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Syed Jawed Akhtar-Zaidi, M.D.; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14–2]

Syed Jawed Akhtar-Zaidi, M.D.; Decision and Order

On February 10, 2014, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision.[1] Both parties filed Exceptions to the ALJ's Recommended Decision.

Having reviewed the entire record, including the parties' Exceptions, I have decided to adopt the ALJ's findings of fact except as discussed below. I further adopt the ALJ's conclusions of law that:

(1) Respondent issued prescriptions for controlled substances to three undercover officers outside the usual course of professional practice and which lacked a legitimate medical purpose;

(2) Respondent violated Federal law when he issued controlled substance prescriptions which did not include the patient's address;

(3) Respondent violated Ohio law requiring that he ''complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of [his] patients,'' when, with respect to the three undercover officers, he ''falsely reported the extent and nature of his examination of [them] and falsely reported the patients' reports of pain'';

(4) Respondent ''failed to comply with the requirements of Ohio law applicable to the treatment of chronic pain.'' R.D. 81–86. Finally, I adopt the ALJ's ultimate conclusions of law that the Government has met its *prima facie* burden of showing that ''Respondent's continued . . . registration is inconsistent with the public interest'' and that ''Respondent has failed to rebut the Government's *prima facie* case.'' *Id.* at 87.

According to the ALJ's Recommended Decision, Respondent's registration was due to expire on June 30, 2014, and according to the registration records of the Agency, of which I take official notice, *see 5* U.S.C. 556(e), Respondent has not filed either a renewal or new application. While ordinarily, these findings would render a case moot, *see Ronald J. Riegel,* 63 FR 67132, 67133 (1998), this Agency has recognized that where a registrant is served with an Immediate Suspension Order, there may be collateral consequences which preclude a finding of mootness. Here for example, the Immediate Suspension Order authorized the Government to seize any controlled substances it found at Respondent's registered location, *see* ALJ Ex. 1, at 4 (citation omitted); and pursuant to 21 U.S.C. 824(f), ''[u]pon a revocation order becoming final, all such controlled substances . . . shall be forfeited to the United States'' and ''[a]ll right, title, and interest in such controlled substances . . . shall vest in the United States upon a revocation order becoming final.'' *See also* 21 CFR 1301.36(f)). Moreover, the Agency has held that a registrant, who has been issued an Immediate Suspension Order, cannot defeat the effect of this provision by allowing his registration to expire. *Meetinghouse Community Pharmacy, Inc.,* 74 FR 10073, 10074 n.5 (2009).

Accordingly, on May 8, 2015, the former Administrator issued an Order directing the parties to address whether the case was moot. Thereafter, both parties filed responses asserting that the case remains a live controversy, with the Government specifically noting that various controlled substances including Demerol, morphine sulfate, hydrocodone, and midazolam were seized from Respondent's office during service of the Immediate Suspension Order. Gov't Response to Order, at 2. The Government further represents that there are no other proceedings pending to determine title to the drugs and therefore requests that I issue a final order to resolve this issue.

Accordingly, I conclude that this proceeding presents the collateral consequence of who has title to the controlled substances seized by the Government. While I do not adopt the ALJ's recommended order that I revoke Respondent's registration and deny any pending application to renew or modify his registration, I will affirm the issuance of the Immediate Suspension Order and declare that all right, title, and interest in the seized drugs is forfeited to the United States. A discussion of Respondent's Exceptions follows.[2]

Exception One—The ALJ Arbitrarily and Capriciously Barred Respondent From Presenting the Testimony of His Expert Witness, His Employees, and His Patients

Respondent argues that the ALJ's refusal to allow him to present testimony from his expert, Dr. Richard Stieg, three of his employees, and his patients, ''was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.'' Resp. Exceptions, at 1–2. While I find the ALJ's ruling denying Respondent the right to call Dr. Stieg to be problematic, for reasons explained below, I hold that Respondent has not demonstrated that the ALJ committed prejudicial error. I further find that Respondent has failed to demonstrate that the ALJ erred when he barred the employees and the patients from testifying, let alone that the error was prejudicial.

The ALJ's Ruling Barring Dr. Stieg's Testimony

Respondent argues that even before the proceeding was initiated, ''the Government had several months in which to . . . obtain an expert witness'' and have the expert review the evidence against him. Resp. Exceptions, at 2. By contrast, Respondent argues he ''had a very limited period of time in which to . . . retain an expert and have the expert review the documents and files'' and form his opinion. *Id.* Noting that the ALJ ''placed near complete reliance on the testimony of the Government's expert,'' *id.* at 3, Respondent contends

[1] All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

[2] The Government takes exception to the ALJ's discussion of factor two and whether the Agency has properly applied it in revocation proceedings because the factor refers only to ''the applicant's'' experience in dispensing controlled substances. *See* R.D. at 54–58. The Government's exception is well taken.

Pursuant to Congress's direction in 21 U.S.C. 824(a)(4) that the Agency may revoke a registration ''upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest *as determined under such section,''* every Administrator and Deputy Administrator who has exercised the authority granted by section 824 has rejected the ALJ's view. Moreover, in *Clair L. Pettinger, M.D.,* 78 FR 61592 (2013), the Administrator thoroughly addressed and rejected the ALJ's reasoning. Indeed, no court has ever questioned the Agency's interpretation that it is required to consider (although not necessarily make findings with respect to) each of the public interest factors in a revocation proceeding. *See Dewey C. MacKay,* 664 F.3d 808, 816 (10th Cir. 2011) (noting, in revocation proceeding, that ''[t]he agency is required to consider five factors '[i]n determining the public interest' ''); *id.* at 819 (upholding agency's determination that evidence that physician diverted controlled substances was relevant under both factors two and four); *Morall v DEA,* 412 F.3d 165, 173 (D.C. Cir. 2005) (noting, in revocation proceeding, that ''[s]ection 823(f) provides the factors to be considered '[i]n determining the public interest' '' and listing all five factors).

Thus, the issue has been conclusively decided. Because the ALJ's decision is only a recommendation, the Agency has no obligation to publish any portion of it, let alone that which persists in re-arguing that which has been long decided. *See Iran Air* v. *Kugelman,* 996 F.2d 1253, 1260 (D.C. Cir. 1993) (quoting Joseph Zwerdling, *Reflections on the Role of an Administrative Law Judge,* 25 Admin. L. Rev. 9, 12–13 (1973) (an ALJ '' 'is governed, as is the case of any trial court, by the applicable and controlling precedents. These precedents include . . . the agency's policies as laid down in its published decisions. . . . Once the agency has ruled on a given matter . . . it is not open to reargument by the administrative law judge' '')). Accordingly, I decline to publish the ALJ's discussion regarding the applicability of factor two in revocation proceedings.

that ''expert testimony [was] critical to establishing [his] defense,'' *id.* at 2, and that Dr. Stieg (his expert), ''was prepared to testify that contrary to the Government's position, he did not fail to meet the standard of care in pain medicine.'' *Id.* at 3.

Respondent further contends that he ''was placed in a perilous position by the'' ALJ, apparently because after Respondent identified Dr. Stieg and disclosed ''his expected testimony,'' he ''also discovered that Dr. Stieg'' had a serious medical condition and was to undergo treatment on the dates set for the hearing (December 16–17, 2013) and ''would be unable to testify.'' *Id.* Respondent then notes that ''[u]pon discovering this information,'' he immediately moved for a continuance of the proceeding, but that the ALJ denied his motion.

Respondent further argues that the ALJ's basis for denying his motion was inconsistent with agency precedent. In his Recommended Decision, the ALJ explained that he found Dr. Stieg's testimony ''would likely have little probative value, as the witness did not appear to be familiar with Ohio medical practice standards.'' R.D. at 4. Respondent argues that the ALJ's reason is ''arbitrary, capricious, an abuse of discretion, and not in accord with DEA precedent,'' noting that in *Mireille Lalanne,* 78 FR 47750, 47759 (2013), the Agency held that evidence as to ''generally recognized and accepted medical practices'' may be admitted to show ''the usual course of professional practice'' under the CSA and the Agency's regulations. R.D. at 4 (other citation omitted). He then notes that several of the factors which the Agency is required to consider under the public interest standard are ''not set by state law.'' Resp. Exceptions, at 5. Moreover, Respondent suggests that the ALJ made inconsistent findings when he held that Respondent had not demonstrated that the exclusion of Dr. Stieg's testimony would cause him ''substantial prejudice,'' while at the same time he held that the Government would be prejudiced by the testimony. *Id.* at 4.

Finally, Respondent notes that while the ALJ had initially considered allowing Dr. Stieg to testify through video teleconference (and be taken out of order), he reversed his position after Respondent invoked his Fifth Amendment privilege and refused to testify when called as a witness by the Government. *Id.* at 5 (citing Tr. 248). According to Respondent, the ALJ's ruling was an ''attempt to punish Respondent for exercising his constitutional right.'' *Id.*

While some of Respondent's arguments are well taken, I hold that Respondent has failed to demonstrate prejudicial error. *See* 5 U.S.C. 706. As several federal courts have explained, an ALJ's discretion ''includes the power to make reasonable, nonarbitrary decisions regarding the admission or exclusion of evidence.'' *Gunderson* v. *Department of Labor,* 601 F.3d 1013, 1021 (10th Cir. 2010). However, even where it is shown that an ALJ erred in excluding evidence, that error must '' 'prejudicially affect a substantial right of a party.' '' *Id.* (quoting *Sanjuan* v. *IBP, Inc.,* 160 F.3d 1291, 1296 (10th Cir. 1998)). *See also Air Canada* v. *Department of Trans.,* 148 F.3d 1142, 1156 (D.C. Cir. 1998) (''As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error.'') (citing 5 U.S.C. 706).

Moreover, ''[a]n error is prejudicial only 'if it can be reasonably concluded that with . . . such evidence, there would have been a contrary result.' '' *Gunderson,* 601 F.3d at 1021 (quoting *Sanjuan,* 160 F.3d at 1296). Applying this standard, Respondent cannot prevail.

According to Respondent's proffer, ''Dr. Stieg would have testified that there is no 'gold standard' or one defined standard which defines with certainty the accepted and prevailing standards of care for pain medicine medical services'' and that ''whether a physician has met the accepted and prevailing standards of care for pain medicine service is a case by case analysis, taking into account the individual circumstances of each patient and the relevant medical decisions in connection with the treatment of that patient.'' Resp. Offer of Proof, at 3.

Moreover, Dr. Stieg ''would have testified that a physician in [Respondent's] position has an ethical duty to believe what his patient tells him regarding his or her medical condition, and has a duty to attempt to provide appropriate treatment which he believes helps his patient with the condition the patient represents to him,'' and that it is ''reasonable and ethically imperative to believe'' the patient until a ''physician is presented with objective evidence that the patient is lying . . . or is otherwise non-compliant.'' *Id.* at 3–4. Dr. Stieg would have further testified that various actions Respondent took in prescribing to the undercover officers were ''appropriate and . . . within the accepted and prevailing standard of care,'' as well as being ''appropriate to protect against addiction, diversion, and misuse.'' *Id.* at 4.

Respondent further proffered that Dr. Stieg would testify ''that the physician/patient relationship for pain medicine must evolve over time,'' *id.,* and that the ''approximately three to four month[ ]'' periods in which Respondent treated the undercover officers ''is an extremely short period which provided additional difficulties [in] discover[ing] the lies told to him by the undercover agents.'' *Id.* at 4–5.

On the issue of the adequacy of the physical exams, Respondent proffered that ''Dr. Stieg would testify that there is no single standard to determine exactly what an adequate physical examination requires in every circumstance'' and that ''there is a consensus standard that a physical examination should focus on the cause of the pain.'' *Id.* at 5. Moreover, Dr. Stieg would have testified ''that a full physical examination is usually not required for every pain medicine encounter.'' *Id.*

Respondent also proffered that ''Dr. Stieg would have testified that the diagnosis made by Dr. Zaidi for each undercover agent were [sic] within the accepted and prevailing standards of care,'' that the initial ''diagnosis often becomes clearer as the physician/patient relationship yields more information over time,'' and while an ''MRI and further testing may have revealed [a] more specific pathological diagnosis . . . the diagnosis of lumbago and lumbar radiculosis can be justified, pending further analysis.'' *Id.* at 6. Finally, Respondent proffered that Dr. Stieg would have testified that given ''the short treatment period, the standard of care'' did not require that Respondent demand that the undercover officers undergo ''additional expensive treatment at that time, such as physical therapy,'' and that Respondent acted within the standard of care by considering the undercover officers' representations that they were unable ''to pay for the'' MRIs and alternative treatments. *Id.* Thus, Dr. Stieg would have testified that Respondent's ''treatment of the undercover agents was for legitimate medical purposes.'' *Id.* at 3.

I agree with Respondent that it was not reasonable to require him to identify his expert witness, have the expert review the Government's evidence against him, and prepare an adequate summary of the expert's testimony within the time period provided for in the ALJ's pre-hearing ruling. Indeed, it is not clear on this record how Respondent could have provided an adequate summary of his expert's

testimony in his prehearing statement when, under the ALJ's Order for Prehearing Statements, he was required to file the statement one week before the parties were even required to exchange their proposed exhibits. *See* ALJ Exs. 3 & 4. I also agree with Respondent that it was not reasonable for the ALJ to deny his request for a continuance after he determined that his expert was unable to attend the hearing because he needed to undergo treatment for a serious medical condition. Finally, I agree with Respondent that under agency precedent, evidence as to ''generally recognized and accepted medical practices'' remains admissible to show whether a physician acted within ''the usual course of professional practice'' under federal law. *See Mireille Lalanne,* 78 FR 47750, 47759 (2013). While Dr. Stieg's apparent lack of familiarity with the State of Ohio's medical practice standards might properly lead to giving his testimony less weight, especially when it was weighed against that of an expert who is knowledgeable in the Ohio standards and who has served as an expert reviewer for the State's medical board, it was not a *per se* bar to its admission.

This aside, much of the proffered testimony is consistent with that given by the Government's expert. But most significantly, this is not a case in which the evidence is limited to the testimony of dueling experts. Rather, the Government presented substantial evidence beyond the testimony of its expert to support the conclusion that Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescriptions to the undercover officers. Thus, even if Dr. Stieg had testified that Respondent acted within the accepted standard of care in making the diagnoses and prescribing controlled substances to the undercover patients, as ultimate factfinder, I would not find this sufficient to reject the ALJ's findings. *Gunderson,* 601 F.3d at 1021 (quoting *Sanjuan,* 160 F.3d at 1296).

Here, with respect to each of the undercover officers, the record is replete with evidence that Respondent falsified each officer's medical record at every visit to document both: (1) The performance of physical exam tests which he never conducted, and (2) pain levels which were higher than the officers actually reported. Nothing in the proffered testimony of Dr. Stieg refutes the fair inference which arises from the falsifications—that Respondent falsified the records in order to justify the prescribing of controlled substances, and that in prescribing the controlled substances, Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose. *See* 21 CFR 1306.04(a) (''A prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.'').

This conclusion is buttressed by Respondent's invocation of his Fifth Amendment privilege when called to testify by the Government. As the Supreme Court has explained, ''the Fifth Amendment does not forbid adverse inference against parties to civil actions when they refuse to testify in response *to probative evidence* offered against them.'' *Baxter* v. *Palmigiano,* 425 U.S. 308, 318 (1976) (emphasis added); *see also MacKay* v. *DEA,* 664 F.3d 808, 820 (10th Cir. 2011) (quoting *Keating* v. *Office of Thrift Supervision,* 45 F.3d 322, 326 (9th Cir. 1995) (''Not only is it permissible to conduct a civil [administrative] proceeding at the same time as a related criminal proceeding, even if that necessitates invocation of the Fifth Amendment privilege, but it is even permissible for the trier of fact to draw adverse inferences from the invocation of the Fifth Amendment in a civil [administrative] proceeding.'')); *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005).

In its prehearing statement, the Government provided notice that it intended to call Respondent to testify ''that his treatment of the undercover officers fell below accepted medical standards and that the controlled drugs [were not] prescribed in the usual course of professional practice or for a legitimate medical purposes,'' as well as ''that his documentation of his examinations of [each undercover officer] was inaccurate and not based on objective data that he gathered during the exams.'' ALJ Ex. 8. Respondent's invocation of his Fifth Amendment privilege, considered in light of the probative evidence weighed by the ALJ, thus supports the inference that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the undercover officers.[3] *See T.J. McNichol,* 77 FR 57133, 57150 (2012) (drawing adverse inference that physician knowingly diverted controlled substances when he failed to testify ''notwithstanding the substantial probative evidence of irregularities in his prescribing practices'').[4]

The ALJ's Ruling Barring Testimony From Respondent's Employees

Respondent further argues that the ALJ acted arbitrarily and capriciously when he barred the testimony of three employees (C.B., J.B., and R.Z.). Exceptions, at 5–6. Respondent maintains that the employees ''were directly involved in the patient care of the undercover [officers] and were also interviewed by the . . . Agents when they raided [his] office.'' *Id.* at 5.

In his proffer, Respondent stated that C.B. is a certified medical assistant who took each undercover officer's history and that she ''did extensive histories on

[3] The ALJ also found credible the testimony of a DEA Diversion Investigator that during an interview, Respondent was asked why the pain levels documented in the medical record of one the undercover officers were different than what the undercover officer had said during the visits. R.D. 27 (citing Tr. 620). While Respondent was allowed to look at the undercover chart, Tr. 621, he ''did not have a response'' to the question. *Id.* at 620. This testimony, which was unrefuted, also supports an inference that Respondent falsified the undercover officers' medical records.

[4] I further find that Respondent has not demonstrated that the ALJ committed prejudicial error when he barred Dr. Stieg's testimony. As noted above, Respondent also contended that the ALJ's ruling barring Dr. Stieg's testimony was an attempt to punish him for exercising his Fifth Amendment privilege. For purposes of resolving his contention, I assume, without deciding, that the ALJ violated Respondent's rights under the Fifth Amendment when he relied on Respondent's failure to testify as a ground for his ruling. *See* Tr. 248.

