'' [123] Gov't Ex. 15 at 4. The Board restored the medical privileges that had been the subject of a prior emergency suspension,[124] but sanctioned the Respondent with a five-year term of probation upon her license, coupled with specific monitoring and training requirements and a $1,000.00 civil penalty. *Id.* at 5.

While the action of a state medical board must be considered under Factor 1, a state's action pertaining to the Respondent's medical license or ability to handle controlled substances (falling short of an executed revocation) is not dispositive in DEA's determination regarding the appropriateness of a sanction. *See Mathew,* 75 Fed. Reg. at 66145 (wherein DEA declines to adopt as dispositive under Factor 1 the state medical board's sanction of suspending respondent's medical license, then staying the suspension, in case where respondent was prescribing controlled substances without physically examining patients or maintaining medical records). On the one hand, the Tennessee Medical Board obviously concluded that it could discharge its responsibility to safeguard the public with something less than an outright revocation. On the other hand, the high level of required retraining and copious mandated monitoring hardly constitute a vote of confidence in the Respondent's abilities as a physician. Although the record contains no evidence that the Respondent has been non-compliant with the terms imposed by the state medical board, the relatively brief period of time that has passed since the issuance of the Medical Board's Order, and that by her own admission, the Respondent has not been practicing medicine to any degree since early 2009,[125] do not allow for a meaningful extrapolation regarding the Respondent's level of compliance with the probationary terms over the duration of the probation.

Thus, consideration of the evidence under this factor presents something of a mixed bag regarding the application and does not militate for or against revocation.

Factor 3: The Respondent's Conviction Record

Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

As discussed elsewhere in this decision, the record reflects that the Respondent was convicted [126] in a Kentucky state court of one count for the facilitation of trafficking of a controlled substance in the first degree. Stipulation F. Under Kentucky law:

> A person is guilty of criminal facilitation when, *acting with knowledge* that another person is committing or intends to commit a crime, he engages in conduct which *knowingly provides* such person with means or opportunity for the commission of the crime and which in fact aids such person to commit the crime.

Ky. Rev. Stat. Ann. § 506.080(1) (emphasis supplied). The object crime of the Respondent's guilty plea, first degree controlled substance trafficking, requires proof that the trafficker(s) (in this case, the facilitated individuals),

[122] Tenn. Code Ann. § 63–6–214(b)(1).

[123] Tenn. Code Ann. § 63–6–214(b)(10).

[124] Gov't Ex. 14.

[125] Tr. 1044.

[126] Pursuant to the terms of a plea agreement, the Respondent made an *Alford* plea to a single misdemeanor count of facilitation of trafficking in controlled substances in the first degree. Stipulation F. Consistent with the plea agreement provisions, other counts, including facilitating the activities of a criminal syndicate trafficking in controlled substances, second degree assault, and wanton endangerment, were dismissed in satisfaction. *Id.*

knowingly and unlawfully trafficked a controlled substance. Ky. Rev. Stat. Ann. § 218A.1412(1). Kentucky includes distribution under the definition of trafficking,[127] and the statutory definition of distribution is defined as ''to deliver other than by administering and dispensing a controlled substance.'' Ky. Rev. Stat. Ann. § 218A.010(10).

The inchoate nature of criminal facilitation requires that resort be had to the conduct that established her guilt in determining whether her conviction relates to distributing or dispensing under this factor. The means of the Respondent's facilitation in the criminal matter was exclusively the writing of the controlled substance prescriptions that were utilized to secure the controlled substances trafficked by the facilitated patients. Inasmuch as the federal definition of ''dispense'' under the CSA includes prescribing,[128] and knowingly prescribing controlled substances to the facilitated traffickers defined her culpability under state law, it is clear that she was convicted of a state crime relating to the dispensing of controlled substances, and equally clear that consideration of the evidence under this factor, which supports a finding that actual diversion occurred, militates against granting the application.

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 offered in opposition to the application, 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 her practice relative to prescribing controlled substances and acts allegedly committed in connection with that practice that formed the basis of her state criminal conviction and her state medical board sanctions. Thus, it is analytically logical to consider public interest factors two, four, and five together. That being said, factors two and four involve analysis of both common and distinct considerations.