However, even in criminal cases, the Supreme Court has held that a violation of a defendant's Fifth Amendment privilege is subject to harmless-error analysis. *Neder* v. *United States,* 527 U.S. 1, 18 (1999) (''The erroneous admission of evidence in violation of the Fifth Amendment's guarantee against self-incrimination . . . and the erroneous exclusion of evidence in violation of the right to confront witnesses guaranteed by the Sixth Amendment . . . are both subject to harmless-error analysis under our cases.''). In this proceeding, the standard for assessing whether an error is prejudicial is whether '''it can be reasonably concluded that with . . . such evidence, there would have been a contrary result.'' *Gunderson,* 601 F.3d at 1021 (quoting *Sanjuan,* 160 F.3d at 1296). As explained above, Respondent has not made such a showing. *See United States* v. *Local 560, Int'l Bhd. of Teamsters,* 780 F.2d 267, 292 n.32 (3d Cir. 1985) (holding that ''while the district court erred in drawing an [adverse inference from a litigant's invocation of the Fifth Amendment], that error was harmless in light of the independent evidence supporting the district court's conclusion'') (citation omitted).

In justifying his refusal to grant a continuance to Respondent, the ALJ also explained that he was ''guided by the expectation that where doing so is not inconsistent with a litigant's rights under the Due Process Clause or the Administrative Procedure Act, I should endeavor to submit the certified record of these proceedings to the Administrator . . . not later than the 150th day after the issuance of an immediate suspension (excepting any days caused by Respondent's own actions).'' R.D. at 4–5. However, even where an immediate suspension order has been issued, the Administrator has clearly instructed the Agency's ALJs that they may grant a continuance upon a registrant's request. Here, but for the fact that Respondent cannot show prejudicial error, I would have remanded this matter.

them'' as well as other patients. Resp. Offer of Proof, at 9–10. C.B. would also have testified to the procedures used by Respondent in obtaining urine drug screens and reports from the Ohio prescription monitoring program (OARRS). *Id.* at 10. Moreover, C.B. would have testified regarding Respondent's procedures for using ''random urine drug screening and access to the OARRS database with regard to the patients whose charts were offered as Respondent's exhibits, as well as her explanation to patients regarding the [pain] contract.'' *Id.* C.B. would have also testified as to various patients Respondent discharged because they ''engaged in the use of illegal drugs and/or the misuse of controlled substances prescribed by'' Respondent, and finally, C.B. would have testified to Respondent's treatment of various patients and ''how [he] has helped these patients regain functionality and control over their debilitating pain.'' *Id.*

According to his proffer, R.O. would have largely duplicated C.B.'s testimony regarding Respondent's treatment of the patients, whom he helped to regain functionality and control of their pain, as well as those patients who were discharged for using either illegal drugs or for misusing drugs he had prescribed. *Id.* at 11. R.O. would also have ''testified regarding the contract signed by the undercover agents and her explanation to those agents of the contents of the contract.'' *Id.*

Finally, J.B. ''would have testified regarding her observations concerning [Respondent's] interaction with and treatment of patients including the undercover agents and those patients'' identified in Respondent's Exhibits A through R, as well as regarding the patients that Respondent discharged. *Id.* at 12. J.B. would also have testified that she is the record custodian for Respondent's practice and that these records were authentic. *Id.*

The ALJ barred Respondent from presenting the testimony of these three witnesses because the substance of their testimony was not timely disclosed and did not sufficiently establish relevance. Here, in contrast to the ALJ's rulings on Respondent's proposed expert, I conclude that the ALJ did not err in barring the testimony on the ground that it was not timely disclosed. Respondent had more than one month from the date of the ALJ's prehearing order to determine whether his employees could offer relevant evidence in the matter and a week from the time the Government provided a detailed summary of the testimony of each of its witnesses to disclose their anticipated testimony. Moreover, Respondent's proffer (which was filed even after the testimonial phase of the hearing was concluded) does not identify any material fact which any of the employees would have refuted. Accordingly, I conclude that Respondent has also failed to establish prejudice.[5]

The ALJ's Rulings Barring Evidence Regarding Respondent's Treatment of Other Patients

Respondent also sought to elicit testimony from ten patients regarding the care they received from Respondent and how his treatment of them ''dramatically improved their lives, functionality, and ability to tolerate their ongoing pain.'' Resp. Proffer, at 13; *see also* Resp. Exceptions, at 1 & 6.[6] Because DEA is not a state medical board, whether Respondent improved the lives and functionality of these patients is not relevant under any of the public interest factors. While evidence of Respondent's lawful prescribing and compliance with federal and state controlled substances rules with respect to these patients would be relevant under the public interest standard, no such proffer was made. Accordingly, the ALJ did not err in barring this testimony.[7]

[5] While the proffered testimony was arguably relevant to an assessment of Respondent's experience in dispensing controlled substances (factor two) and his compliance with applicable laws related to controlled substances (factor four), the fact that a physician engaged in the legitimate practice of medicine with respect to other patients does not refute a *prima facie* showing that a physician knowingly diverted controlled substances. *See MacKay* v. *DEA,* 664 F.3d at 808, 819 (10th Cir. 2011) (''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 [the two patients] is sufficient to support her determination that his continued registration is inconsistent with the public interest.''); *see also Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (holding that, even assuming that physician has treated thousands of other patients in compliance with the CSA, these prescribings did not ''render her prescribings to the undercover officers any less unlawful . . . [b]ecause under law, registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals[;] [thus] every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career'').

[6] Respondent also proffered that Dr. Stieg would have testified regarding the patients whose records were offered in Respondent's Exhibits A through R, as well as those patients Respondent discharged for noncompliance, and that Respondent met the standard of care in treating both categories of patients. Resp. Offer of Proof, at 7–9. While the ALJ also barred this testimony, Respondent does not raise the issue in his Exceptions. Therefore, I deem it waived.

[7] Respondent's proffered exhibits also includes his curriculum vitae showing his professional experience, as well as certificates showing that he is a diplomate of the American Board of Physical Medicine and Rehabilitation, with a subspecialty of pain medicine; a diplomate of the American Board of Pain Medicine; a Diplomate of the American Board of Electrodiagnostic Medicine; and a Fellow of Interventional Pain Practice. To be sure, this evidence may have had some probative value in assessing his experience as a dispenser of controlled substances. However, in his Exceptions, Respondent makes no argument that the ALJ improperly excluded these exhibits.

Exception Two—The ALJ Erred in Applying Ohio Revised Code § 4731.052 and Ohio Admin. Code § 4731–21–02 as the Standard for Determining Whether Respondent Violated 21 CFR 1306.04(a)

Respondent argues that ''the Government's expert failed to establish with any degree of medical certainty the standard of care which Respondent . . . failed to meet'' and that the ALJ erred in applying Ohio Revised Code § 4731.052 and Ohio Admin. Code § 4731–21–02 ''as the sole standard'' when he held that Respondent violated 21 CFR 1306.04(a) when he prescribed to the undercover officers. Resp. Exceptions, at 6. Respondent argues that the ALJ's reliance on these provisions was misplaced because they apply only to the treatment of chronic or intractable pain and not acute pain, which was the condition presented by the undercover officers. *Id.* at 7.

I reject Respondent's exception. Contrary to his contention, the ALJ specifically acknowledged (as did the Government's expert) that the Ohio provisions did ''not apply during that phase of treatment where the diagnosis is of acute pain, but appl[ied] only after the treatment extend[ed] past twelve weeks.'' R.D. at 69. However, as the ALJ explained, Ohio law defines ''chronic pain'' as ''pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months.'' *Id.* at 70. Here, each of three undercover officers received controlled substances from Respondent for more than three months after they initially saw Respondent and received a controlled-substance prescription.[8] Yet, as the

[8] I agree with Respondent that the undercover agents did not present as suffering from ''intractable pain,'' as that term is defined by Ohio's regulation. Resp. Exceptions, at 7. The regulation defines ''intractable pain'' as ''a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.'' Ohio Admin. Code § 4731–21–01(G). Here, Respondent did not make a diagnosis of intractable pain with respect to any of the undercover officers. Nor is it clear how any such diagnosis could have been made given that Respondent did not perform anything more than a cursory physical exam at the

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Government's expert testified, Respondent did not comply with the heightened standards imposed on prescribing controlled substances to treat chronic pain.

Moreover, notwithstanding that neither of the Ohio provisions applied in the initial three-month period of the undercover officers' treatment, the record contains substantial evidence to support the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed to each of the undercover officers during this period. For example, with respect to Patient Tyler Williams, Respondent diagnosed him as having ''thoracic and lumbar radiculitis, lumbago.'' GX 12, at 8. However, the Government's expert testified that he had reviewed the video recording of the UC's first visit and found that while Respondent documented that he had performed numerous tests during the physical examination, many of the tests were actually not performed. Tr. 71–76. The expert thus explained that his ''impression of the physical examination is that it is falsified, it is embellished, and it is inaccurate, to the point that much of it, though documented here, was not performed.'' *Id.* at 76.

The Government's expert then explained that Respondent's diagnosis was not justified by the patient's history and the physical examination and that the diagnosis of radiculitis was ''blatantly inaccurate.'' *Id.* at 78. The expert further opined that Respondent's issuance of a prescription for Percocet was ''not justified by the presentation of the patient.'' *Id.* at 79.

The progress note for the UC's second visit states that he had ''moderate tenderness and spasm in paralumbar muscles with guarding in forward flexion'' and that the ''lower extremity examination is normal to sensory and motor testing.'' GX 12, at 12. Here again, the Government's expert reviewed the recording and transcript of the visit and found that Respondent did not perform a physical examination (while documenting that he did) and that the findings were falsified. Tr. 80–81. He further noted that while the progress note stated that the treatment plan included a home exercise program (in addition to controlled substances), there was no evidence of ''any educational endeavor that would allow someone to conduct a home exercise program.'' *Id.* at 81; *see also id.* at 83–85. As for Respondent's prescription for Percocet, the expert opined that it was ''not justified'' and was ''prescribed outside the usual course of professional practice.'' *Id.* at 86.

With respect to the third visit, the Government's expert similarly observed that there was no evidence that Respondent had examined the UC's lumbar spine or performed sensory or motor testing of his lower extremities, *id.* at 88, although Respondent documented having done so. GX 12, at 11. The expert also noted that the progress note documented a pain level of ''5,'' which was higher than what the UC reported. Tr. 88. Indeed, the UC reported that his present pain level was a ''2,'' and that the worst it had been in the past week was a ''3.'' GX 12, at 18. Once again, the expert testified that Respondent's diagnosis of lumbar radiculitis could not be justified based on the ''the entirety of the history and the physical examination.'' Tr. 89.

With respect to the UC's fourth and fifth visits, the expert again found that there was no justification for the lumbar radiculitis diagnosis and that Respondent did not physically examine the UC's lumbar region and lower extremities while documenting that he did. Tr. 97–99. Moreover, at the fourth visit, Respondent again documented that the UC had a pain level of 5, although the transcript contains no indication that the UC was asked about his pain level by Respondent.[9] GX 9, at 20–22.[10]

Respondent further contends that the ALJ erred in concluding that he ''failed to fully document his periodic assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the interference with activities of daily living, quality of family life and social activities.'' Exceptions, at 7 (quoting R.D. 79, Conclusion of Law #8). Respondent asserts that Ohio law does not require ''a prescribing physician to perform these measures for acute pain patients.'' *Id.* Apparently, Respondent's view is that notwithstanding that he treated each of the UCs for pain with controlled substances for ''longer than three continuous months,'' Ohio Rev. Code § 4731.052(A)(1), he cannot be held to have violated the Ohio statute because he never actually diagnosed the patients as having chronic pain. *See* Resp. Post-Hrng. Br., at 7–9. (''The express language of . . . § 4731.052 requires a physician diagnosis of 'chronic pain.' The statute does not mandate a diagnosis of chronic pain, but rather is instructive as to what is required after such a diagnosis. In the present case, none of the undercover . . . Agents was diagnosed by Dr. Zaidi as having chronic pain.'').

Notably, the Government's expert (who has been an expert reviewer for the state medical board) explained that at twelve weeks, Ohio law considers this to be ''protracted prescribing,'' which requires ''a much higher level of intensity of service.'' Tr. 100; *see also id.* at 285–87.[11] But even if it is the case that a physician can avoid having to comply with the requirements section 4731.052 imposes after three months by simply failing to make a diagnosis of chronic pain, I would still conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing to the undercover officers.

As the Government's expert explained, the prescriptions ''were not for a legitimate medical purpose,'' Tr. 103, because the diagnosis of lumbar radiculitis ''is not justified or substantiated by either the history or the physical examination.'' *Id.* at 107; *see also id.* at 268 (expert finding ''no

initial visit and generally no exam at subsequent visits, and never recommended that his patients even modify their daily activities, let alone undergo physical therapy. Tr. 118, 125. I therefore reject the ALJ's conclusion of law Number 11. R.D. at 84–85 (concluding ''that Respondent failed to comply with the requirements of Ohio law for the treatment of intractable pain'').

However, based on the length of the prescribings, I agree with the ALJ's conclusion that Respondent failed to comply with Ohio's chronic pain statute. *See* Ohio Rev. Code § 4731.052. This provision defines ''chronic pain'' as ''pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months.'' *Id.* at § (A)(1). Thus, this provision does not appear to require that the pain be incapable of being cured.

[9] Nor does the medical record contain an entry for this visit in the Nursing Progress Record (as it does for the other visits). GX 12, at 18. Respondent's signed progress note for the UC's fifth and final visit does not contain a numerical entry for his pain level; however, the Nursing Progress Record documents both the present level of his pain, and its worst level during the week as a ''2.'' *Id.*

[10] The record also contains substantial evidence to support findings that Respondent failed to perform physical examinations of the two other undercover officers while documenting that he had done so, as well as that he documented that the undercover officers reported higher pain levels than they actually had. *See* R.D. at 79 (FoF #7).

[11] As the expert testified:

That 90 days is a pause, and it is a method of communicating very forcefully to the physician, that if this is going on for that time, there better be quite a bit of substantiation behind it, and intensity of service needs to justify the continued uses of that medication. . . . It's not reasonable, especially when a patient is being seen acutely, that even we see from the emergency department with several weeks of pain, it's really not reasonable to know how long that prediction is. But what the law is saying is that if somebody needs controlled substances that long, this is the level of intensity of service that somewhere along the line, needs to have been accomplished.

Id. at 286–87.

supporting evidence'' for a diagnosis of lumbar radiculitis). The expert also observed that if he had ''reviewed only the medical record . . . [he] would have arrived at a different opinion'' than what he did having been able ''to see a transcript and watch an audio/visual recording of what actually occurred during that encounter,'' and that the medical record ''makes it appear that the severity of the patient['s] condition is much more severe than what I'm seeing when I actually am watching and listening to the recording of the events.'' *Id.* at 108. Given what the video recordings of the UC's visits with Respondent show, I agree.[12]

Also, the expert explained that the treatment plan ''focuse[d] only on controlled substances and not on other alternative approaches to care,'' *id.* at 103, such as ''physical therapy'' and ''non-controlled'' medications such as non-steroidal anti-inflammatories, neuro-modulators, and tricyclic medications. *Id.* at 107. And while the progress notes after the undercover officer's first visit list a ''home exercise program'' as part of the treatment plan, as the expert explained, there was no evidence that Respondent provided such a program to the undercover officer. *Id.* at 108; *see also* Tr. 82.

Respondent also asserts that the Government's expert applied ''his own subjective interpretation of how he believed a physical examination should be conducted and diagnosis determined'' and that ''[t]here is no evidence in the record to establish what a physical exam or diagnosis requires.'' Resp. Post-Hrng. Br., at 11. It is noted, however, that the Government's expert is board certified in anesthesiology, internal medicine, and pain medicine; that he is the Director of Pain Medicine Services and the Pain Medicine Fellowship at the Ohio State University Medical Center; that he has taught courses in Acute Pain, Chronic Pain, and Chronic Back Pain; and that he has served as an expert reviewer in pain medicine for the State Medical Board of Ohio. GX 2.

Moreover, in his testimony, the Government's expert acknowledged the ''concept described as [the] minimal standard of care,'' which he explained as ''those actions and decisions that would be made by a reasonable physician under similar circumstances.'' Tr. 204. The expert then testified that in the ''environment under which we discuss this case, that standard of care and the minimal standard of care can be considered one [and] the same,'' and that if a physician meets the minimal standard of care, he meets the standard of care. *Id.* at 204–05. Thus, I reject Respondent's contention that the expert applied his own subjective standard rather than the standard of a reasonable physician in concluding that Respondent acted outside the usual course of professional practice in prescribing to the undercover officers.

So too, while the expert was not asked what tests are necessary to conduct a physical examination which meets the standard of care with respect to the specific diagnoses made by Respondent, on cross-examination, the expert explained that ''[r]adiculopathy and radiculitis are very similar diagnoses and [have] very similar causes, but the diagnosis of radiculopathy is a nerve injury that is a permanent loss of nerve function and that the distribution of the change in permanent function is that which corresponds to those muscles or portions of . . . the body that that particular nerve serves.'' *Id.* at 203–04. When then asked whether he saw ''any evidence of that type of diagnosis in any of the undercover agents,'' the expert answered that he ''did not see any evidence . . . of them displaying the physical findings or the complaints of a permanent nerve injury.'' *Id.* at 204. Thus, I am satisfied that substantial evidence supports a finding that Respondent's diagnosis of lumbar radiculitis with respect to two of the undercover officers was not justified by their histories and physicals.[13]

I therefore reject Respondent's exception to the ALJ's legal conclusion that the prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice. *See* R.D. at 82–83 (Conclusion of Law #8); Resp. Exceptions, at 6–9.

Exception Three—The ALJ Erred In Evaluating the Public Interest Factors

Respondent further argues that the ALJ ''incorrectly determined that Factors 2, 4, and 5 support revocation'' of his registration. Resp. Exceptions, at 10. While I find that some of Respondent's contentions are well taken, I conclude that the record as a whole supports the ALJ's ultimate conclusions that Respondent has committed such acts as to render his registration inconsistent with the public interest (had he submitted an application), and that Respondent failed to rebut this conclusion. R.D. at 87.

As this Agency has long held, I am not required to make findings under each of the factors and findings under a single factor are sufficient to support the revocation or suspension of a registration. *See Hoxie* v. *DEA,* 419 F.3d, 477 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest.

With respect to factor two—Respondent's experience in dispensing controlled substances—Respondent argues that the Government seized more than 400 patient files from his office ''and failed to present any evidence . . . that the treatment of those patients failed to meet the standard of care.'' Resp. Exceptions, at 10. He also argues that ''there were over 400 additional patients' charts which were not seized and [that] no evidence was presented to question their treatment.'' *Id.* Respondent thus contends that in this matter, ''there was no attempt at 'fair adjudication.' '' *Id.*

The Agency has repeatedly rejected Respondent's contention. *See, e.g., Jayam Krishna-Iyer,* 74 FR 459, 463

[12] For example, at the UC's first visit, Respondent's physical examination was limited to asking the UC to stand up, turn around and show him where the pain was; having the UC bend forward and come back up; and then having the UC walk on his heels, turn, and walk on his toes. GX 3a. The entire encounter between Respondent and the UC lasted four minutes and resulted in Respondent writing a prescription for Percocet. *Id.*

During the UC's subsequent four visits, Respondent never performed a physical exam, while documenting having done so. *See* GX3b, c, d, and e. Moreover, the UC's encounters with Respondent lasted between three minutes and thirty seconds (3′30″) at the second visit and one minute and twenty seconds (1′20″) at the fifth visit. *See id.*

[13] While I have discussed the expert's testimony in addressing Respondent's Exceptions, as stated above, the recordings which show that Respondent falsified the medical records with respect to both the scope of the examinations he performed and the UCs' reported pain levels, the briefness of the encounters, and his refusal to testify, provide sufficient evidence, apart from the expert's testimony, to support a finding that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed to the UCs. *See United States* v. *Pellman,* 668 F.3d 918, 924 (7th Cir. 2012) (quoting *United States* v. *Armstrong,* 550 F.3d 382, 389 (5th Cir. 2008) (''While expert testimony may be both permissible and useful, a jury can reasonably find that a doctor prescribed controlled substances not in the usual course of professional practice or for other than a legitimate medical purpose from adequate lay witness evidence surrounding the facts and circumstances of the prescriptions.'')); *Armstrong,* 550 F.3d at 389 (''Jurors have had a wide variety of their own experiences in doctors' care over their lives, thus . . . expert testimony is not necessarily required for jurors to rationally conclude that seeing patients for as little as two or three minutes before prescribing powerful narcotics is not in the usual course of professional practice.'')). *See also T.J. McNichol,* 77 FR 57133, 57147 (2012) (discussing both judicial and administrative cases); *Jack A. Danton,* 76 FR 60900, 60901 (2011).

(2009). In *Krishna-Iyer,* a case in which the Government relied solely on evidence of the physician's unlawful prescribing to several confidential sources, the Agency assumed that the physician's prescribing to 12 patients whose files were seized but were not relied on by the Government in presenting its case, as well as thousands of other patients (other than the undercover operatives), constituted evidence of dispensing controlled substances in circumstances which did not constitute diversion. *Id.*

However, as the Agency explained, the physician's ''prescribings to thousands of other patients do not . . . render her prescribings to the undercover officers any less unlawful, or any less acts which are 'inconsistent with the public interest.' '' *Id.* The Agency further explained that:

> under the CSA, a practitioner is not entitled to a registration unless she ''is authorized to dispense . . . controlled substances under the laws of the State in which [she] practices.'' 21 U.S.C. 823(f). Because under law, registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career. Thus, in past cases, this Agency has given no more than nominal weight to a practitioner's evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion.

Id. (citations omitted); *see also Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (2008) (even though pharmacy ''had 17,000 patients,'' ''[n]o amount of legitimate dispensings'' could render the pharmacy's ''flagrant violations [acts which are] 'consistent with the public interest' ''), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008).

Accordingly, in *Krishna-Iyer,* the Agency held that ''evidence that a practitioner has treated thousands of patients [without violating the CSA] does not negate a *prima facie* showing that a practitioner has committed acts inconsistent with the public interest.'' 74 FR at 463. The Agency thus explained that ''[w]hile such evidence may be of some weight in assessing whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, such evidence is entitled to no weight.'' *Id.*

Subsequent to *Krishna-Iyer,* the Agency adhered to this rule in *Dewey C. MacKay,* 75 FR 49956 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). Based on the substantial evidence that the physician had knowingly diverted controlled substances to two patients who acted in an undercover capacity, the Agency held that the Government had satisfied its *prima facie* burden of showing that Respondent had committed acts which rendered his registration inconsistent with the public interest. 75 FR 49977.

The Agency also addressed and rejected the physician's contention that ''[a] better assessment of [his] medical practice and habits can be ascertained from [his] numerous positive experiences in prescribing controlled substances, some of which were recounted by the patients themselves . . . at the hearing.'' *Id.* (quoting Resp. Br. at 3). As the Agency explained: ''even assuming, without deciding, that Respondent's prescribing practices to all of his other patients (including those whose medical records were reviewed by the Government's expert but who did not perform undercover visits [14]) fully complied with the CSA and Utah law, these prescribings do not refute the evidence showing that he intentionally diverted to [the two undercovers] in violation of both the CSA and Utah law.'' 75 FR at 49977. Noting that the physician had failed to testify and offer evidence that he recognized the extent of his misconduct and was prepared to remedy his unlawful practices, the Agency revoked his registration.

The Tenth Circuit denied the physician's petition for review. *MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). Of relevance here, the Tenth Circuit specifically addressed and rejected the physician's argument that the Agency had failed to consider his ''positive experience'' in dispensing controlled substances to other patients. As the Court of Appeals explained:

> Despite Dr. MacKay's claim to the contrary, the Deputy Administrator considered the entire record, including the evidence in Dr. MacKay's favor. She determined, however, that none of Dr. MacKay's evidence negated the DEA's prima facie showing that Dr. MacKay had intentionally diverted drugs to K.D. and M.R. Indeed, she found that even if Dr. MacKay had provided proper medical care to all of his other patients, that fact would not overcome the government's evidence with regard to M.R. and K.D.
>
> None of the evidence presented by Dr. MacKay undermines the evidence relating to M.R. and K.D. Although numerous patients and colleagues of Dr. MacKay related their positive experiences with him, none had any personal knowledge regarding his treatment of M.R. and K.R. Notably, Dr. MacKay's medical expert, Dr. Fine, failed to specifically discuss and justify Dr. MacKay's treatment of M.R. and K.D. As a result, none of Dr. MacKay's evidence contradicts the testimony and evidence presented by the DEA relating to the knowing diversion of drugs to these two patients.

664 F.3d at 819.

The Court of Appeals thus concluded that ''[a]lthough 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 K.D. and M.R. is sufficient to support her determination that his continued registration is inconsistent with the public interest.'' *Id.*

In this matter, I have assumed that Respondent lawfully complied with the CSA whenever he prescribed controlled substances to all of his patients (including the 800 patients with respect to whom no evidence was offered) other than the undercover officers.[15] But even assuming that Respondent lawfully prescribed controlled substances to all of these other patients, the evidence still supports a finding that he knowingly and intentionally diverted controlled substances to the undercover officers.[16] This finding is relevant in assessing both his experience in dispensing controlled substances (factor two) and his compliance with applicable laws related to controlled substances (factor

[14] In light of the evidence provided by the undercover visits of the two patients, the Agency found it unnecessary to make any findings based on the expert's chart review. 75 FR 49972.

[15] This is not a case in which there is any ambiguity as to Respondent's intent when he prescribed controlled substances to the undercover officers. Thus, evidence of his lawful prescribings to others would not lead any reasonable factfinder to conclude that he acted within the usual course of professional practice when he prescribed to the undercover officers.

[16] In his decision, the ALJ also observed that Respondent's ''decision to manage a pain clinic using a protocol that permitted the issuance of prescriptions for controlled substances without conducting physical examinations threatens the public safety. Either through ignorance or deliberate indifference, [his] decision to establish such operations indicates he lacks sufficient insight and experience to be trusted to participate in the controlled substances distribution process.'' R.D. at 50–51.

Given that Respondent was the only doctor at the clinic, there is no need to decide whether the evidence establishes the existence of such a protocol (whether written or not) or whether such ''operations'' were established. As the evidence shows, Respondent repeatedly failed to perform physical examinations (or performed inadequate exams) and then falsified the undercover officers' medical records to reflect his having performed such exams; he also falsified the medical records by documenting higher pain levels than those reported by the undercover officers. As explained above, this evidence establishes that Respondent *knowingly* diverted controlled substances. Indeed, the ALJ specifically found that Respondent violated 21 CFR 1306.04(a) when he issued prescriptions that lacked ''a legitimate medical . . . purpose and were not written in the ordinary course of [his] professional practice.'' R.D. 83. I therefore reject it.

four), and by itself, it is sufficient to satisfy the Government's *prima facie* burden of showing that Respondent ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' [17]

With respect to factor four, Respondent contends that the ALJ took a ''quantum leap'' when he found ''that Respondent intentionally kept inconsistent medical records on [the UC's] pain levels in order to protect himself from an audit.'' Resp. Exceptions, at 13 (citing R.D. 66). According to Respondent, ''[i]t defies logic to believe that [he] would attempt to intentionally create a false medical record by increasing a pain level from 3 to 4 or 5 on a 1–10 scale, especially knowing the chart accurately contains references to [the] pain levels communicated by the DEA agent,'' which are still ''in the same moderate range.'' *Id.*

It is true that the undercover officers' charts contain a nursing progress record which accurately reflects what they reported to Respondent's medical assistant. That being said, Respondent does not challenge the ALJ's findings that he falsified the medical records by documenting having performed various tests as part of a physical examination which he failed to do. Based on this evidence, as well as Respondent's refusal to testify and explain the disparity in the pain levels, I draw the same inference that the ALJ did—that the pain levels were falsified (along with the results of physical examinations he did not perform) to provide documentation to support the prescriptions.[18] I therefore reject Respondent's exception.

Respondent's diversion of controlled substances is properly considered as evidence of his lack of compliance with applicable laws related to controlled substances. So too, his failure to comply with Ohio's regulation which requires that ''[a] physician shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients,'' Ohio Admin. Code § 4731–11–02(D), is also relevant in assessing his compliance with applicable laws related to controlled substances.[19]

Exception Four—The ALJ's Recommended Order of Revocation is not Warranted

While merged with his exception to the ALJ's factor five analysis, Respondent also takes exception to the ALJ's recommended order of revocation, arguing that this sanction ''is unwarranted in law and without justification in fact.'' Resp. Exceptions, at 16. He further asserts—notwithstanding his refusal to testify—that he ''has accepted responsibility for

[17] Respondent also takes exception to the ALJ's finding that he did not adequately address various red flags presented by the undercover officers. Resp. Exceptions, at 11–12. Among the red flags cited by the ALJ were the UCs requesting specific drugs such as OxyContin, Percocet, and Opana, which are highly diverted; the UCs seeking increases in the quantities of the prescriptions; a UC being unable to produce his driver's license; a UC's report of having obtained medication from his wife; and the UCs' non-compliance with Respondent's recommendations that they obtain MRIs or receive cortisone injections. R.D. at 79–80.

Respondent notes that when the undercover officer posing as Patrick Tock requested that he be prescribed Opana (because a friend had said it worked for him), Respondent warned him about the dangers of the drug and did not prescribe the drug. Resp. Exceptions, at 11. Respondent further notes the testimony of the Government's expert that Respondent's decision not to prescribe the medication was appropriate. *Id.* (citing Tr. 200). Moreover, in other instances, the Government's expert conceded that Respondent could properly take into consideration a patient's ability to pay for a test or procedure. Respondent thus contends that the ALJ's finding ''ignores the undisputed evidence'' and was arbitrary and capricious. *Id.*

While I agree with the ALJ's reasoning that ''[a] practitioner's failure to resolve red flags strongly suggests that the practitioner's subsequent dispensation of controlled substances to that patient is not for a legitimate medical purpose,'' R.D. at 60, this is so because such evidence is probative of the physician's knowledge or intent. However, in this matter, there is no need to resolve the issue of whether Respondent adequately addressed various red flags. This is so because the evidence that: 1) Respondent failed to performed physical exams (as well as various tests as part of the physical exams) yet falsified the medical records by documenting that he did, 2) falsified the medical records to reflect higher pain levels than those actually reported by the undercover officers, as well as 3) the adverse inference to be drawn from his refusal to testify, conclusively prove that Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the undercover officers and thus knowingly diverted controlled substances.

Thus, to the extent Respondent failed to address any red flags, this is simply additional evidence probative of the illegality of the prescriptions. *See United States* v. *Moore,* 423 U.S. 122, 142–43 (1975). Proof that a physician knowingly diverted controlled substances is the best evidence for assessing his experience in dispensing controlled substances, although it is also relevant in assessing his compliance with applicable laws related to controlled substances. However, while such evidence is relevant under both factors two and four, in making the public interest determination, the Agency does not adjudicate the case by mechanically counting up the number of factors that favor each party and declare a winner. Rather, consistent with the statute, the Agency's inquiry focuses on whether the registrant ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Thus, what matters is the egregiousness of the proven misconduct, the need to deter future noncompliance by both the specific registrant and the community of registrants, and the registrant's evidence of remediation and acceptance of responsibility.

[18] Contrary to Respondent, it does not necessarily defy logic to conclude that he intentionally falsified the record by listing a higher pain level than that documented by his medical assistant in the nursing progress record. Respondent may not have even bothered to read the nursing progress record.

[19] With respect to factor five, the Government argued that Respondent ''maintained policies [that] were contrary to Federal law,'' in that his ''employees were forbidden from contacting law enforcement in the event they suspected patients were obtaining multiple prescriptions for controlled substances from multiple doctors.'' Gov. Post-Hrng. Br., at 26. While the ALJ found that the evidence did not support the existence of such a policy, he then noted that one of Respondent's employees testified that she ''felt that laws regarding patient privacy prohibited her from reporting patient activities to law enforcement authorities'' and that she and Respondent ''never talked about it.'' R.D. at 74. The ALJ then opined that:

> a strong argument can be made for the proposition that [Respondent's] failure to correctly understand the law enforcement exceptions to HIPAA and to discuss with his staff the role law enforcement plays in preventing abuse and diversion is important. If pain management staff members observe evidence of doctor shopping or diversion of prescribed narcotics, those staff members should be familiar with steps they can and must take to alert the relevant authorities of possible illicit action. [Respondent] is responsible for ensuring that his staff understands the practitioner's role in preventing abuse and diversion of controlled substances.

Id. at 75–76. The ALJ then found that Respondent's ''office practice generally created a risk to the public safety in failing to properly train his staff regarding the role of law enforcement officers in detecting abuse and diversion of controlled substances.'' *Id.*

Respondent takes exception to the ALJ's findings and legal conclusions, noting that while the ''HIPAA provides certain law enforcement exceptions to the confidentiality of protected health information, there is no provision in HIPAA that requires an office practice to report 'doctor shopping' to law enforcement.'' Resp. Exceptions, at 15. Respondent further notes that ''[i]n this case, there is not even any evidence of 'doctor shopping.' '' *Id.*

I agree with Respondent that the HIPAA does not require such reporting (as well as that there is no evidence of doctor shopping in this case). Moreover, in this case, there is no evidence that either Ohio law or the standards of professional practice require a doctor to report a doctor shopper to law enforcement, and there may be valid reasons why a physician, who acts entirely within the bounds of both the law and the standards of professional practice, would take issue with the notion that his/her employees should report instances of doctor shopping to the authorities rather than to him or herself.

Accordingly, I reject the ALJ's reasoning. I also reject his finding of fact number twelve, to the extent it states that Respondent ''did not provide training to his staff regarding exceptions to patient privacy laws that apply when the staff members observe behavior relating to controlled substance abuse, misuse, or diversion,'' R.D. at 80, as well as his conclusion of law number thirteen. *Id.* at 86 (concluding that Respondent's ''actions or omissions'' constitute ''other conduct which may threaten public health and safety'' because he ''failed to provide training to his staff regarding exceptions to patient privacy laws that apply when staff members observe behavior relating to controlled substance abuse, misuse, or diversion'').

While I reject the ALJ's finding and conclusion of law on this issue, I agree with the ALJ's finding that the pre-signing of prescriptions, even if there is no proof that the prescriptions were issued on a subsequent day, constitutes conduct which may threaten public health and safety.

his recordkeeping issues'' and that ''[t]hrough his counsel, [he] states that he is willing, if given the opportunity, to remediate these issues in order to avoid future misconduct.'' *Id.* This issue, however, is rendered moot by Respondent's failure to file a renewal application. *See Darryl J. Mohr,* 77 FR 34998, 34999 (2012) (''While this Agency has recognized that because an immediate suspension order involves the exercise of summary process, it is reviewable in a proceeding under 21 U.S.C. 824, even where collateral consequences exist, review of the order is limited to challenging its factual and legal basis. Whether a former registrant has accepted responsibility for his misconduct has no bearing on the validity of the suspension order.'').

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I affirm the Order of Immediate Suspension of DEA Certificate of Registration BA3842259, issued to Syed Jawed Akhtar-Zaidi, M.D. Also, pursuant to the authority vested in me by 21 U.S.C. 824(f), I further order that all right, title, and interest in the controlled substances seized by the Government during the execution of the Order of Immediate Suspension be, and hereby is, vested in the United States.[20]

Dated: July 13, 2015.

Chuck Rosenberg,

Acting Administrator.