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

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

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

In *Jayam Krishna-Iyer,* 74 Fed. Reg. at 463, DEA policy regarding this aspect of the public interest determination was clarified. The decision in that case acknowledged the reality that even a significant and sustained history of uneventful practice under a DEA certificate can be offset by proof that a registrant has committed acts inconsistent with the public interest. *Id.; see also Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8235 (2010) (acknowledging Agency precedential rejection of the concept that conduct which is inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities which occurred in substantially higher numbers); *Paul J. Cargine, Jr.,* 63 Fed. Reg. 51592, 51560 (1998) (''[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.''). In the context of a pharmacy registrant, Agency precedent has consistently held that even a significant level of legitimate dispensing cannot offset flagrant violations. *See, e.g., Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 386 & n.56 (2008).

The Agency, in its administrative precedent (notwithstanding what might be perceived as an arguable lack of at least readily-apparent ambiguity employed by Congress in the language of the statute),[129] has further curtailed the scope of Factor 2. The Agency's current view regarding Factor 2 is that while evidence of a registrant's experience handling controlled substances may be entitled to some weight in assessing whether errant practices have been reformed, it is entitled to no weight where a practitioner fails to acknowledge wrongdoing. *Cynthia M. Cadet, M.D.,* 76 Fed. Reg. 19450 n.3 (2011); *Roni Dreszer, M.D.,* 76 Fed. Reg. 19434 n.3 (2011); *Michael J. Aruta, M.D.,* 76 Fed. Reg. 19420 n.3 (2011); *Jacobo Dreszer, M.D.,* 76 Fed. Reg. 19386–87 n.3 (2011).

As discussed in more detail *infra,* inasmuch as the Respondent has accepted no measure of responsibility for her actions in this case, Agency precedent diminishes the availability of any consideration of those elements of her prior practice that reflect past compliance, ability, or competence in the handling of controlled substances.[130]

[127] Ky. Rev. Stat. Ann. § 218A.010(42).

[128] 21 U.S.C. § 802(10); *see also* Ky. Rev. Stat. Ann. § 218A.010(8) (Kentucky law to same effect).

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

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

467 U.S. at 842–43.

[130] However, the Respondent's evidence in this regard would not have altered the result in her

Continued

Many of the Respondent's controlled substance prescribing practices impact not only Factor 2 (experience dispensing [131] controlled substances), but also on Factors 4 (compliance with federal and state law relating to controlled substances) and 5 (other conduct which may threaten public health and safety). As discussed elsewhere in this decision, the Respondent stands convicted of a Kentucky state count of facilitation of trafficking of a controlled substance in the first degree. Stipulation F. Under Kentucky law:

> A person is guilty of criminal facilitation when, *acting with knowledge* that another person is committing or intends to commit a crime, he engages in conduct which *knowingly provides* such person with means or opportunity for the commission of the crime and which in fact aids such person to commit the crime.

Ky Rev. Stat. Ann. § 506.080(1) (emphasis supplied). The notations that the Respondent added to the current application that she was convicted of an ''unintentional'' violation of that provision,[132] and her consistent position from the outset of these proceedings that the impact of her guilty plea is significantly altered here because it was tendered as an *Alford* plea, are both of equally little moment in these proceedings. 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 Fed. Reg. 28068, 28069 (2010) (quoting *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*[.]''); *see Robert L. Dougherty, M.D.,* 76 Fed. Reg. 16823, 16830 (2011) (recognizing that absent an established exception, *res judicata* bars relitigation of factual findings and conclusions of law of prior DEA proceedings, state board decisions, and criminal convictions). This tribunal is without authority to relitigate the merits of the Kentucky state criminal conviction, or the plea, and there is certainly no warrant in the CSA or its implementing regulations to pass judgment on the propriety of the state court proceedings conducted in Harlan County, Kentucky. A conviction under the facilitation crime to which the Respondent pled guilty requires that the defendant ''act[ed] with knowledge'' that the facilitated person or persons was committing or intending to commit the crime that is the object of the charge. Ky. Rev. Stat. Ann. § 506.080(1). Furthermore, a conviction under this provision requires that the conduct that ''provide[d] the means or opportunity for the commission of the crime'' ''knowingly provide[d]'' the facilitated criminal(s) with the means or opportunity for a crime that was actually committed. *Id.* Thus, the Respondent was convicted under a criminal statute that requires that she had knowledge that she was facilitating the drug-trafficker patients that were the recipients of her controlled substance prescriptions and that her actions were done knowingly. The matter is *res judicata* in these proceedings. End of story.