Frank W. Mann, Esq., *for the Government*

Walter F. Ehrnfelt, Esq., *for the Respondent*

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

Nature of the Case

Administrative Law Judge Christopher B. McNeil. These are proceedings before the Drug Enforcement Administration and the United States Department of Justice, under docket number 14–2, captioned In the Matter of Syed Akhtar-Zaidi, M.D. The proceedings are being held pursuant to sections 303 and 304 of the Controlled Substances Act, Title 21 United States Code sections 823 and 824.

On October 8, 2013, the Drug Enforcement Administrator through her Deputy Administrator issued an order to show cause why the Administrator should not revoke DEA Certificate of Registration number BA3842259, issued to Syed Jawed Akhtar-Zaidi, M.D., and should not deny any application for renewal or modification of the same.[1] That certificate authorizes distribution of controlled substances out of an office located at 34055 Solon Road, Suite 201, Solon, Ohio 44139.[2] The order also immediately suspended this DEA registration, under the authority found in 21 CFR 1301.36(e) and 1301.37(c).

In the order, the Deputy Administrator alleged that Dr. Zaidi's continued registration is inconsistent with the public interest, in that between September 2012 and May 2013, Dr. Zaidi distributed controlled substances by issuing prescriptions under conditions that fell outside the usual course of professional practice or were for other than legitimate medical purposes.[3] Further, the Administrator determined that based on reports presented to her, Dr. Zaidi's continued DEA registration constitutes an imminent danger to the public health and safety, warranting the immediate suspension of Dr. Zaidi's registration, which is to remain in effect until a final determination is reached in these proceedings.[4]

On October 23, 2013, the Office of Administrative Law Judges for the DEA received Respondent's Request for a Hearing to determine whether Dr. Zaidi's continued registration would be consistent with the public interest.[5]

I granted Respondent's request for a hearing, and in advance of the hearing I asked the parties to offer prehearing statements that included summaries of proposed testimony along with proposed stipulations of fact, with the Government being directed to file their proposal by November 19, 2013, and Respondent by November 26, 2013. I also set the matter for hearing to commence on December 10, 2013, with non-testimonial presentations to be held at the DEA's hearing facility in Arlington, Virginia, and with testimony to be taken during the week beginning January 6, 2014, in Cleveland, Ohio.[6]

On November 6, 2013 I received the parties' consent motion to accelerate the hearing.[7] Upon this motion on November 6, 2013, I ordered the testimonial hearing to begin on December 16, 2013, in Cleveland, and retained all other procedural deadlines.[8]

On December 10, 2013, the initial day of the hearing, federal offices were closed due to winter weather, and I ordered the cancelation of the initial day of hearing.[9] Upon Respondent's request, a prehearing telephone conference was held on December 12, 2013, in order to address pending procedural issues.[10]

At that time I had before me the Government's motion for an order *in limine* and Respondent's motion to delay the evidentiary hearing scheduled to begin four days later.[11] The core premise relied upon by the Government in support of its motion was Respondent's failure to timely comply with the procedural orders set forth in my prehearing order of October 24, 2013, particularly with respect to the failure to timely identify Respondent's expert witness and the substance of his testimony, and Respondent's failure to provide sufficient descriptions of expected testimony.[12] Further, the Government argued that witness descriptions provided by Respondent's prehearing statement indicate the proposed testimony would be irrelevant or otherwise inadmissible.[13]

Respondent, on the other hand, sought to delay the hearing in order to accommodate his expert witness, whom he described as having medical problems that prevented his appearance on December 16 or 17, 2013.[14]

During the prehearing teleconference on December 12, 2013, I denied Respondent's renewed motion to delay the hearing, finding cause had not been shown to require a delay in the testimonial segment of this proceeding. Respondent first sought to delay the hearing on November 25, 2013, the day before prehearing statements were due, in order to have ''adequate time to prepare,'' citing the difficulties in doing so occasioned by the Government's ''prehearing seizure of effectively all of Respondent's liquid assets.'' [15] I considered the balancing of convenience to the litigants, witnesses, counsel, and the Office of Administrative Law Judges, the complexity of the case, and whether denial of the request would result in

[20] For the same reasons that led me to immediately suspend Respondent's registration, I conclude that this Order should be effective immediately. 21 CFR 1316.67.

[1] ALJ Ex. One at 1.

[2] Gov't Ex. One.

[3] ALJ Ex. One at 1–3.

[4] *Id.* at 4.

[5] ALJ Ex. Two at 1.

[6] ALJ Ex. Three.

[7] ALJ Ex. Five

[8] ALJ Ex. Six.

[9] ALJ Ex. 21.

[10] ALJ Ex. 24.

[11] See ALJ Exs. 22 & 20.

[12] ALJ Ex. 20.

[13] *Id.*

[14] ALJ Ex. 22.

[15] ALJ Ex. Nine.

identifiable prejudice to Respondent.[16] Upon considering these factors I found cause had not been shown to delay either the scheduled hearing or the pre-hearing deadlines.

I received Respondent's second request to delay the hearing on December 6, 2013.[17] This was based on the representation that an expert witness, Richard Stieg, M.D., would be unavailable on the dates set for hearing.[18] I considered the factors set forth above, and found cause had not been shown to delay the hearing in an order dated December 6, 2013.[19] On December 12, 2013, I received Respondent's motion for reconsideration of the order denying Respondent's second requested continuance.[20] In denying the motion during the prehearing teleconference, I considered the premises presented in support of the motion, including the premise that the continuance was needed to permit Respondent's medical expert to testify.

In reviewing Respondent's prehearing statement and each supplement thereto, I found that the proposed expert witness's testimony as summarized by Respondent did not need to be presented at the same time as the rest of the testimony being offered, and could be taken out of order without prejudice to Respondent. I further found that the evidence would likely have little probative value, as the witness did not appear to be familiar with Ohio medical practice standards. I also considered the uncertain nature of the length of the delay that would be needed to accommodate Dr. Stieg.

Additionally, I considered the potential adverse effects of such an uncertain delay in resolving this matter. In this regard I am guided by the expectation that where doing so is not inconsistent with a litigant's rights under the Due Process Clause or the Administrative Procedure Act, I should endeavor to submit the certified record of these proceedings to the Administrator in accordance with 21 CFR 1316.65 not later than the 150th day after the issuance of an immediate suspension (excepting any days caused by Respondent's own actions).[21] I also considered the possible prejudice to either party were the hearing to proceed as scheduled, and found no substantial prejudice had been demonstrated. I also considered the potential importance of the testimony being sought, should a delay be granted. Upon weighing these factors and exercising the discretion delegated to me,[22] I found cause had not been shown to delay the testimonial portion of this proceeding. I also permitted Respondent to proffer the medical expert's report for the Administrator's review, so that the hearing could proceed expeditiously while allowing Respondent to present the substance of that report to the Administrator, for her consideration.

Further, I granted the Government's motion for an order *in limine,* finding the proffer of testimony presented with respect to witnesses Elizabeth and Larry Bloch, Patricia Gray, Carolyn Hamilton, Beverly and Virgil Humphreys, James Justice, Greg Ratesic, Lorinda Rose, and Carl Shortridge was insufficient to establish that their testimony would be relevant to the issues before me. I found Respondent's proffer of testimony from his employees Christi Barrett, Julie Brzozwski, and Ricki Zotto was untimely and was insufficient to establish that their testimony would be relevant, and for those reasons I sustained the motion with respect to those three witnesses. I noted that Respondent's employee, Kim Maniglia, was identified as a Government witness and determined that there was no reason to bar her from testifying on behalf of Respondent.

With respect to testimony from Respondent's expert, I found sufficient prejudice had been shown by the Government to sustain its motion and bar the testimony of Dr. Stieg, due to the untimely disclosure of the identity of the expert and the nature of his testimony, and due to the lack of detail in the description of the proposed testimony, including the description presented in Respondent's December 12, 2013 supplemental prehearing statement.

Regarding the lack of specificity and detail provided regarding Respondent's own testimony, I found Respondent's prehearing statement did not comply with my prehearing order in that it did not indicate clearly each and every matter as to which he intended to testify. While cause had been shown to bar Respondent's testimony, the Government did not seek to bar Respondent from testifying but instead sought to have Respondent supply the required summary prior to the conclusion of the first day of hearing, which had been scheduled for December 10, 2013.[23] Although I found sufficient cause including clear prejudice to the Government due to Respondent's failure to comply with my prehearing order, Respondent was not barred from testifying but his testimony was limited to responding to the areas of inquiry presented in the Government's prehearing statement along with any areas set forth in a more complete summary which I allowed to be filed by not later than 2 p.m. on Friday, December 13, 2013. Although Respondent filed a ''Brief in Opposition to the Government's Motion *in Limine''* describing testimony he would elicit from other witnesses,[24] he provided no supplemental statement describing the scope of his own testimony.

When the parties convened in Cleveland for the testimonial portion of the hearing, acting on the advice of his attorney, Dr. Zaidi exercised his constitutional right against compulsory self-incrimination and, after being sworn and identifying himself, declined to answer questions presented to him on direct examination by the Government.[25] The Government presented the testimony of its medical expert, four investigative witnesses, and Dr. Zaidi's billing clerk. Dr. Zaidi presented no testimony, but offered documents which have been identified as proffers and have been included in the record for the Administrator's review. I did not, however, consider Respondent's proffered exhibits in reaching my Recommended Decision.

Summary of the Evidence

The Government's case was presented through testimony of three undercover agents who posed as patients; Dr. Zaidi's billing clerk, Kim Maniglia; Diversion Investigator Scott A. Brinks; and Steven Severyn, M.D., who testified as the Government's medical expert.[26]

Testimony of the Government's Medical Expert

Dr. Severyn practices medicine at the Comprehensive Spine Center located at The Ohio State University Wexner Medical Center, in Columbus, Ohio.[27] He is licensed to practice medicine in Ohio, and serves as the Director of the Pain Medicine Services office of the Medical Center's Department of Anesthesiology, the Director of the Medical Center's Pain Medicine Fellowship, and the Director of the Pain

[16] See *Fitzhugh* v. *Drug Enforcement Administration,* 813 F.2d 1248, 1252 (D.C. Cir. 1987).

[17] ALJ Ex. Seventeen.

[18] *Id.*

[19] ALJ Ex. Eighteen.

[20] ALJ Ex. 22.

[21] See Memorandum re: Immediate Suspension of DEA Registration; Hearing Process DFN: 301–01, October 4, 2006 at 1 (copy attached as Appendix).

[22] See *Richard A. Herbert, M.D.,* 76 FR 53942–02, 53942 (DEA Aug. 30, 2011).

[23] ALJ Ex. 20 at 7.

[24] ALJ Ex. 25.

[25] Tr. at 50.

[26] *Id.* at 51.

[27] *Id.* at 52.

Services section of the Spine Center.[28] He is an assistant professor of clinical anesthesiology, teaching on almost a daily basis in clinical and educational capacities, and practices in the Spine Center and throughout the hospitals of The Ohio State University.[29] He estimated that 50 percent to two-thirds of the patients he treats for pain are prescribed controlled substances for that pain.[30]

Dr. Severyn holds a baccalaureate degree from Johns Hopkins University, a medical degree from The Ohio State University, a master's degree in business administration from Ohio University, and a master's degree in strategic studies at the United States Army War College.[31] He completed an internal medicine residency at Riverside Methodist Hospital, as well as a residency in anesthesiology at The Ohio State University.[32] He holds board certifications with the American Board of Internal Medicine, the American Board of Anesthesiology, and that Board's pain medicine subspecialty.[33]

In his current medical practice, Dr. Severyn works full time in the sub-specialty of pain medicine.[34] He stated that on a typical clinical day he will encounter approximately 30 patients, and on a typical surgical day he will perform between three and six operative procedures.[35] He explained that his patients predominantly are persons without cancer-related diagnoses who are seen on an out-patient basis and are experiencing acute and chronic intractable pain, although some are treated on an in-patient basis for post-operative pain.[36]

Dr. Severyn stated that he has been qualified in the past as an expert witness in matters concerning the evaluation and treatment of patients using controlled substances, for both the DEA and the United States Department of Justice.[37] Without objection, Dr. Severyn was recognized as an expert in the field of pain management in these proceedings.[38]

In preparing to testify in this matter, Dr. Severyn reviewed video recordings of interactions between undercover agents Parkison, Leonard, and Moses, and Dr. Zaidi.[39] He also read the transcripts from those interactions, and the medical records maintained by Dr. Zaidi regarding the treatment of these three patients.[40] In his review, Dr. Severyn applied his understanding of provisions in Ohio law, including section 4731–21–02 of the Ohio Administrative Code, regarding the treatment of intractable chronic pain.[41] Based on this review and applying his understanding of the requirements for the treatment of pain using controlled substances applicable in Ohio, Dr. Severyn concluded that Dr. Zaidi prescribed controlled substances to each of these patients outside the usual course of professional practice[42] and for other than a legitimate medical purpose.[43]

In reaching these conclusions, Dr. Severyn noted the requirements found in the Ohio Administrative Code regarding the use of controlled substances for the treatment of pain.[44] According to Dr. Severyn,

> When selecting a treatment for a patient, the first principle is evaluation, establishing of a diagnosis, the considering of alternative treatments in making a recommendation to a patient [in] regard to treatment, a provision of the risk of each of those alternatives, and then the treating of the patients in a way that conforms with current professional standards of care.[45]

Further, he stated that one part of the professional standard of care for such providers is that when prescribing controlled substances for the treatment of pain, a provider must take into account the medication's potential for diversion and abuse.[46] In addition, in those cases where controlled substances are being considered as part of the treatment plan, ''the standard of care, and the prevailing practice of physicians, is to perform a diligent and a very sophisticated and intense evaluation.''[47] In this context, Dr. Severyn stated that the minimal standard of care would be ''those actions and decisions that would be made by a reasonable physician under similar circumstances.''[48] ''It establishes,'' according to Dr. Severyn, ''what would be the least degree of response or establishes the least degree of care in the provision of treatment, when a physician is faced with a clinical decision, resulting in action or inaction'' and equals the minimal standard of care.[49]

Dr. Severyn noted that when referring to the minimal standard of care throughout his testimony, he regards this as describing the standard of care for pain medicine physicians.[50] He noted further that his own practice differs from many pain medicine practices because his patients all have been referred to his clinic by other medical providers in the OSU health care system.[51] In this respect, Dr. Severyn distinguished what a reasonable physician would do at the initial appointment from what he does in his own practice, because in the initial appointment stage of his own practice all of his patients are either referred by other OSU medical offices or have recently undergone emergency treatment.[52]

Beyond this, however, Dr. Severyn stated that in a pain medicine practice, there are ''additional requirements for the specificity and the degree of detail in keeping medical records when prescribing controlled substances on a protracted basis, greater than twelve weeks,'' calculated from the initial prescribing encounter.[53] He said, however, that there is no federal or state law that defines the types or amounts of drugs that should be prescribed in any particular situation—that this is a decision to be made by the doctor.[54] That decision, according to Dr. Severyn, is to be based on ''[e]xpertise, experience, intensity of service, diligence of work, assessment of the situation, integration of all available information, previous red flags [and] current events.''[55]

Dr. Severyn explained that before a physician may prescribe controlled substances for pain, he or she must reach a medical diagnosis and determine the appropriate treatment plan.[56] In the treatment plan, the physician and patient interact, ''availing themselves of alternative approaches for care, and will go about certain actions'' regarding both procedures and medication, which may then ''be re-evaluated at a later time, so as to determine the efficacy of the original plan.''[57]

Such a treatment plan would need to include ''regular follow up and monitoring, not only of the patient

[28] *Id.* at 52–53.
[29] *Id.* at 53–54, 58–59.
[30] *Id.* at 166.
[31] *Id.* at 54.
[32] *Id.*
[33] *Id.* at 56.
[34] *Id.* at 55.
[35] *Id.* at 58.
[36] *Id.* at 55.
[37] *Id.* at 60.
[38] *Id.* at 61.
[39] *Id.*
[40] *Id.* at 61–62.
[41] *Id.* at 167.
[42] *Id.* at 104, 130, 153.
[43] *Id.* at 103, 130, 153.
[44] *Id.* at 62.
[45] *Id.*
[46] *Id.* at 63.
[47] *Id.* at 65.
[48] *Id.* at 204.
[49] *Id.* at 204–05.
[50] *Id.* at 205.
[51] *Id.* at 263.
[52] *Id.*
[53] *Id.* at 64, 256.
[54] *Id.* at 206.
[55] *Id.* at 207.
[56] *Id.* at 65.
[57] *Id.* at 65–66.

condition, but also of the response to treatment.'' [58] Monitoring in this context is performed through ''medical encounters, history, physical, imaging studies, social history, family history, response to medications, and it takes time to develop that, and also, attention to other details, accuracies, and any unusual events that are occurring,'' along with reviewing the OARRS report.[59] The resulting plan ''needs to include the thought processes of the physician'' in order to fulfill ''the physician's fiduciary responsibility to the patient.'' [60]

In those cases where a physician in Ohio prescribes controlled substances for pain on a protracted basis, which in this case means for greater than twelve weeks, Dr. Severyn said that the physician must obtain the patient's consent and inform the patient of the risks and benefits associated with such a treatment plan.[61] Dr. Severyn said the consent needs to be in writing and needs to reflect that the physician has educated the patient ''as to the nature of the condition, makes a recommendation about the approach for care, describes the risks of each of those alternatives, describes the benefits of each[,] and . . . explores alternative approaches.'' [62] Also in cases where treatment is on a protracted basis, the physician needs to assess the patient's functional status, which includes determining how the pain is interfering with the patient's ability to work, with activities of daily living, with social activities, and with the quality of family life.[63]

Dr. Severyn agreed with the proposition, presented during cross examination, that it will sometimes take a period of time and a number of visits for a physician to observe and evaluate a patient with respect to red flags associated with controlled substance diversion, misuse, or addiction.[64] When asked about the length of time Dr. Zaidi spent monitoring the progress of the cases of the three undercover agents, Dr. Severyn opined that the five or six months spent was a ''moderate'' amount of time.[65] He also explained that while the DEA maintains on its Web site a list of relevant red flags, he personally was ''not familiar enough with that Web site and each and every flag, for me to say that I'm going to use that as my only standard.'' [66] He added, however, that the ''Web site does contain a number of causes for a physician to be suspic[ious] that the seeking of the medication may not be strictly for the treatment of the condition for which the physician intends to prescribe.'' [67]

When asked whether he believes community-based pain management clinics (*i.e.,* clinics not in an academic setting) have a place in medicine and serve a legitimate purpose, Dr. Severyn said they certainly do have a role.[68] He also agreed with the proposition, asked during cross examination, that the patient's ability to pay ''does have more relevance now than it did in the past few years, in the informing of a physician's recommendation or offer of care to the patient.'' [69] When asked, however, whether he would dismiss a patient who elected (on the basis of cost) to forgo a recommended MRI, Dr. Severyn said he would dismiss the patient ''[i]f I felt strongly enough about it.'' [70] Elaborating, he said that if a patient was presenting signs and symptoms ''of a worsening nerve injury'' and if he felt the patient's health ''would be permanently impaired because of a nerve injury and if the patient continued to insist that they were not going to or be able to obtain an MRI, I would seriously consider withdrawing care from that [patient].'' [71]

Another resource available to physicians in Ohio, according to Dr. Severyn, is the Ohio Automated Rx Reporting System, or OARRS.[72] Asked during cross examination whether consulting this reporting system constitutes an attempt by a physician to address a red flag, Dr. Severyn said yes, ''OARRS reports are tremendously helpful and the requirement to check them, as a standard of care, is valid.'' [73] Dr. Severyn was asked if he knew Dr. Zaidi conducted such a check on each patient.[74] Dr. Severyn indicated that he was not aware that this was a part of Dr. Zaidi's prescription practice.[75] There is, however, some evidence from Ms. Maniglia that she would print out an OARRS report for every new patient.[76]

Dr. Severyn also was asked whether transitioning from an immediate-release form of Oxycodone to a time-released form is another means of responding to red flags.[77] After noting that time-released OxyContin ''can be converted to immediate release Oxycodone by crushing or chewing or otherwise altering it,'' Dr. Severyn stated that while there is some protection against abuse, ''the choice of a time release medication is less driven by red flags and the issue of abuse than it is driven by the intent to follow a medical treatment plan that provides a more steady state of medication.'' [78] He said time-release OxyContin is ''less likely, to a degree, to lead to diversion or to lead to addiction, but . . . [i]t's only to a degree that makes it a little more difficult for the patient who seeks to be abusing the medication or seeks to divert the medication, to do so successfully.'' [79]

Two of the undercover agents represented to Dr. Zaidi they suffered from pain or stiffness in the lower back.[80] When asked what he does when a patient presents with a complaint of back pain, Dr. Severyn gave this response:

> I want to find out some basic information about the patient. Where is your pain? Does it radiate into the legs? For how long have you had it? What makes it better? What makes it worse? Have any procedures or surgeries been done to make a difference in this, in the past, and zero to ten, what is your severity of pain? Have you had physical therapy? Has that been helpful for you in the past? Might it be something to consider again? Then I look at the OARRS report, because I want to know how accurate is my patient's reported history in comparison to what has already been documented as being dispensed. Next, I look through the medical record to see if at Ohio State, during any of the time that the patient has been seen, there is a urine drug screen present. If so, I copy it into the medical record and make a decision, then and there, if I'm going to be obtaining another one.[81]

Dr. Severyn explained that because his practice at The Ohio State University is a referral practice, the patients he sees usually are being cared for by other members of OSU's medical staff.[82] He said if he is prescribing controlled substances he will order a urine drug screen, and ''go through all of the areas of the portion of the administrative rule that pertains to the initial prescribing'' of controlled substances.[83] After that, he will review ''the past medical history, which, of course, is medical history, surgical history, medication history, [and] social

[58] *Id.* at 66.

[59] *Id.* at 223. OARRS is the Ohio Automated Rx Reporting System. Tr. at 471, 602.

[60] Tr. at 233.

[61] *Id.* at 67.

[62] *Id.*

[63] *Id.* at 68.

[64] *Id.* at 173.

[65] *Id.* at 224–25.

[66] *Id.* at 172.

[67] *Id.*

[68] *Id.* at 182.

[69] *Id.* at 184–85.

[70] *Id.* at 185.

[71] *Id.*

[72] *Id.* at 178.

[73] *Id.*

[74] *Id.*

[75] *Id.*

[76] *Id.* at 414.

[77] *Id.* at 180.

[78] *Id.*

[79] *Id.* at 213–14.

[80] Gov't Ex. Nine at 3; Gov't Ex. Ten at 6.

[81] Tr. at 216–17.

[82] Tr. at 220.

[83] *Id.*

history. After that, it's going to be a review of symptoms, which is about 50 specific symptoms to do, and then I'm going to go through my physical examination.'' [84] He would then check for imaging, if any is available, and following that he would make his assessment and diagnosis, which he will discuss with the patient.[85] From there, the patient must decide the course of action based on Dr. Severyn's recommended course of action, after which prescriptions can be written along with any other orders, and arrangements are made for follow up visits.[86]

Dr. Zaidi's Treatment of Officer Tyler Parkison (Under the Name Tyler Williams)

Tyler Parkison is a DEA Special Agent, a position he has held since 2008.[87] Between 2005 and 2008 he was a DEA Diversion Investigator, having graduated from the DEA's twelve-week training academy at Quantico, Virginia.[88] As a diversion investigator, Agent Parkison was trained in the investigation of criminal and regulatory cases, including those involving drug audits and identification and the execution of warrants.[89] Agent Parkison has been trained in the use of firearms, undercover operations, surveillance, physical fitness, financial investigations, and drug identification.[90]

Agent Parkison stated that the investigation into Dr. Zaidi's prescription practice began after an agent in his office received a complaint indicating ''suspicious prescribing involving controlled substances'' along with a complaint alleging a family member of the complainant ''was addicted to Dilaudid'' and an allegation that ''there were drug transactions taking place in the parking lot'' of Dr. Zaidi's practice.[91] Included in the report by the complainant was the assertion that ''patients were going in and out very quickly, that they were seeing up to ten to fifteen people in an hour.'' [92] Acting on this information, Agent Parkison obtained a report from OARRS setting forth the prescription history for Dr. Zaidi, revealing that ''the amounts of Schedule II drugs that he was prescribing was very high.'' [93] When asked to elaborate on this during cross examination, Agent Parkison said that based on his experience, Dr. Zaidi's prescriptions for Schedule II drugs seemed high when compared with ''a couple'' of other physicians he had been investigating.[94] Given this information, Agent Parkison ''decided to schedule an office visit at Pain Management of Northern Ohio.'' [95]

In his investigation of Dr. Zaidi, Agent Parkison acted in an undercover capacity under the name Tyler Williams,[96] and also was part of the team that executed a search warrant and retrieved records from Dr. Zaidi's office.[97] He acknowledged, during cross examination, that he approached Dr. Zaidi as an undercover agent intending to falsely report that he had pain, but he denied attempting to fool Dr. Zaidi.[98]

Agent Parkison's first of five visits to Dr. Zaidi's office was recorded in audio and audio/video recordings, the transcripts of which are in our record.[99] Agent Parkison explained that the first visit took place on September 11, 2012, and confirmed that Government Exhibit 3a contains a video recording of that visit.[100] I viewed this video, and found that Dr. Zaidi's medical office appears to be furnished and staffed in a manner similar to many office practices: The office is located in an office complex, and upon passing through a hallway, Agent Parkison opened the door to find a reception area in which a receptionist took his name and driver's license, while a billing clerk (later identified as Kim Maniglia) spoke on the telephone regarding authorization for an imaging procedure and another staff member in clinical garb entered and left the receptionist's office.[101]

Ms. Maniglia explained that she has been employed at Pain Management of Northern Ohio for twelve and a half years.[102] She said Dr. Zaidi owns the business, and that she does all of the billing for the business, and also works at the front desk.[103] She explained that while she has no medical training and does not participate in patient treatment, she does have a role in filling out prescriptions for the office.[104] She stated that for every new patient, Dr. Zaidi runs an OARRS report—she prints out the report and puts them in the new patient's file for Dr. Zaidi to review.[105] The reports indicate what prescriptions the patient is getting and what doctors the patient has seen.[106] According to Ms. Maniglia, after Dr. Zaidi sees a patient, the patient's medical chart comes to her, at which point she reads what Dr. Zaidi has written and logs prescription information into the back of the chart.[107] After the patient is seen, she shreds the OARRS report.[108]

According to Ms. Maniglia, Dr. Zaidi requires urine drug screening for all new patients, and uses such screens periodically throughout the patient's treatment.[109] She added that if a patient does not ''have good urine Dr. Zaidi usually writes on the bottom not to fill any scripts for them'' or may indicate ''NPUS'' on the chart, to direct ''no prescriptions until seen.'' [110] Based on what Dr. Zaidi has written, Ms. Maniglia will write the prescription information on a blank prescription form.[111] She said that Dr. Zaidi would sign blank prescriptions in the morning, and after they were signed she would fill out the prescriptions throughout the day, using the signed forms.[112]

Ms. Maniglia explained that there may be days when prescriptions that Dr. Zaidi has signed are not actually needed that day, so ''[t]here might have been a few left over,'' but when that happens the signed prescriptions are stored ''triple-locked up in the drug cart'' and are used the next day.[113] Ms. Maniglia acknowledged that some of these prescriptions have been for controlled substances.[114] She said Dr. Zaidi trained her in this aspect of her job, and she has performed these tasks for more than twelve years.[115] When asked whether Dr. Zaidi ever mentioned the need to have a patient's address on the prescription, Ms. Maniglia said no, even with prescriptions for controlled substances, ''we just need two identities, just the birth date and the name.'' [116]

Affixed to the window separating the waiting area from the receptionists office are stickers indicating payment could be made using Visa, Diners Club, MasterCard and Discover, along with a sign that states the staff is not permitted

[84] *Id.*
[85] *Id.* at 221.
[86] *Id.*
[87] *Id.* at 296.
[88] *Id.*
[89] *Id.* at 297.
[90] *Id.* at 299.
[91] *Id.* at 320.
[92] *Id.*
[93] *Id.* at 320–21.
[94] *Id.* at 436.
[95] *Id.* at 321.
[96] *Id.* at 309.
[97] *Id.* at 299.
[98] *Id.* at 445.
[99] Gov't Exs. 3a through 3e; Gov't Ex. Nine.
[100] Tr. at 300–01.
[101] Gov't Ex. 3a, folder AudioVideo Recordings—09–11–12, file 105605 at 10:57:05–10:59:43.
[102] Tr. at 406.
[103] *Id.*
[104] *Id.* at 407.
[105] *Id.* at 414.
[106] *Id.* at 415.
[107] *Id.* at 407.
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] *Id.*
[113] *Id.* at 408–09.
[114] *Id.* at 410.
[115] *Id.* at 428–29.
[116] *Id.* at 429.

to accept any homemade food, and another that states co-payments are to be paid at the time of the office visit.[117] The waiting area is appropriate in size, judging from the eight to ten office chairs that were visible in the video, and was sufficient for the three or four patients waiting in the room.[118]

The receptionist area appeared to be equipped with telephones, computers, fax, copy, or multifunction machines, and file cabinets that typically are found in offices of this size.[119] The overall impression was that this was a fully functional small medical practice. According to Agent Parkison, Dr. Zaidi was the only doctor at the office of Pain Management of Northern Ohio.[120] There was no evidence that the office accepted only cash, or that it refused to treat persons covered by insurance. In fact, Ms. Maniglia can be heard on the phone confirming approval for a ''three-level lumbar discogram,'' which suggests she was confirming this service would be paid for by the patient's health insurance.[121] During the hearing, Ms. Maniglia explained that on average, the office will deposit about $3,000 per week in cash, but that most of the office gross receipts, roughly 80 percent, come from insurance providers.[122]

Ms. Maniglia was asked to recall what she was asked when DEA agents came to Dr. Zaidi's office to search the premises.[123] She said the agent, whom she referred to only as Damien, asked about Dr. Zaidi's children, the car he drives, and his religion.[124] She said they also asked if Dr. Zaidi kept controlled substances in the office, and she responded that he does not, not even samples.[125]

Ms. Maniglia also testified about what she told DEA investigators with respect to doctor shopping. She said she understood doctor shopping involved patients going to different doctors in order to get multiple prescriptions for controlled substances.[126] She was asked whether she was aware of any instances where Dr. Zaidi's patients may have been accused of doctor shopping, and responded that she has ''nothing to do with the patients'' when they are in the back being examined by Dr. Zaidi.[127] She did, however, recall being asked by law enforcement officers during the search of Dr. Zaidi's office, about patients who might be involved in doctor shopping.[128] She said the officer who claims she told him she was not allowed to report such patients to law enforcement misunderstood her—that under HIPAA ''we weren't allowed to discuss anything'' regarding such patients.[129] Apparently Ms. Maniglia understood that under HIPAA, staff members were not permitted to contact law enforcement due to ''patient confidentiality,'' but she added that her understanding was not the result of instructions from Dr. Zaidi.[130] Rather, her understanding of this restriction was based on her work ''in the field for 20 years and we're not allowed to talk about any patient confidentiality stuff.'' [131] She denied, however, being instructed not to call authorities if there were dirty urine screens or if an OARRS report showed multiple doctor encounters, adding, ''We've never talked about it.'' [132]

At the time search warrants were being executed, DEA Diversion Investigator Scott Brinks questioned Dr. Zaidi regarding his office practice.[133] Investigator Brinks said Dr. Zaidi consented to the interview, and when asked about pre-signed prescriptions found in the office, responded by telling Investigator Brinks that he did pre-sign them, and agreed that they were presently blank but for the signature.[134] Investigator Brinks also stated Dr. Zaidi confirmed writing a prescription for Vicodin to his daughter.[135] He added, however, that he did not know whether the prescription was for emergency treatment, nor whether the prescription was ever filled.[136]

In addition to providing insight into the operations of Dr. Zaidi's medical office at the time of the execution of the DEA's search warrant, the Government also included in the record transcripts and recording showing how Dr. Zaidi's office staff handled patient visits. Generally, a staff assistant would conduct an initial intake interview with the patient, and then Dr. Zaidi would review the intake forms and meet with the patient.[137] At subsequent office visits, the staff member would continue to conduct an initial review of current symptoms with the patient, and thereafter Dr. Zaidi would briefly meet with the patient and determine whether to continue to prescribe controlled substances.[138]

Christy Barrett, a member of Dr. Zaidi's office staff, conducted an intake interview with Agent Parkison, lasting approximately nine minutes.[139] During this interview, Ms. Barrett took Agent Parkison's blood pressure; pulse; and pulse oxygen levels; asked his height and weight; inquired about his level of pain and location of pain; use of tobacco, alcohol, and caffeine; past surgeries and physical therapy; past MRIs; use of blood thinners; and could be seen filling out the medical intake form.[140] She then went through the contents of a pain management contract, which Agent Parkison had signed prior to this interview.[141] At the end of the intake interview, she directed Agent Parkison to provide a urine sample for a drug screen.[142]

The doctor's examination took place in a room that appeared to be well-equipped with modern, functional furnishings, including a full-size examination table.[143] Dr. Zaidi greeted Agent Parkison as ''Mr. Tyler,'' reviewed papers contained in a folder, and asked questions regarding his medical history for approximately one minute.[144] Although Agent Parkison told Dr. Zaidi he did concrete work, there was never any discussion about whether the work involved heavy lifting or any other physical activity.[145] Also, although Agent Parkison wrote in his history that he had a work-related injury, during the interview with Dr. Zaidi he denied being injured; yet, according to Agent Parkison, this inconsistency was never addressed by Dr. Zaidi.[146]

Dr. Zaidi discussed Agent Parkison's hypertension, and then had Agent Parkison stand, bend from the waist forward then back, walk on his toes and heels, and thereafter told Agent Parkison he had slight scoliosis, ending the examination after approximately 60

[117] Gov't Ex. 3a, folder AudioVideo Recordings—09–11–12, file 105605 at 10:59:08–09.

[118] *Id.* at 11:00:37–11:01:27.

[119] *Id.* at 10:57:44–10:57:46.

[120] Tr. at 339.

[121] Gov't Ex. 3a, folder AudioVideo Recordings—09–11–12, file 105605 at 10:57:51–10:58:13.

[122] Tr. at 426.

[123] *Id.* at 420–21.

[124] *Id.* at 421.

[125] *Id.*

[126] *Id.* at 410.

[127] *Id.*

[128] *Id.* at 411.

[129] *Id.*

[130] *Id.* at 412.

[131] *Id.*

[132] *Id.* at 416.

[133] *Id.* at 618.

[134] *Id.* at 618–19.

[135] *Id.* at 619.

[136] *Id.* at 620.

[137] See, *e.g.,* Gov't Ex. 3a folder AudioVideo Recordings 09–11–12, file 114021.

[138] See, *e.g.,* Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 115238.

[139] Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 114021.

[140] *Id.* at 11:40 to 11:47; Gov't Ex. Twelve at 19.

[141] Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 114021 at 11:47 to 11:49; Gov't Ex. Twelve at 25.

[142] Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 114021 at 11:49 to 11:51.

[143] Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 115238.

[144] *Id.* at 11:54 to 11:55.

[145] Tr. at 331.