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 C.F.R. § 1306.04(a). Furthermore, ''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly . . . issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id.*

A registered practitioner is authorized to dispense,[133] which, as discussed elsewhere in this decision, the CSA defines as ''to deliver a controlled substance to an ultimate user [134] . . . by, or pursuant to the lawful order of a practitioner.'' 21 U.S.C. 802(10); *see also Rose Mary Jacinta Lewis,* 72 Fed. Reg. 4035, 4040 (2007). The prescription requirement is designed to ensure that controlled substances are used under the supervision of a doctor as a bulwark against the risk of addiction and recreational abuse. *Aycock,* 74 Fed. Reg. at 17541 (citing *Gonzales v. Oregon,* 546 U.S. 243, 274 (2006); *United States v. Moore,* 423 U.S. 122, 135, 142–43 (1975) (noting that evidence established that a physician exceeded the bounds of professional practice when he gave inadequate examinations or none at all, ignored the results of the tests he did make, and took no precautions against misuse and diversion)). The prescription requirement likewise stands as a proscription against doctors ''peddling to patients who crave the drugs for those prohibited uses.'' *Gonzalez,* 546 U.S. at 274. 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 insofar 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 909–10, an evaluation of cognizant state standards is essential, *Joseph Gaudio, M.D.,* 74 Fed. Reg. 10083, 10090 (2009); *Kamir Garces-Mejias, M.D.,* 72 Fed. Reg. 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 Fed. Reg. 50397, 50407 (2007). In this adjudication, the evaluation of the Respondent's prescribing practices must be consistent with the CSA's recognition of state regulation of the medical profession and its bar on physicians from peddling to patients who crave drugs for prohibited uses. The analysis must be ''tethered securely'' to state law and federal regulations in application of the public interest factors, and may not be based on a mere disagreement between experts as to the most efficacious way to prescribe controlled

favor, even if the Agency precedent was otherwise. Beyond the Respondent's representations that she has practiced uneventfully, the record contains no evidence regarding her experience as a registrant prior to her current difficulties that would tend to shift the balance of the equities in favor of granting a registration. There is no evidence from peers, former supervisors, or other medical professionals that would lend any support towards considering her past history as a registrant as a positive factor. Regarding her past experience, the record establishes that she was trained as a physician and granted a registration. Nothing more.

[131] As noted *supra* note 128 and accompanying text, the statutory definition of the term ''dispense'' includes the prescribing and administering of controlled substances. 21 U.S.C. § 802(10).

[132] Gov't Ex. 2 at 2.

[133] 21 U.S.C. § 823(f).

[134] ''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).

substances to treat chronic pain sufferers. *Volkman v. DEA,* 567 F.3d 215, 223 (6th Cir. 2009) (citing *Gonzales,* 546 U.S. at 272, 274). Here the Government's expert couched his opinions, which are credited in this recommended decision, in terms of generally acceptable medical practice, a standard which has also been embraced as a suitable measure by the Agency and numerous courts of appeal. *Jacobo Dreszer, M.D.,* 76 Fed. Reg. 19386 (2011) (quoting *United States v. Smith,* 573 F.3d 639, 647–48 (8th Cir. 2009) (internal quotation marks omitted) (citing *United States v. Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008)).

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

A Tennessee statute lists the grounds by which the Board of Medical Examiners (Tennessee Medical Board) may, *inter alia,* suspend, revoke, or limit a physician's license to practice medicine within the state. *See* Tenn. Code Ann. § 63–6–214 (2011). Among the included grounds, a license may be revoked for committing an act of ''[u]nprofessional, dishonorable, or unethical conduct;'' as well as a ''conviction of any offense under state . . . laws relative to drugs;'' or ''prescribing . . . any controlled substance . . . not in the course of professional practice, or not in good faith to relieve pain and suffering . . . in amounts and/or for durations not medically necessary, advisable or justified for a diagnosed condition.'' *Id.* § 63–6–214(b)(1), (b)(10)–(12). Likewise, a physician who prescribes ''controlled substances in amounts or for durations not medically necessary, advisable or justified is considered to be practicing beyond the scope of the professional practice.'' Tenn. Comp. R. & Regs. 0880–02–.14(2)(d) (2010). Thus, Dr. Miller's uncontroverted testimony about the improvidence of prescribing methadone simultaneously with Oxycontin [135] arguably support a finding that these prescriptions were issued outside the scope of a professional practice. Equal grounds for revocation include ''prescribing . . . a controlled substance [to a] person [who] is addicted to the habit of using controlled substances without making a bona fide effort to cure the habit of such patient,'' or ''prescribing . . . any controlled substance . . . in violation of any law of [Tennessee] or of the United States.'' Tenn. Code Ann. § 63–6–214(b)(13) (14). Prescribing controlled substances to patients who have demonstrated, through irregular UDS results, potential addiction, are likewise improper under Tennessee state law.

In addition to the statutory requirements related to controlled prescriptions, the Tennessee Medical Board (apparently unbeknownst to the experts who testified in this case) adopted regulations pursuant to the Tennessee Intractable Pain Treatment Act, Tenn. Code Ann. § 63–6–1105, –1111, governing the authority physicians have to prescribe controlled substances, Tenn. Comp. R. & Regs. 0880–02–.14(6), necessary prerequisites prior to issuing prescriptions, *id.* at 0880–02–.14(7), and guidelines carrying the force of law for using controlled substances to treat pain, *id.* at 0880–02–.14(6)(e). Recognizing that controlled substances are indispensable for the treatment of pain, physicians only have the authority [136] to prescribe them ''after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time.'' *Id.* at 0880–02–.14(6). Furthermore, to the extent pain management for intractable pain becomes the focus of the physician's practice, regardless of whether he prescribes opiates, he or she must have documented specialized education in pain management on causes, different and recommended treatment modalities, chemical dependency,[137] and psycho/social aspects of the condition sufficient to bring the practitioner into the current standard of care in the pain management field. *Id.* at 0880–02–.14(6)(c).

As conditions precedent to prescribing controlled substances, the Tennessee Medical Board promulgated a rule mandating compliance with several requirements regarding patient history, examination, testing, diagnosis, and treatment plan. In fact, according to the rule, prescribing a controlled drug is a *prima facie* violation of the statute that requires such medications to be issued only in the course of professional practice (and in amounts and durations medically necessary, advisable, and justified for a diagnosed condition), *unless* the physician has ''first done and *appropriately documented* . . . *all* of the following,'' *id.* at –.14(7) (emphasis supplied):

1. Performed an appropriate history and physical examination; and

2. Made a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care; and

3. Formulated a therapeutic plan, and discussed it, along with the basis for it and the risks and benefits of various treatments options, a part of which might be the prescription or dispensed drug, with the patient; and

4. Insured availability of the physician or coverage for the patient for appropriate follow-up care.

Id. [138] It is also a *prima facie* violation to prescribe controlled drugs based solely upon ''answers to a set of questions.'' *Id.* at –.14(7)(c).

The state pain management guidelines adopted by the Tennessee Medical Board through regulation (Tennessee Guidelines), which closely track the statutory language and requirements of the Tennessee Intractable Pain Treatment Act,[139] affirm that prescribing controlled substances for the treatment of pain will be considered for a legitimate medical purpose if ''based upon accepted scientific knowledge of the treatment of pain,'' not in violation of applicable Tennessee or federal laws, and prescribed in compliance with the Tennessee Guidelines where appropriate and as necessary depending on individual patient needs.[140] The Tennessee Guidelines, noted as follows, command that prescriptions may only be made:

1. After a documented medical history is taken from the patient and physical examination is conducted by the physician, including ''an assessment and consideration of the pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized

[135] Tr. 584–85, 610–11.

[136] General authority to prescribe controlled substances as a course of treatment for patients suffering from intractable pain is granted in the Tennessee Intractable Pain Treatment Act. Tenn. Code Ann. § 63–6–1105 (2011).

[137] Physicians treating pain patients who require treatment for chemical dependency as well must also comply with the Intractable Pain Treatment Act. Tenn. Comp. R. & Regs. 0880–02–.14(d); *see* Tenn Code Ann. § 63–6–1107(c), (d).

[138] An exception is made that a new physical examination is not required for established patients before issuing new prescriptions so long as that determination is made by the physician based upon ''sound medical practices.'' Tenn. Comp. R. & Regs. 0880–02–.14(7)(b)(4).

[139] *See* Tenn. Code Ann. § 63–6–1107.