[146] *Id.*

seconds.[147] After confirming he had no medical insurance, Dr. Zaidi told Agent Parkison that he would order an MRI, but it would be acceptable if Agent Parkison elected to wait for two weeks before getting the imaging, and added that there was a source for MRIs that would provide the service for $350 to uninsured patients of the office, if that was what Agent Parkison decided to do.[148]

Without discussing the possibility of physical therapy or home exercises,[149] Dr. Zaidi wrote a prescription for 20 tablets of Percocet five mg,[150] charged a $300 fee for the office visit,[151] and directed that Agent Parkison return in two weeks.[152] Dr. Zaidi added that they could discuss whether epidural injections might help, asked additional questions regarding Agent Parkison's medical history and ended the visit (although at this time Dr. Zaidi took no further notes while on camera).[153] [154]

After confirming that he reviewed the undercover recordings and the entire medical record maintained by Dr. Zaidi regarding treatment of Agent Parkison (under the name Tyler Williams), Dr. Severyn expressed opinions regarding both Dr. Zaidi's physical examination of Agent Parkison and the medical history that supported Dr. Zaidi's decision to prescribe controlled substances to this patient.[155] As noted above, prior to meeting with Dr. Zaidi, Agent Parkison met with and was interviewed by Christy Barrett.[156] Dr. Severyn opined that when Ms. Barrett took Agent Parkison's blood pressure and pulse oximetry readings, inquired of his medical history, and inquired of his pain level and functional capacities,[157] ''that encounter and the collection of information satisfies the requirement of a minimum standard of care'' for taking the history of a patient, but not ''for initially prescribing a controlled substance to a patient who will ultimately be receiving it for longer than twelve weeks.'' [158]

Dr. Severyn noted that the patient ''is acknowledging no past medical history, no past surgical history, and having been completely healthy all of his life'' until two weeks prior to the visit, when he experienced lower back pain.[159] Rating his pain at a four (on a ten-point scale), the patient did not acknowledge having any pain radiating to his legs, nor any weakness or numbness; and indicated he was employed as a concrete worker at a construction company at the time of the office visit.[160]

When Dr. Severyn compared what was in the written medical chart [161] with what he observed while watching the audio/video recording of the initial office visit, he noted the following. First, he noted that the written medical chart indicates that the patient's pupils were equal when reacting to light, and explained that to make this determination, ''[the] physician needs to shine a light into one pupil and then into the other pupil. And I didn't find any evidence in the video recording or in the transcript that that was occurring'' during this office visit.[162] Similarly, he found the written entry indicating that the oral mucosa (*i.e.,* the inside of the mouth) was moist and pink, but saw no evidence that the patient was ever asked to open his mouth while Dr. Zaidi examined its interior.[163]

Next, Dr. Severyn noted that a cranial nerve examination was indicated in the written notes.[164] He explained that an examination of the cranial nerve is conducted by touching the neck to determine the size of the thyroid gland, and by touching the armpits to determine whether the axillary lymph nodes were enlarged—neither of which were performed during this examination.[165] Also included in such an examination is a range of motion test for the neck, which Dr. Severyn said he did not find in the recording or the transcript.[166]

Similarly, although the medical record indicates normal sensory and motor testing, ''[t]here was no testing that went on with sensation of the arms, the hands, or the range of motion or strength of the fingers, the wrists, the biceps, and triceps.'' [167] Further, there is an entry indicating normal range of motion in all the joints of the upper extremities, but such an examination did not occur, according to Dr. Severyn.[168]

Dr. Severyn noted that Dr. Zaidi reported mild scoliosis without deformity, but also that the lower extremities were normal with respect to sensation and strength, and that the ''[a]bdomen is soft and nontender.'' [169] Dr. Severyn said that Dr. Zaidi certainly would have seen the patient walk as part of the office visit, and would thereby be able to report that the patient's balance and coordination were normal, and confirmed that Dr. Zaidi had the patient perform heel and toe walking (which were described as normal).[170] He did not, however, see Dr. Zaidi touch the patient's abdomen to test it for softness and for the presence of tenderness.[171]

Next, Dr. Severyn said that while the medical records indicate a chest examination was performed, ''to do that requires the use of a stethoscope, and a stethoscope was nothing that I could observe during any of the recording of this encounter.'' [172] He said the same was true regarding the notation of normal heart sounds—heart sound examinations require a stethoscope, but none was observed during the video recording of this examination.[173]

Dr. Severyn opined that the report of this patient's examination was falsified in that ''it is embellished, and it is inaccurate, to the point that much of it, though documented here, was not performed.'' [174] Moreover, in his opinion, the medical history described a patient with ''an acute condition of mild severity and of a generally benign nature'' that would not ''justify prescribing a controlled substance or relying upon a controlled substance as the predominant approach to treatment.'' [175]

Also of concern, according to Dr. Severyn, was Dr. Zaidi's diagnosis indicating thoracic and lumbar radiculitis. Dr. Severyn stated:

> Radiculitis is a diagnosis of nerve root dysfunction at the level of the spine, at the level where the nerve roots exit the spine. If it is lumbar radiculitis, then it is a nerve root that's exiting in the lumbar area, and so for the thoracic area, radiculitis is a condition

[147] Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 115238 at 11:55:17 to 11:56:15.

[148] *Id.* at 11:56:16 to 11:57:300.

[149] Tr. at 333.

[150] Percocet is the brand name of a combination of Oxycodone and Acetaminophen. Tr. at 254.

[151] Tr. at 309.

[152] Gov't Ex. Nine at 8.

[153] Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 115238 at 11:56:38 to 11:58:16.

[154] Gov't Ex. 3a also included files 111619, 112129, and 112930. After I watched and listened to each of these, I found no information relevant to this proceeding in these files. The exhibit also includes an audio-only file identified as CCR_0001, which neither party referred to during the hearing and which did not appear to have any information relevant to this proceeding.

[155] Tr. at 69–70.

[156] Gov't Ex. Nine at 1–6.

[157] *Id.*

[158] Tr. at 237–39.

[159] *Id.* at 70–71.

[160] *Id.* at 71; Gov't Ex. Twelve at 19.

[161] Gov't Ex. Twelve at 7.

[162] Gov't Ex. Twelve at 7; Tr. at 72.

[163] Gov't Ex. Twelve at 7; Tr. at 72–73.

[164] Gov't Ex. Twelve at 7; Tr. at 73.

[165] Gov't Ex. Twelve at 7; Tr. at 73.

[166] Tr. at 73.

[167] Gov't Ex. Twelve at 7; Tr. at 73–74.

[168] Gov't Ex. Twelve at 7; Tr. at 74.

[169] Gov't Ex. Twelve at 7; Tr. at 74.

[170] Gov't Ex. Twelve at 7; Tr. at 75.

[171] Gov't Ex. Twelve at 7; Tr. at 75.

[172] Gov't Ex. Twelve at 7; Tr. at 75.

[173] Gov't Ex. Twelve at 7; Tr. at 75.

[174] *Id.* at 76.

[175] *Id.*

that will then affect the entire nerve root to some degree or another, but it is not pain that is limited to just the portion of the back. We call that instead axial pain. It has other causes. That is the use of the word lumbago, which is lumbar pain.

But, putting a diagnosis of radiculitis as opposed to other causes, that, based on this history and the lumbar portion of the examination are much more reasonable, brings to my mind the question as to the accuracy of that diagnosis, because I think that an experienced physician, especially one in the field of pain medicine, would recognize that this is not the presentation and the examination that's compatible with a diagnosis of radiculitis. This diagnosis is blatantly inaccurate.[176]

Accordingly, Dr. Severyn opined that both the treatment plan and the recommendation for this patient were ''not justified by the presentation of this patient.'' [177]

Dr. Severyn expressed the same opinion regarding Dr. Zaidi's diagnosis of lumbar radiculitis during the follow-up visit on October 4, 2012, based on what he observed from the recordings of the follow-up visit and what appears in Dr. Zaidi's written notes of that encounter.[178] He said Dr. Zaidi's notation that he conducted a physical examination during that visit allowing him to find moderate tenderness and spasm in the paralumbar muscles (with guarding and forward flexing) was falsified, as was his description of a lower extremity examination establishing normal sensory and motor testing.[179]

The October 4, 2012 visit began with Ms. Barrett [180] taking Agent Parkison's blood pressure and pulse oximetry,[181] and recording her findings while seated and using the examination table as her desk.[182] Ms. Barrett inquired of Agent Parkison's current pain level, which he stated was three or four, with the best level around two and worst pain at four.[183] Those pain levels are recorded in notes apparently written by Ms. Barrett, indicating current pain as a four, with worst pain at four and best pain at two.[184] At no time did Agent Parkison indicate a pain level as high as five.

As Ms. Barrett finished her notes in the file, Dr. Zaidi entered and Ms. Barrett stood up from behind the examination table, at which point Dr. Zaidi took the seat and briefly turned his back to Agent Parkison and consulted his computer monitor.[185] Dr. Zaidi then turned to face Agent Parkison, and began his interview, asking about whether the Percocet had been effective and discussing his concerns about Agent Parkison's blood pressure, which he said was high and created the risk of stroke.[186] When Dr. Zaidi asked how the Percocet was working, Agent Parkison stated ''it worked pretty good, it worked alright; I just felt like I didn't quite have enough of it.'' [187] They did not, however, discuss whether Agent Parkison had taken all of the prescribed Percocet.[188]

Agent Parkison then asked Dr. Zaidi ''if I could get a little bit more'' and hoped ''to try two in the morning and two in the evening.'' [189] Without more, Dr. Zaidi stated ''Okay. So I'll give you four a day.'' [190] Based on this examination, Dr. Zaidi gave Agent Parkison a prescription for 56 Percocet five mg tablets.[191]

In his transcribed notes for the subjective examination, Dr. Zaidi wrote:

> [Agent Parkison] is stable with his lower back pain at 5 on a scale of 0–10. No change in his personal, family, or social history. No focal weakness or numbness. No abdominal or chest pain. His blood pressure is again very elevated. We again discuss the potential complications from such high blood pressure and he is to go and see his PCP today or ER to have that addressed. Otherwise, no abdominal or chest pain at present. No headaches. No visual disturbances.[192]

In his report of objective findings, Dr. Zaidi wrote that Agent Parkison's ''vital signs are stable though blood pressure is elevated. Moderate tenderness and spasm in paralumbar muscles with guarding in forward flexion. Lower extremity examination is normal to sensory and motor testing. His gait is normal.'' [193] Having seen the audio-video recording of this encounter, I find no evidence that Dr. Zaidi has accurately described the scope of his physical examination, and consistent with Dr. Severyn's findings, I find this to be a falsified examination report.

By this point in the visit, Dr. Zaidi had spent approximately two minutes in the room with Agent Parkison, all of it seated, with the examination table between himself and Agent Parkison.[194] As Dr. Severyn noted, there is no evidence that Dr. Zaidi performed any physical examination either before or after agreeing to increase the Percocet prescription.[195] Indeed, the discussion predominating this visit addressed Agent Parkison's high blood pressure, not his pain or his treatment for pain. There was no discussion about exercise, physical therapy, injections, alternatives to the use of controlled substances, or Agent Parkison's functional capacity.

Dr. Severyn remarked that there was a notation regarding home exercise as part of the plan of treatment.[196] He added, however, that he found nothing in the material that ''contained any educational endeavor that would allow someone to conduct a home exercise program.'' [197] He explained that in order to provide a home exercise program to a patient, ''there would need to be either verbal or oral communication. It would include instructions as to what are the physical maneuvers to be performed, the frequency, the timing, and the expected response and instructions as to how to avoid exacerbating the condition.'' [198] While this could be accomplished by handing the patient various brochures that might explain a home exercise program for this kind of pain, there is nothing in the record to indicate such education took place.[199] Agent Parkison confirmed this, testifying that at no time during any of his office visits did Dr. Zaidi provide him with examples of exercises he could perform to treat his back pain, nor was there any discussion about a home exercise program.[200]

Despite the paucity of information gathered during this second visit, Dr. Zaidi increased by one hundred percent the number of Percocet tablets he prescribed to Agent Parkison.[201] According to Dr. Severyn, there was no justification presented in the medical record for doubling the amount of Percocet to Agent Parkison.[202] Dr. Severyn explained that while Agent Parkison's continued complaint of pain should be considered, Dr. Zaidi should have considered alternatives to

[176] *Id.* at 77–78.

[177] *Id.* at 79.

[178] *Id.* at 80.

[179] Gov't Ex. Twelve at 12; Tr. at 81.

[180] Gov't Ex. Nine at 11.

[181] Tr. at 232.

[182] Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04–12, file 102359 at 10:24:38 to 10:26:40.

[183] *Id.;* Gov't Ex. Nine at 11.

[184] Gov't Ex. Twelve at 18.

[185] Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04–12, file 102359 at 10:26:31–10:27:05.

[186] Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04 12, file 102359 at 10:27:05 to 10:28:11.

[187] *Id.;* Gov't. Ex. Nine at 13.

[188] Tr. at 336.

[189] Gov't Ex. Nine at 13.

[190] *Id.*

[191] Tr. at 310; Gov't Ex. Fifteen at 2.

[192] Gov't Ex. Twelve at 12.

[193] *Id.*

[194] Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04 12, file 102359 at 10:26:31 to 10:28:40.

[195] Tr. at 80.

[196] *Id.* at 81.

[197] *Id.*

[198] *Id.* at 84–85.

[199] *Id.* at 85.

[200] *Id.* at 350.

[201] *Id.* at 85.

[202] *Id.*

controlled substances as treatment.[203] Dr. Severyn opined that when Dr. Zaidi prescribed 56 Percocet tablets for Agent Parkison during this visit, he did so outside the usual course of professional practice.[204]

According to Dr. Severyn, Agent Parkison's next visit, on November 14, 2012, did not include an examination of the lumbar spine, nor any testing for guarding in forward flexion, nor was there any sensory or motor testing of the lower extremities.[205]

Having reviewed the audio-video recording of the November 14, 2012 office visit, I concur with Dr. Severyn's assessment and find there was no examination of Agent Parkison's lumbar spine during this visit, nor was there any testing for guarding in forward flexion, nor was there any sensory or motor testing of the lower extremities.[206]

Agent Parkison stated that for this visit, he reported a current pain level of two and the worst level had been a three.[207] In taking his history for this visit, Ms. Barrett accurately recorded in his patient medical chart that Agent Parkison reported a maximum pain level of three, a minimum of two, and a present level of two.[208] After Ms. Barrett obtained Agent Parkison's blood pressure and oximetry readings and recorded his responses to her questions about current and recent pain levels, Ms. Barrett left the room and Dr. Zaidi entered shortly thereafter.[209] Dr. Zaidi remained standing near the office door and reviewed the chart provided to him by Ms. Barrett, and for approximately two minutes discussed with Agent Parkison his high blood pressure and the steps he should be taking to address that problem.[210] At no time did Dr. Zaidi place his hands on Agent Parkison or approach him—instead, he stood by the chart until he determined that the pain medication was working and completed his discussion regarding the seriousness of Agent Parkison's elevated blood pressure.[211]

Based on this encounter, Dr. Zaidi made written subjective findings, stating that Agent Parkison's ''lumbar pain is at 5 on a scale of 0–10'' despite the notations to the contrary in the chart prepared by Ms. Barrett and despite the absence of any evidence indicating Agent Parkison was reporting pain at that level.[212] Despite the lack of questions (by either Ms. Barrett or Dr. Zaidi) addressing these subjects, Dr. Zaidi wrote there was ''[n]o change in his personal, family, or social history.'' [213] Despite the absence of any physical examination or questions presented to Agent Parkison regarding these areas, Dr. Zaidi wrote in his subjective findings that there were no abdominal or chest pains, and no focal weakness or numbness.[214]

Consistent with what Agent Parkison told Dr. Zaidi, in the Objective findings section Dr. Zaidi noted Agent Parkison's continued high blood pressure, adding, ''He has seen his PCP and has been asked to monitor it at home, and I asked him to make a follow-up again very soon.'' [215] Dr. Zaidi accurately reported that they again discussed the potential complications of hypertension.[216] He continued, however, to report ''[m]oderate tenderness and spasm in paralumbar muscles with guarding in forward flexion. Lower extremity examination is normal to sensory and motor testing.'' [217] Also, despite the fact that Agent Parkison was seated throughout his encounter with Dr. Zaidi during this visit, Dr. Zaidi wrote that Agent Parkison's ''gait is normal.'' [218] Based on these subjective and objective findings, Dr. Zaidi wrote that the impression is that of lumbar radiculitis, and issued a prescription for 56 tablets of Percocet five mg.[219]

Dr. Severyn opined that Dr. Zaidi's diagnosis of lumbar radiculitis ''is a more severe condition than what this patient is voicing complaints [] of,'' and ''is not justified on the basis of the entirety of the history and the physical examination.'' [220] He explained that the objective findings that appear in Dr. Zaidi's written report of the November 14, 2012 visit—including spasms in paralumbar muscles and guarding in forward flexion—could not be reached without a physical examination, but that there was no evidence that such an examination occurred.[221] I too saw no evidence of an examination during this visit.

Dr. Severyn also noted that while the written record of treatment for November 14, 2012, reports Agent Parkison reported pain at level five (on a scale of ten), the recording and transcript show that Agent Parkison reported pain at level two to three—and there is no explanation to account for this difference.[222]

The Government also presented testimony from DEA Diversion Investigator Brinks, who was present when Agent Parkison interviewed Dr. Zaidi at the time the DEA's search warrant was executed.[223] Investigator Brinks testified that Agent Parkison had the medical chart reflecting pain levels higher than Agent Parkison reported to either Dr. Zaidi or Ms. Barrett, and asked Dr. Zaidi if he could explain this difference.[224] According to Investigator Brinks, Dr. Zaidi had no response when presented with Agent Parkison's treatment chart.[225]

Dr. Severyn was asked to interpret the exchange between Dr. Zaidi and Agent Parkison, where the latter, during his visit of December 12, 2012, told Dr. Zaidi that his current medication has ''been helping some at the end of the day,'' but that he had ''a little bit of nagging stiffness,'' adding that one of his ''buddies said something that [OxyContin] kind of helps him.'' [226] Without more, according to Dr. Severyn, this would not be a sufficient justification for changing a medication to OxyContin, but that is what Dr. Zaidi did.[227]

The audio-video recording of the December 12, 2012 visit confirms Dr. Severyn's description of the sequence leading to this change in medication. For this visit, Ms. Barrett does not appear to have taken a history or recorded Agent Parkison's blood pressure, and Dr. Zaidi met with Agent Parkison for slightly less than three minutes.[228] For the first minute or so, Dr. Zaidi did not actually look at Agent Parkison, but instead was apparently reviewing his medical chart.[229] While still studying the chart, Dr. Zaidi inquired how Agent Parkison was doing, and Agent Parkison responded

[203] *Id.* at 86.