[140] Tenn. Comp. R. & Regs. 0880–02–.14(6)(e)(3).

medical indication for the use of a . . . controlled substance;'' [141]

2. ''Pursuant to a written treatment plan tailored for the individual needs of the patient'' that takes into account treatment progress and success as evaluated with stated objectives, like pain relief or improved physical or psychosocial function.[142] The written treatment plan requires consideration of the relevant patient medical history, physical examination conducted, and any need for further testing, consultation, referral, or employment of alternative treatment modalities; [143]

3. Following a discussion between the physician and the patient regarding the weighed risks and benefits of treatment through the use of controlled substances.[144]

4. ''Subject to documented periodic review'' of the treatment plan at reasonable intervals relative to any progress toward the defined treatment objectives;[145] and

5. While keeping ''[c]omplete and accurate records of the care'' listed above, including specific details of each prescription for a controlled substance.[146]

The Guidelines further provide that the validity of a physician's prescribing, including the quantities of drugs and chronicity of the prescribing, will be judged based on ''the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out by [the Guidelines].'' *Id.* at –.14(6)(e)(6). Moreover, special attention and consideration is to be given to patients who have a history of substance abuse or live in an environment which poses a risk for drug misuse or diversion. *Id.* at –.14(6)(e)(3)(v); *see* Tenn. Code Ann. § 63–6–1107. Such scrutiny may be in the form of closer monitoring or consultation with other appropriate healthcare professionals. *Id.* Deviation from strict adherence to the Tennessee Guidelines, absent good cause, is grounds by the Tennessee Medical Board to take disciplinary action. *Id.* at –.14(6)(e)(8). Prescribing for other than legitimate medical purposes, writing false or fictitious controlled-substance prescriptions, or prescribing controlled medications in a manner inconsistent with the public health and welfare are all explicit bases for medical license cancellation, suspension, or revocation. Tenn. Code Ann. § 63–6–1108.

As demonstrated above, it is abundantly clear from the plain language of both the Tennessee statutes and regulations, including the Tennessee Guidelines, that the drafters placed critical emphasis on the need to document the objective signs and rationale employed in the course of pain treatment through the prescription of controlled substances. Conscientious documentation is 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 Respondent's documentation regarding UDS anomalies, follow-up, and recordkeeping, like her level of motivation in procuring prior medical records and referrals, were, based on the testimony of every witness (including herself), woefully inadequate and, based on expert testimony and practices readily apparent in the patient charts of evidence discussed elsewhere identified by the DIs as well as through review made by this tribunal, clearly noncompliant with the standards and law related to controlled substance prescribing in the state of Tennessee.

Suffice it to say that the Respondent's prescribing practices did little to advance the position that she fulfilled her obligations as a registrant to safeguard against diversion in any meaningful way. When pressed on the issue at the hearing, the Respondent acknowledged that even she no longer believes that her approach to minimizing diversion risks had been an effective one. Tr. 895–96. This tacit admission of dereliction notwithstanding, both the plain language employed by the Respondent and the tenor of her testimony as observed at the hearing revealed more of a resignation about specific deficiencies brought to her attention during the course of her testimony than any significant level of acknowledgment of wrongdoing and acceptance of responsibility. Her lackluster testimonial epiphanies occurred only at her own administrative hearing sporadically at times when confronted with the realities of the manner in which she discharged her obligations as a registrant. According to the Respondent, despite years of prescribing in the face of negative drug screens that were plainly divergent from any reasonable expectation, and/or prescribing immediately at the first visit without UDS results or even prior medical records, it was, according to her, only during the course of these proceedings that she discovered the weaknesses in her prescribing methods. In her testimony, when asked about whether she believed the approach in her practice regarding tolerance for aberrant UDS conduct was correct, the Respondent remarked that ''a few charts that [she] has looked over'' demonstrated suspicious UDS result fluctuations and that as to ''one patient eventually, we had to discharge that patient just because we found out that she was doctor shopping in one of the charts that I've looked here.'' Tr. 895–96. Another discovery that, according to the Respondent, was not made until hearing testimony (from no less than her own expert witness) at the hearing, was that controlled opioid prescription drugs can be abused in the same manner as illicit street drugs, and that she ''feel[s] that probably something needs to be done about it.'' [147] Tr. 896–97. The recency of her realizations stand in sharp contrast with the depth and breadth of her extensive training and experience in the fields of anesthesiology and pain management. Given the Respondent's years and level of practice, it would greatly strain credulity to accept that it was only the unfolding of the Government's evidence during litigation that lifted the shroud of confusion from her eyes and allowed her to see a better way to prescribe controlled substances. It is certainly more plausible to conclude that the Respondent was well aware of what her obligations required and intentionally turned a blind eye. A practitioner registrant may be charged with knowledge that prescriptions were for a non-legitimate purpose under a theory of deliberate ignorance based on his/her interactions with patients and other circumstances associated with the issuance of prescriptions to those persons. *Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8228 (2010) (finding that the frequency of prescribing in the face of red flags supported the conclusion that Respondent was not negligent, but knowingly prescribed without a legitimate medical purpose); *see United States v. Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006) (knowledge can be inferred when a practitioner is put ''on notice that criminal activity was particularly likely and yet . . . failed to investigate those facts'') (other citations and quotations omitted).

In like fashion, the Respondent's assertion that she now realizes the error of what was essentially intentional ignorance of obvious red flags, has procured guidance from other pain management specialists, and now has the ability and inclination to procure

[141] *Id.* at –.14(6)(e)(3)(i).

[142] *Id.* at –.14(6)(e)(3)(ii).

[143] *Id.*

[144] *Id.* at –.14(6)(e)(3)(iii).

[145] *Id.* at –.14(6)(e)(3)(iv).

[146] *Id.* at –.14(6)(e)(3)(v).

[147] Presumably, the Respondent was alluding to measures beyond criminal prosecutions and administrative proceedings brought against DEA registrants.

the services of a practice mentor, such as Dr. Miller, are equally unavailing on this record. The Agency has recognized that a cessation of illegal behavior only when ''DEA comes knocking at one's door,'' can be afforded a diminished weight borne of its own opportunistic timing. *Liddy's Pharmacy, L.L.C.,* 76 Fed. Reg. 48887, 48897 (2011). Despite her impressive pain management and anesthesiology credentials, the Respondent stopped prescribing controlled substances recklessly and dangerously only after she was caught. Plans to hire a practice monitor, taken under these conditions, when viewed in the context of the Respondent's level of pain management expertise, is hardly a consideration that militates in favor of her application with any appreciable momentum. *See also, Southwood Pharm., Inc.,* 72 Fed. Reg. at 36503 (DEA afforded no weight to registrant's ''stroke-of-midnight decision'' to cease illegal conduct and hire an experienced compliance officer).

During the course of the hearing and in her brief, a significant measure of the Respondent's case focused upon the possibility that there could have been valid reasons that several of the UDS results from her patients could have reflected negative results for controlled substance medications that were prescribed.[148] But that there could have been legitimate explanations supplied by patients and considered by the Respondent misses the point. Valid medically-based justifications credited by a prescribing physician for seemingly errant UDS reports certainly could have ranged from the expected to the outlandish. The problem for the Respondent here, is that there is no documented explanation or analysis for many instances where some explanation was demanded by reason and the applicable medical standards. The patient charts do not reflect a thought process that analyzed red flags and demonstrated any effort on the part of the Respondent to discharge her duty as a DEA registrant and vanguard within the closed regulatory system. Whether the potential universe of reasons that could have been offered by her patients ranged from the perfectly reasonable to the eccentric, they were clearly not part of the equation that resulted in the Respondent's documented prescribing methodology. What was apparent is that her patients demonstrated a disturbing level of potential diversion red flags that were met with a correspondingly disturbing level of complacency on her part. The uncontroverted expert testimony of record establishes that as a registrant, the Respondent was required to recognize diversion red flags, to confront the source of those red flags, and make controlled substance prescribing decisions that reflected due regard to her obligations as the holder of a DEA controlled substance registration. In this regard, she was deficient, and repeatedly so.

Similarly, the Respondent has pointed to the fact that entries corresponding to patient care performed by her former medical partner, Dr. Vilvarajah, are also reflected in the reviewed charts.[149] Tr. 258–262, 268, 284, 287–88, 292–95, 298–99, 305–09. These concerns are similarly unavailing, as the evidence demonstrates that the Respondent prescribed controlled substances without documented hesitation where accepted medical practice and her duties as a registrant required additional diligence. Dr. Loyd persuasively testified that even when patient responsibilities are shared between partners, it is incumbent upon the physician about to prescribe controlled substances to go back through the chart and see what has been done before. Tr. 333. Whatever Dr. Vilvarajah's failings were, they did not in any way diminish the Respondent's responsibilities to review the chart of the patients to whom she was prescribing controlled substances and to ask the required hard questions. The Respondent failed in this regard.