[204] *Id.*

[205] *Id.* at 88.

[206] Gov't Ex. 3c, folder Tyler UC Visit 3, subfolder AudioVideo—11–14 12, file 094453. Note that Government Exhibit 3c also includes an audio-only recording, which was not discussed by the parties and which contains no information relevant to this matter that is not also available in the audio-video recording.

[207] Tr. at 341.

[208] Gov't Ex. 3c, folder Tyler UC Visit 3, subfolder AudioVideo—11–14 12, file 094453 at 10:00:26 to 10:02:25; Gov't Ex. Twelve at 18.

[209] *Id.* at 10:00:37 to 10:04:56.

[210] *Id.* at 10:04:56 to 10:06:57.

[211] *Id.*

[212] Gov't Ex. Twelve at 11; cf. *Id.* at 18.

[213] *Id.* at 11.

[214] *Id.*

[215] *Id.*

[216] *Id.*

[217] *Id.*

[218] *Id.*

[219] *Id.;* Tr. at 341.

[220] Tr. at 88–89.

[221] *Id.* at 90–91.

[222] *Id.* at 92.

[223] *Id.* at 618, 620.

[224] *Id.* at 619–20.

[225] *Id.* at 620.

[226] *Id.* at 95; Gov't Ex. Nine at 20.

[227] Tr. at 95.

[228] Gov't Ex. 3d, folder Tyler UC Visit, subfolder AudioVideo—12–12–12, file 132123 at 13:48:56—13:51:17.

[229] *Id.* at 13:48:56—13:50:18.

that he had been experiencing some ''nagging stiffness'' and remarked that one of his ''buddies'' had suggested ''Oxy kind of helps him.'' [230] Without a pause (other than to observe that such a change would be ''a lot more dose'' and would be more expensive), Dr. Zaidi wrote a prescription for 42 ten mg tablets of OxyContin.[231]

Dr. Zaidi then engaged Agent Parkison with questions and advice about his blood pressure (although it appears no one recorded Agent Parkison's blood pressure for this visit).[232] In his treatment notes under the ''Subjective'' section for the visit on December 12, 2012, Dr. Zaidi wrote that Agent Parkison's pain level is ''5 on a scale of 0–10,'' although there is nothing in the medical chart nor the recording that supports this finding.[233] Further, Dr. Zaidi wrote that Agent Parkison ''is not tolerating Percocet, which is lasting only a couple of hours and we are going to change that to OxyContin 10 mg three times a day.'' [234] There was, however, nothing in either the recording or the patient medical records that indicates the Percocet was lasting only a couple of hours nor that Agent Parkison was not tolerating Percocet—only that he had some ''nagging stiffness'' and a ''buddy'' said OxyContin helped.[235]

Dr. Severyn said that requesting OxyContin under these circumstances ''raises in my mind, as it does in that of my associates and colleagues, a question of why is this patient asking for a specific medication by name, instead of relying on my expertise to introduce a specific medication. . . .'' [236] He said that ''these are red flags that I've heard in . . . national medical conferences for a decade or more.'' [237]

Dr. Severyn next explained there are more rigorous standards that apply in Ohio when using controlled substances to treat pain that no longer can be described as acute but is instead chronic or intractable.[238] After reviewing patient treatment records for treatment during the first twelve weeks, Dr. Severyn stated that by January 2013, ''the medical care is entering into that portion that the statutes in Ohio consider as protracted prescribing.'' [239] According to Dr. Severyn,

> At that point, there is a much higher level of service reflected by documentation that needs to take place. Some of those [include an] evaluation of what is the current employment history, what is the activity of daily living. . . . Is the treatment plan justified? [W]hat is the effectiveness of the treatment plan? That is not recorded here.[240]

Dr. Severyn explained that by the time the protracted prescribing of controlled substances has begun, ''the diagnosis needs to be substantiated by the physical findings and my opinion is that they are not, and it needs to be substantiated by the history, and my opinion is that it is not.'' [241]

Because Dr. Zaidi had been treating Agent Parkison for more than twelve weeks by January 2013, ''[a]n entirely elevated level of service is called for,'' which was not evidenced in either the medical chart or the recordings of the office visits from January 2013 forward.[242]

In reviewing the audio-video recording of the January 9, 2013 visit, I found no examination took place other than the taking of Agent Parkison's blood pressure and oxygen levels by Ms. Barrett.[243] Dr. Zaidi's report of Agent Parkison's subjective symptoms indicates ''[h]e is doing better with OxyContin, but it is not strong enough and I am going to increase OxyContin to 15 mg three times a day.'' [244] Apparently this was based entirely on Agent Parkison stating, ''I was wondering if I could get maybe just a little bit stronger'' notwithstanding that he reported to Ms. Barrett reductions in his pain level—that at its worst the pain was at level two.[245] Further, despite there being no discussion of Agent Parkison's personal, family, or social history, Dr. Zaidi reported no changes in those histories.[246] Similarly, notwithstanding the absence of any physical examination, Dr. Zaidi wrote that for the subjective examination there were no abdominal or chest pains, no shortness of breath or dizziness.[247] Further, without actually conducting an examination to support these findings, Dr. Zaidi wrote in his objective findings:

> Pupils are equal and reacting to light. Skin is warm and dry. Moderate diffuse tenderness and spasm in paralumbar muscles with minimal guarding in forward flexion and extension. Lower extremity examination is normal to sensory and motor testing. His gait is normal.[248]

During cross examination, Agent Parkison stated that after this visit, he determined no additional visits were warranted.[249] He said he had worked cases like these in the past, and in those cases the DEA stopped after the third visit.[250] By the fifth visit with Dr. Zaidi, Agent Parkison ''felt it was pretty clear that I had been issued prescriptions other than for a legitimate medical purpose and didn't feel that I needed to continue to go'' back for additional treatment.[251] He said by this fifth visit, he had seen that Dr. Zaidi would not question him when he asked for more medication and would not check to see if there was something that was causing him to be in more pain.[252]

According to Dr. Severyn, Dr. Zaidi to this point had failed to make an adequate assessment of Agent Parkison' functional status, or of his activities of daily living.[253] Further, and as was the case in the three prior office visits, while Dr. Zaidi indicates a plan of treatment that includes a ''home exercise program,'' [254] there was no discussion of any home exercises during the office visit, nor is there any evidence that written details of such a program were ever provided to Agent Parkison at any visit.

Dr. Severyn also noted that when a patient reports ''stiffness'' in the mid-back, as Agent Parkison did during the visit on January 9, 2013,[255] this is significant ''because if a patient is describing stiffness as opposed to pain, then whatever treatment plan has brought that patient to that stiffness . . . [is] a medical success. That's quite good. That sounds like improvement over time. . . . [I]t's an indication that this patient may be getting better, and probably is.'' [256] Stiffness and pain are, in Dr. Severyn's view, dissimilar, in that ''a patient who is complaining of

[230] *Id.* at 13:49:10—13:50:00; Gov't Ex. Nine at 20.

[231] *Id.* at 13:49:00—13:50:00; Gov't Ex. Nine at 20; Tr. at 313.

[232] Gov't Ex. 3d, folder Tyler UC Visit, subfolder AudioVideo—12–12–12, file 132123 at 13:50:00–13:50:46; see also Gov't Ex. Twelve at 18 (chart notations indicating blood pressure readings during office visits on October 4, 2012, November 14, 2012, and January 9, 2013, but not for December 12, 2012).

[233] Gov't Ex. Twelve at 10.

[234] *Id.*

[235] Gov't Ex. Nine at 20.

[236] Tr. at 96.

[237] *Id.*

[238] *Id.* at 100–01.

[239] *Id.* at 100.

[240] *Id.*

[241] *Id.* at 100–01.

[242] *Id.* at 101.

[243] Gov't Ex. 3e at 14:01:29 to 14:02:21. Note that in Government Exhibit 3e at folder labeled Audio 01–09–13 contains a file named 01–09–13, appears to contain an audio-only recording of Agent Parkison's January 13, 2013 office visit. As neither party referred to this recording it has not been reviewed here. Similarly, Government Exhibit 3e in folder AudioVideo 01–09–13 contains a file named Thumbs, which was not referred to by either party and which I was not able to access. Accordingly, it has not been reviewed here.

[244] Gov't Ex. Twelve at 9.

[245] Gov't Ex. 3e at 14:05:22 to 14:05:57; Gov't Ex. Nine at 23–24.

[246] Gov't Ex. Twelve at 9.

[247] *Id.*

[248] *Id.*

[249] Tr. at 465–66.

[250] *Id.* at 466.

[251] *Id.*

[252] *Id.*

[253] *Id.* at 102–03.

[254] Gov't Ex. Twelve at 9–12.

[255] *Id.*

[256] Tr. at 108–09.

stiffness is a patient for whom pain has been well-controlled. The etiology and cause appears to be in regression or remission and their response to treatment is quite good.'' [257] When presented with a patient who complains of stiffness but also indicates pain at a level four on a ten point scale, Dr. Severyn stated that a physician can reconcile this by ''just asking the patient to be a little more clear'' in response to the physician's questions.[258]

Such a complaint would not justify prescribing controlled substances in the manner shown in the records for Agent Parkison, according to Dr. Severyn, ''because there are so many less risky alternatives that can be offered, including muscle relaxants that can be very helpful here, and other approaches to care.'' [259] Dr. Severyn found, however, no evidence that these alternatives were considered.[260]

In Dr. Severyn's opinion, Dr. Zaidi's controlled substance prescriptions for Agent Parkison were based on a diagnosis that is ''completely inaccurate'' and ''focuses only on controlled substances and not on the several other alternative approaches to care [including] physical therapy, non-controlled substance medication, [and] the medications in several different classes.'' [261] He also noted that by January 2013, there was no proper informed consent obtained by Dr. Zaidi for this patient.[262] Dr. Severyn acknowledged the form Agent Parkison signed on September 11, 2012 (at the start of his treatment) states, ''I consent at this time for treatment with medications and therapeutic procedures.'' [263] According to Dr. Severyn, however, this does not constitute informed consent, as it ''does not sufficiently describe the risks that can go along with using a controlled substance on a regular basis,'' including ''delayed breathing, slowed breathing, risk of overdose, risk of drug withdrawal, risk of diversion of medications, risk of becoming addicted, risk of being a victim of theft and home break-in, and the risk actually for the worsening of pain over time . . . .'' [264]

Dr. Severyn noted that by his fourth visit, Agent Parkison asked for OxyContin by name, something Dr. Severyn regarded as a red flag.[265] He explained that ''OxyContin has been a largely diverted and abused medication, and a patient asking for that medicine . . . by name . . . should and would arise suspicion in the mind of a prescribing physician.'' [266] Further, during the fifth visit, when Agent Parkison asked for an increase in OxyContin, this too would be considered a red flag, given that there was no physical examination conducted at that visit, and given that it appeared the existing treatment plan was ''achieving what it had meant to achieve.'' [267] Dr. Severyn found no evidence, however, that Dr. Zaidi tried to resolve any of these red flags.[268]

When asked how a physician should respond to a patient who sees an advertisement for a particular drug, Dr. Severyn stated that if the drug was a controlled substance, he would ''incorporate that into the remainder of the medical decision-making process'' although this did not mean the incident would necessarily be noted in the patient's medical record.[269] He added, however, that in none of the three undercover cases did it appear that the patient told Dr. Zaidi he wanted a particular drug because he had seen the drug advertised.[270]

When asked on cross examination about things a physician must do to resolve red flags associated with potential diversion, misuse, or addiction, Dr. Severyn stated that first the physician must observe the patient over time, note the ''maturation'' of what is observed, and when encountering more than one ''element of discontinuity'' more than just observation is called for.[271] ''The ultimate 'to-do' always is to say, 'You know, this is not a treatment that I am going to continue for this patient.' That's one approach. Another alternative is other medication, physical therapy, [and] referrals, those are important.'' [272]

Dr. Severyn agreed, on cross examination, that there may have been instances where patients have deceived him without his knowledge.[273] He recalled one such instance where he discovered the deception only after evaluating the results of a urine screen—a test he requires at the initial encounter (as does Dr. Zaidi [274]), and thereafter at ''every encounter'' for patients receiving controlled substances on a protracted basis.[275] He added, however, that Ohio law does not require testing at every encounter, so he would not opine that Dr. Zaidi should have conducted a urine screen each time these patients visited the office.[276] Further, Dr. Severyn noted that by seeing his patients at least once a month, Dr. Zaidi complied with the standard of care in frequency of patient visits, agreeing during cross examination that this practice is another way to help protect against misuse, diversion, or addiction.[277]

Regarding a patient's decision not to seek treatment (such as a recommended epidural injection) or diagnostic measures (such as an MRI), Dr. Severyn was asked if he recalled whether the patient attributed the decision to cost or an inability to pay.[278] He said he did recall discussions about patients wishing to await the availability of insurance.[279] He noted, however, that ''I also see in the record before me, receipts for medical encounters of $300 cash on a frequent basis.'' [280] When he stated he thought these were on a monthly basis, he initially indicated that there were at least two such payments made by Agent Parkison.[281] The record, however, does not support this, and instead indicates the $300 cash payment was made only at the initial visit, and $95 was charged for all subsequent visits.[282] After this discrepancy was brought to his attention, Dr. Severyn was asked whether he believed these patients could afford MRIs or injections if these were indicated, and he stated he did not agree that the patients could have afforded those procedures.[283]

Dr. Severyn stated that an MRI is helpful in the context of pain medicine, ''when it answers, in the mind of the physician . . . what is the cause of this patient's complaints, the etiology of the physical findings and the implication and impact of learning that information upon the recommendation to be made to the patient and the treatment plan to be put into effect.'' [284] When asked on cross examination whether it was appropriate for Dr. Zaidi to advise Agent Parkison to have an MRI ''because of the vague symptom that he has in his lower back,'' [285] Dr. Severyn said no, and agreed that the fact that no MRI was

[257] *Id.* at 259.
[258] *Id.* at 261.
[259] *Id.* at 109.
[260] *Id.* at 109–10.
[261] *Id.* at 103.
[262] *Id.* at 104–05.
[263] *Id.* at 104–05; Gov't Ex. Twelve at 25.
[264] Tr. at 105–06.
[265] *Id.* at 113.
[266] *Id.*
[267] *Id.*
[268] *Id.* at 114.
[269] *Id.* at 199.
[270] *Id.* at 280.
[271] *Id.* at 173–74.
[272] *Id.* at 174–75.
[273] *Id.* at 191.
[274] *Id.* at 193.
[275] *Id.* at 191–92.
[276] *Id.* at 194.
[277] *Id.* at 196.
[278] *Id.* at 187.
[279] *Id.*
[280] *Id.*
[281] *Id.*
[282] *Id.* at 187–88; Gov't Ex. Sixteen.
[283] Tr. at 188.
[284] *Id.* at 240.
[285] Gov't Ex. 12 at 8.

ever performed did not breach the standard of care.[286]

On cross examination, Dr. Severyn agreed that one appropriate means of responding to red flags in the context of prescribing pain medication is to use urine drug screens, and he acknowledged that Dr. Zaidi used these screens as part of his prescription practice.[287]

Dr. Severyn next explained why the inaccuracies found in Dr. Zaidi's medical records of Agent Parkison's treatment are important in the review of Dr. Zaidi's prescription practice:

> There is inaccuracy and a listing of a more severe level of pain than what the patient is actually voicing during the encounter with staff or with the physician. The diagnosis, the impression that is listed here, the most impressive and important of them, with regards to guiding the patient through treatment, would be the lumbar radiculitis, and that is not justified or substantiated by either the history or the physical examination. Finally, the approach to treatment that relies on only a controlled substance and does not include many of the other approaches, such as non-steroidal anti-inflammatory, neuromodulator, tricyclic medications [and] physical therapy. Those are absent. The home exercise program, I found no evidence that that is being provided.
>
> I found, to a large degree, that if I were to have reviewed only the medical record, as it was presented here, I would have arrived at a different opinion than I am able to, having now had the ability to see a transcript and watch an audio/visual recording of what actually occurred during that encounter.[288]

For these reasons, Dr. Severyn opined that Dr. Zaidi's prescriptions of controlled substances for Agent Parkison ''were well outside the usual course of professional practice . . . .'' [289]

Dr. Zaidi's Treatment of Officer Patrick Leonard (Under the Name Patrick Tock)

Patrick James Leonard has been employed at the Akron (Ohio) Police Department for about 20 years, the last sixteen of which he has been a detective in the narcotics diversion department.[290] In addition, for the past two years Detective Leonard has been assigned to the DEA as a task force officer, serving in an undercover capacity in the investigation of physicians and others suspected of illicit drug transactions.[291] He was trained as a military police officer in the United States Army, has completed training at the Ohio Police Officer Training Academy, and received training in pharmaceutical diversion through the Ohio Board of Pharmacy.[292]

Detective Leonard participated in the surveillance of Dr. Zaidi's medical office and was a patient in an undercover capacity, under the name Patrick J. Tock.[293] In his role as a patient, Detective Leonard attended six office visits with Dr. Zaidi, and in each visit received prescriptions for controlled substances.[294] Each of these visits were surreptitiously recorded, and both the recordings and the transcriptions of the relevant portions of those recordings are included in our record.[295] He agreed on cross examination that in his undercover capacity, he was engaged in misleading Dr. Zaidi and his staff during these visits.[296] He denied, however, that there was ''any trickery involved. We presented a certain set of facts and waited to see if Dr. Zaidi would write prescriptions.'' [297]

In his role as Patrick Tock, Detective Leonard reported that he had stiffness in his lower back.[298] In his initial interview with Christy Barrett, Detective Leonard reported pain levels of between three and four on a ten-point scale, denying any pain in his legs.[299] He also denied ever being treated for this condition, and denied ever having an MRI or x-ray with respect to the condition.[300] At the conclusion of the initial office visit, he obtained from Dr. Zaidi a prescription for 42 tablets of Percocet five mg.[301] According to Detective Leonard, at no time did Dr. Zaidi suggest any treatment for his condition other than controlled substances, nor did Dr. Zaidi suggest physical therapy, exercise, or any other non-medication treatment.[302] He said Dr. Zaidi did recommend that he obtain an MRI, providing to Detective Leonard the name of a provider whose charges for this service were reduced for persons, like Detective Leonard, who lacked health insurance.[303] Despite this recommendation, Detective Leonard returned to Dr. Zaidi's office five more times without obtaining an MRI, and on each occasion Dr. Zaidi prescribed him controlled substances.[304] According to Detective Leonard, while Dr. Zaidi did conduct a physical examination during the first office visit, he conducted no physical examinations during any of the subsequent visits.[305]

As was the case with his review of Agent Parkison's treatment, Dr. Severyn reviewed the medical charts, transcripts, and recordings [306] relating to Dr. Zaidi's treatment of Officer Leonard during six visits to that office.[307] And as was the case with the records of treatment of Agent Parkison, Dr. Severyn noted material differences between what appears in Officer Leonard's written medical chart and what actually occurred during Dr. Zaidi's treatment of the patient.