Thus, evaluating her level of compliance with applicable medical standards and adherence to state and federal regulatory guidance, consideration of the second and fourth factors militate powerfully against granting the Respondent's application.

The Fifth statutory factor, which plays a critical role in a disposition of this case given the facts presented, permits the Administrator to consider ''other conduct which may threaten the public health and safety.'' 21 U.S.C. § 823(f)(5). Under current Agency precedent, this factor encompasses ''conduct which creates a probably or possible threat . . . to public health and safety. *Cadet,* 76 Fed. Reg. at 19450 n.3; *Dreszer* 76 Fed. Reg. at 19386–87 n.3; *Dreszer,*76 Fed. Reg. at 19434 n.3; *Aruta,*76 Fed. Reg. at 19420 n.3. Many of the details of the Respondent's conduct that have been detailed elsewhere in this recommended decision under other public interest factor categories are also relevant under Factor 5.

Many of the details of the Respondent's conduct that have been detailed elsewhere in this recommended decision under other public interest factor categories are also relevant under Factor 5. The sheer volume of controlled substance prescriptions issued to patients in the face of uninvestigated diversion red flags created a situation where many people were provided with dangerous and addictive medications without adequate consideration about whether the patients were addicted or pumping out drugs into their communities to feed the habits of others who might be. The sheer numbers of prescriptions involved, coupled with the slipshod level of monitoring conducted by this registrant clearly threatened the public health and safety. Consideration of the evidence under Factor 5, like Factors 2 and 4, militates compellingly against the Respondent's application for a COR.

Recommendation

In cases, such as the present case, where the Government has made out a *prima facie* case that the Respondent has committed acts that render registration inconsistent with the public interest, Agency precedent has firmly placed acknowledgement of guilt and acceptance of responsibility as conditions precedent to merit the granting or continuation of status as a registrant. *Hoxie v. DEA,* 419 F.3d 477, 483 (6th Cir. 2005); *Hassman,* 75 FR at 8236; *Ronald Lynch, M.D.,* 75 Fed. Reg. 78745, 78749 (Respondent's attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.,* 75 Fed. Reg. 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.,* 74 Fed. Reg. 17529, 17543 (2009); *Steven M. Abbadessa, D.O.,* 74 Fed. Reg. 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 463 (2009); *Medicine Shoppe-Jonesborough,* 73 Fed. Reg. 364, 387 (2008). A balancing of the statutory public interest factors supports the denial of the Respondent's application for a COR. The Respondent has not accepted responsibility for her actions, persuasively expressed remorse for her conduct, or presented evidence that could reasonably support a finding that the Administrator should entrust her with a registration. In light of current Agency precedent, her election to maintain her innocence in the face of her criminal conviction, her state board

[148] *See* Tr. 240–41, 291 (Xanax was prescribed on an ''as needed'' basis); *id.* at 297 (Xanax is short acting and can be eliminated from the body in a relatively short period of time); *id.* at 242–45 (oxycodone is a medication that can result in false negative results).

[149] Part of the confusion regarding multiple physicians arose from Dr. Loyd's initial, erroneous assumption during his chart review that the Tennessee Medical Board cover sheet in the front of each patient chart copy provided to him by DEA was evidence that the Respondent was that patient's treating physician and responsible for all notations within the chart. Tr. 335, 826.

proceedings, and the persuasive evidence offered against her in these proceedings was taken at her own procedural peril. Under current Agency precedent the present record supports and compels the Agency to deny her COR application, which is the course recommended by this decision.

Accordingly, the Respondent's application for a Certificate of Registration should be **DENIED.**

Dated: August 18, 2011 s/JOHN J. MULROONEY, II

Chief Administrative Law Judge

[FR Doc. 2013–18922 Filed 8–5–13; 8:45 am]

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DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–82,705; TA–W–82,705A; TA–W–82,705B; TA–W–82,705C; TA–W–82,705D; TA–W–82,705E]