In the ''History and Physical Examination'' for the visit on October 23, 2012, Dr. Zaidi reported the patient's ''pupils are equal and reacting to light.'' [308] Dr. Severyn stated that an examination of pupil reaction to light ''was not part of the physical examination that I saw undertaken.'' [309] He explained that ''[r]eactive to light'' means ''that the lighting characteristics in the room changed significantly enough that an evaluation of that could be done.'' [310] This could be done either by shining a light directly into each of the patient's eyes, or directing the patient's head to a window and back, ''to see if each pupil independently and to some degree in a coordinated fashion would react to light.'' [311] Dr. Severyn said he did not see such an examination take place in any of Officer Leonard's office visits where video recordings were part of our record.[312]

I note that of the recordings included in Government Exhibit Four, audiovisual recordings were available only for the examinations of Officer

[286] Tr. at 234.
[287] *Id.* at 175.
[288] *Id.* at 107–08.
[289] *Id.* at 104.
[290] *Id.* at 553.
[291] *Id.* at 554–55.
[292] *Id.* at 555.
[293] *Id.* at 555–56.
[294] *Id.* at 556–64.
[295] *Id.*
[296] *Id.* at 588.
[297] *Id.* at 588–89.
[298] *Id.* at 567.
[299] *Id.* at 568–69.
[300] *Id.* at 571.
[301] *Id.*
[302] *Id.* at 572.
[303] *Id.* at 572–73.
[304] *Id.* at 573; Gov't Ex. Thirteen.
[305] Tr. at 576–83.
[306] The recordings in evidence include Government Exhibits 4a through 4f. Government Exhibit 4a contains two folders, both having to do with Officer Leonard's visit to Dr. Zaidi's office on October 23, 2012. One folder, labeled Audio 10–23–13, consists of one file, identified as CCR_0001. The other folder, identified as AudioVideo 10–23–12, has seven files. Four files, identified as 125939, 130541, 130611, and 132851, contain no information material to this administrative matter. The files identified as 130617 and 135848 depict preliminary stages of an office visit on October 23, 2012, but do not include Dr. Zaidi's examination of Officer Leonard (which apparently was captured only by audio recording). It also contains a file identified as Thumbs, which I was unable to access and which has not been referred to by either party, and thus is not part of my review of this record.
[307] Tr. at 115.
[308] Gov't Ex. Thirteen at 9.
[309] Tr. at 115–16.
[310] *Id.* at 126.
[311] *Id.*
[312] *Id.* at 126–27.

Leonard conducted on December 13, 2012, and February 21, 2013. Although Dr. Zaidi reported the results of light reaction examinations in those two reports and in the examinations conducted on October 23, 2012; November 15, 2012; January 10, 2013; and March 21, 2013,[313] there were no video recordings of these four examinations.[314]

For the examinations conducted on December 13, 2012 and February 21, 2013, it is possible to confirm (and I do confirm) that no examination took place that would provide Dr. Zaidi with objective evidence to support these exam findings,[315] but I do not resolve whether examinations took place on October 23, 2012; November 15, 2012; or January 10 or March 21, 2013.[316]

I find, however, that Dr. Zaidi's determination to remain silent in the face of testimony tending to show no examinations took place gives rise to a negative inference, one that supports a finding that his examinations on November 15, 2012; January 10, 2013; and March 21, 2013, were substantially similar to those shown in the videos of examinations on December 13, 2012 and February 21, 2013, and do not support the findings he reported in these medical records. It is unclear, however, what examinations, if any, took place on the first visit, on October 23, 2012.[317]

Dr. Severyn noted that Officer Leonard reported a dull ache affecting the low back during his initial visit, at level three to four on a ten-point scale, without weakness and without numbness going into the legs.[318] In Dr. Severyn's opinion, this history would support a diagnosis of lumbago, but does not support Dr. Zaidi's diagnosis of radiculitis.[319] As noted above, Dr. Severyn explained that radiculitis calls for ''pain arising in the lumbar spine and clearly following the pathway of a nerve going down into the lower extremity.'' [320] As was the case with Dr. Zaidi's diagnosis of Agent Parkison, Dr. Severyn said not only is the diagnosis of radiculitis for Officer Leonard inaccurate, ''it's blatantly inaccurate.'' [321]

In addition to concerns regarding Dr. Zaidi's written impressions, Dr. Severyn remarked that the patient presented red flags that went unresolved by Dr. Zaidi. One such red flag arose when the patient was unable to produce identification after the initial visit.[322] The patient's past drug use also raised a red flag: ''It's concerning here that the patient, already describing to the physician that the patient has taken some pain medication from his wife, and that it has helped, but that the patient is not able to describe the name of the medication that his wife is taking and that his wife provided to him.'' [323]

According to Dr. Severyn, after Officer Leonard admitted to using his wife's pain medication, Dr. Zaidi should have obtained more information.[324] Calling it ''an element of medical necessity,'' Dr. Severyn opined that Dr. Zaidi should have attempted to learn when Officer Leonard actually used his wife's medication.[325]

Dr. Severyn explained that while Dr. Zaidi did use urine drug screens as part of his prescription practice, the screen would be useful here if Dr. Zaidi could determine when Officer Leonard actually took his wife's medication. ''I think that what is so missing [about] this red flag, about receiving medication from the wife, is we all have no idea when that event would have been said to have occurred. But if it would have been said to have occurred the past day or so, its absence on the urine screen would have been an important red flag. Its presence would be just as important.'' [326]

Also of concern with this patient, according to Dr. Severyn, was the patient's request after the initial visit for an increase in oxycodone; and on the fourth visit the patient's request for Opana.[327] This latter request was ''a huge flag,'' because, according to Dr. Severyn, Opana ''is a drug that is becoming more commonly diverted. It is because Opana is twice as strong, milligram per milligram, in its effects on the mind, as is the drug Oxycodone, [which is] present in Percocet and was present in OxyContin.'' [328] Detective Leonard expressed a similar concern regarding Opana, testifying that ''[i]t's a highly abused narcotic. We're having a problem with it on the street. High resale.'' [329] According to Dr. Severyn, there is, however, no evidence that Dr. Zaidi either recognized or sought to resolve these red flags.[330] After confirming during cross examination that Dr. Zaidi ended up not prescribing Opana, Dr. Severyn said he believed this to be the appropriate decision.[331]

Dr. Severyn noted that at the initial visit, when Officer Leonard produced only a photocopy of his license (under the pretense that the original had been seized recently by the police), there was some mention that he would need to produce a license at the next visit,[332] but there is no evidence that anyone from Dr. Zaidi's office followed through on this at any subsequent office visit.[333] Considering the red flags present here, Dr. Severyn stated that it ''did not appear that there was significant or sufficient attention to the known indications of abuse or diversion that we've been referring to here as red flags.'' [334]

Beyond these red flags, Dr. Severyn opined that even under a diagnosis of lumbar radiculitis, ''[t]his patient has not had benefits of a more conservative plan of treatment. Modification of activities, non-controlled substances, physical therapy are the big three, the main important components of treatment that have to, over a period of several weeks, not result in an improvement'' before resorting to controlled substances as treatment for pain.[335] He noted further that while the plan of treatment included encouragement for the patient to get an MRI done of the lumbar spine,[336] in Dr. Severyn's view a pain management specialist ''would appreciate that an MRI is not indicated at this time, with this patient and with this set of conditions, even were those conditions, as shown in the medical record, accurate.'' [337] He explained that even if

[313] Gov't Ex. Thirteen at 9, 12–16.

[314] See Gov't Ex. Four.

[315] See Gov't Ex. 4c, folder Leonard UC3, AudioVideo 12–13–12, file 083000 at 8:38:52—8:40:31; Gov't Ex. 4e, folder AudioVideo 02–21–13, file 2013–02–21 at 8:58:27—9:00:19.

[316] See Government Exhibits 4a, 4b, and 4d. In Government Exhibit 4b, when I attempted to open the file AudioVideo 142205 in the AudioVideo folder, the file would not play, and instead a message appeared stating ''Windows Media Player cannot play the file. The player might not support the file type or might not support the codec that was used to compress the file.'' Accordingly, the only recording of this visit was contained in the audio-only file identified as CCR_0005, found in the folder labeled Audio 11–15–12. In Gov't Ex. 4d, the only file provided by the Government was an audio-only recording labeled 1–10–13 in a folder labeled Audio 01–10–13.

[317] *See* Gov't Ex. 4a, folder Audio 10–23–12, file CCR_0001 at 49:44—56:00.

[318] Tr. at 117.

[319] *Id.;* Gov't Ex. Thirteen at 9.

[320] Tr. at 117.

[321] *Id.* at 118.

[322] *Id.* at 131.

[323] *Id.* at 117.

[324] *Id.* at 176.

[325] *Id.*

[326] Tr. at 177.

[327] *Id.* at 134.

[328] *Id.*

[329] *Id.* at 578. Detective Leonard testified that Opana 40 mg costs between $4 and $5 per tablet and sells for $50 per tablet on the street, whereas 5/325 mg Percocet costs $.50 per tablet and sells for between $8 and $10 per tablet. Tr. at 615.

[330] *Id.* at 135.

[331] *Id.* at 200–01.

[332] See Gov't Ex. 4a at folder AudioVideo 10–23–12, file 130617 at 13:17:13 to 13:17:27; Gov't Ex. Ten at 3.

[333] Tr. at 135.

[334] *Id.* at 135–36.

[335] *Id.* at 118.

[336] *Id.;* Gov't Ex. Thirteen at 9.

[337] Tr. at 118–19.

an MRI was taken and indicated a significant abnormality associated with lumbar pain,

> [T]he treatment of that abnormality probably would not have taken place because it would not be medically necessary. What is medically necessary is [based on] what does the patient have? How is this affecting quality of life, employment, social history? How is the patient responding to the least risky forms of treatment? [338]

Dr. Severyn stated that he reviewed each of the recordings of Officer Leonard's follow-up visits with Dr. Zaidi, and saw no evidence of any subsequent physical examinations, raising doubts about the validity of the diagnoses appearing in the reports of those visits.[339] Specifically, he saw no evidence of an examination that would support a finding that the patient's pupils were ''equal and reacting to light'' [340] because there was no examination of the pupils with light; [341] there was no touching of the patient, and ''one can only identify and find tenderness by touching the patient;'' [342] there was no evidence of Dr. Zaidi touching Officer Leonard to examine the lumbar spine; [343] there was no examination that would support a finding of ''moderate diffuse tenderness and spasm in paralumbar muscles with minimal guarding in forward flexion and extension;'' and there was no examination that would support a finding regarding motor and sensory functions of the lower extremity,[344] as such testing ''did not occur.'' [345] Considering these inconsistencies, Dr. Severyn opined that ''when a medical record displays the performance of actions that did not occur, the entire validity of the record becomes subject to extreme doubt and questioning.'' [346]

During cross examination, when it was noted that Dr. Zaidi issued an order prescribing an MRI, Dr. Severyn stated that the MRI ''became part of the medical treatment plan, and the patient's lack of follow up of the medical treatment plan is yet another red flag.'' [347] Thus, while he opined that an MRI for this patient was not medically indicated by the patient's history, the physical examination, and the duration of the problem, the patient's failure to follow the order needed to be taken into account by Dr. Zaidi.[348] He agreed, however, that Dr. Zaidi could take into account the patient's representations of not having insurance or funds sufficient for such testing, when evaluating the patient's noncompliance with the MRI order.[349] He also agreed that a similar order was written during Dr. Zaidi's treatment of Agent Parkison.[350]

At the same time, however, Dr. Severyn thought that these patients had paid $300 for their initial office visits and were paying $95 for each subsequent visit.[351] When asked whether there was anything suspicious about a patient's willingness to pay that kind of money for specific drugs while refusing to pay $200 for a cortisone shot or $350 for an MRI, Dr. Severyn stated, ''I believe that is an indication of possible activity, intent or use or misuse, that's not in keeping with what the intended role of that medication is, in the doctor's treatment plan'' and is ''very suspicious and it is a red flag.'' [352]

Dr. Severyn noted that as was the case with his treatment of Agent Parkison, when Officer Leonard's treatment extended beyond twelve consecutive weeks, treatment is considered to be on a protracted basis.[353] The plan of treatment here, however, did not consider alternative and less risky medications than controlled substances; did not include physical therapy; and while the written plan ''includes a notation for [a] home exercise program . . . the rest of the evidence does not provide a mechanism whereby that was ever put into place.'' [354]

Dr. Severyn explained the significance of a course of pain medication that extends beyond twelve weeks. Under Ohio Administrative Code section 4731–21–02, when it appears that a patient will be treated with pain medication for twelve weeks or longer, ''there better be quite a bit of substantiation behind it, and [the] intensity of service needs to justify the continued use of that medication.'' [355] Even though a physician will not always know at the start of treatment that a patient's treatment will last twelve weeks or longer, the regulation provides that if somebody needs controlled substances that long, greater documentation is needed than would be the case when a person is treated for acute pain on a short-term basis.[356] Thus, while a physician may treat a person with acute pain without inquiring into social history, work employment, activities of daily living, and the like, while still meeting the standard of care, such inquiries are required when it becomes clear to the physician that the pain is chronic,[357] rather than acute. Once it appears the pain is chronic or intractable, the physician is required to determine what needs to be done differently in treating the patient for pain under Ohio's administrative rules.[358]

Dr. Severyn also noted the absence of information regarding the patient's functional capacities.[359] After noting the patient indicated employment as a delivery driver, Dr. Severyn said he found no evidence that Dr. Zaidi ever inquired about the degree to which the patient's pain symptoms interfered with this employment or inquired about whether the pain interfered with daily activities, family life, or social activities.[360]

Dr. Severyn expressed the opinion that in prescribing controlled substances for Officer Leonard, Dr. Zaidi did so without having a legitimate medical purpose, because the patient's medical complaints did not justify the use of a controlled substance.[361] He stated that based on what he observed in the recordings of these office visits, ''the prescribing that took place here was not prescribing for a legitimate medical purpose and was not in the usual course of professional practice.'' [362]

Dr. Zaidi's Treatment of Officer Shaun Moses (Under the Name Shaun Chandler)

Shaun Moses is a Special Agent with the DEA, working out of the DEA's Cleveland, Ohio office.[363] As a Special Agent, he enforces provisions of the Controlled Substances Act, and has done so for more than eight years.[364] He has a bachelor's degree in political science from Hiram College, and has completed the sixteen-week training course at the DEA Academy in Quantico, Virginia.[365] On cross examination, he agreed that included in his training for undercover work were ''block[s] of instruction'' to help him deceive the target of the

[338] *Id.* at 120–21.
[339] *Id.* at 121.
[340] *Id.*
[341] *Id.* at 122.
[342] *Id.*
[343] *Id.*
[344] Gov't Ex. Thirteen at 9.
[345] Tr. at 122, 127.
[346] *Id.* at 121.
[347] *Id.* at 270.
[348] *Id.* at 266–67.
[349] *Id.* at 267.
[350] *Id.* at 271.
[351] *Id.* at 277.
[352] *Id.* at 278.
[353] *Id.* at 125.
[354] *Id.* at 125–26.
[355] *Id.* at 286.
[356] *Id.* at 286–87.
[357] *Id.* at 287–88.
[358] *Id.* at 288.
[359] *Id.* at 129–30.
[360] *Id.*
[361] *Id.* at 128.
[362] *Id.*
[363] *Id.* at 473.
[364] *Id.* at 474.
[365] *Id.* at 475.

investigation.[366] He said the goal of the undercover work was to see Dr. Zaidi and after ''giving as little information as possible and being as vague as possible, see what he would prescribe you.'' [367]

Agent Moses visited Dr. Zaidi for treatment on five occasions, under the name Shaun Chandler.[368] He identified the recordings made during these visits, and the transcripts made based on these recordings.[369] In each of these visits, Agent Moses obtained prescriptions for controlled substances from Dr. Zaidi.[370]

Agent Moses described the physical examination performed by Dr. Zaidi in the first visit. Dr. Zaidi directed Agent Moses to roll up his left pant leg, at which point Dr. Zaidi ''squeezed my knee a little bit,'' then directed Agent Moses to walk on his heels and toes, bend over to touch his toes, straighten his leg while seated, and respond to questions about the presence of back pain.[371] He told Dr. Zaidi he worked for the Village of Gates Mills, doing ''[a] lot of manual labor type stuff.'' [372] According to Agent Moses, at no time did Dr. Zaidi examine his neck, shine a light into either eye, or touch his abdomen.[373] Agent Moses said this was the only visit during which Dr. Zaidi conducted any kind of physical examination.[374]

As was the case with his review of Dr. Zaidi's treatment of Agent Parkison and Detective Leonard, Dr. Severyn reviewed the recordings, transcripts, and medical records regarding Dr. Zaidi's treatment of Agent Moses as Shaun Chandler.[375] And, as was the case in the other two undercover agents' medical records, Dr. Severyn found inaccuracies in the written reports of treatment, when compared with what