The Boeing Company Boeing Commercial Aircraft (BCA) Auburn, Washington; The Boeing Company Boeing Commercial Aircraft (BCA) Everett, Washington; The Boeing Company Boeing Commercial Aircraft (BCA) Puyallup, Washington; The Boeing Company Boeing Commercial Aircraft (BCA) Including Four Locations In Renton, Washington; The Boeing Company Boeing Commercial Aircraft (BCA) Seattle, Washington; The Boeing Company Boeing Commercial Aircraft (BCA) Tukwila, Washington: Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on June 12, 2013, applicable to workers and former workers of The Boeing Company, (BCA) Auburn, Washington (TA–W–82,705), Everett, Washington (TA–W–82,705A), Puyallup, Washington (TA–W–82,705B), North 8th and Logan Avenue North, Renton, Washington (TA–W–82,705C), Seattle, Washington (TA–W–82,705D), and Tukwila, Washington (TA–W–82,705E). The workers are engaged in activities related to the production of commercial passenger aircraft. The Department's notice was published in the **Federal Register** on July 2, 2013 (78 FR 39775).

At the request of a union official, the Department reviewed the certification for workers of the subject firm.

New information shows that the correct name of the subject firm in its entirety should read The Boeing Company, Boeing Commercial Aircraft (BCA) located at the above mentioned locations. Information also shows that worker separations occurred during the relevant time period at two additional facilities: 10–16 Building 535 Garden Avenue North, Renton, Washington and 10–18 Building 635 Park Avenue North, Renton, Washington locations of The Boeing Company.

Accordingly, the Department is amending the certification to correctly identify the certified worker group as The Boeing Company, Boeing Commercial Aircraft (BCA) and to include workers at the 10–16 Building 535 Garden Avenue North, Renton, Washington and 10–18 Building 635 Park Avenue North, Renton, Washington facilities of the subject firm.

The amended notice applicable to TA–W–82,705, TA–W–82,705A, TA–W–82,705B, TA–W–82,705C, TA–W–82,705D and TA–W–82,705E is hereby issued as follows:

All workers of The Boeing Company, Boeing Commercial Aircraft (BCA), Auburn, Washington (TA–W–82,705), The Boeing Company, Boeing Commercial Aircraft (BCA), Everett, Washington (TA–W–82,705A), The Boeing Company, Boeing Commercial Aircraft (BCA), Puyallup, Washington (TA–W–82,705B), The Boeing Company, Boeing Commercial Aircraft (BCA), North 8th, Logan Avenue North, 10–16 Building 535 Garden Avenue North and 10–18 Building 635 Park Avenue North, Renton, Washington (TA–W–82,705C), The Boeing Company, Boeing Commercial Aircraft (BCA), Seattle, Washington (TA–W–82,705D) and The Boeing Company, Boeing Commercial Aircraft (BCA), Tukwila, Washington (TA–W–82,705E). who became totally or partially separated from employment on or after April 26, 2012 through June 12, 2015, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 17th day of July, 2013.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2013–18925 Filed 8–5–13; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,968; TA–W–81,968A; TA–W–81,968B]

Verizon Business Networks Services, Inc. Senior Analysts-Sales Impletmentation (SA–SI) Birmingham, Alabama; Verizon Business Networks Services, Inc. Senior Analysts-Sales Impletmentation (SA–SI) Service Program Delivery Division San Francisco, California; Verizon Business Networks Services, Inc.Senior Analysts-Sales Impletmentation (SA–SI) Alpharetta, Georgia: Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on December 7, 2012, applicable to workers of Verizon Business Networks Services, Inc., Senior Analysts-Sales Implementation (SA–SI), Birmingham Alabama (TA–W–81,968) and Verizon Business Network Services, Inc., Senior Analyst-Sales Implementation (SA–SI), and Service Program Delivery Division, San Francisco, California (TA–W–81,968A). The worker group supplies senior analyst-sales implementation and service program delivery services. The notice was published in the **Federal Register** on January 4, 2013 (78 FR 767).

At the request of a company official, the Department reviewed the certification for workers of the subject firm. Information shows that worker separations occurred during the relevant time period at the Senior Analyst-Sales Implementation (SA–SI), Alpharetta, Georgia location of Verizon Business Network Services, Inc. due to a shift in services to a foreign country.

Accordingly, the Department is amending the certification to include workers of the Senior Analyst-Sales Implementation (SA–SI), Alpharetta, Georgia location of Verizon Business Network Services, Inc.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by a shift of senior analyst-sales implementation and service program delivery services to a foreign country.

The amended notice applicable to TA–W–81,968, TA–W–81,968A, and TA–W–81,968B is hereby issued as follows: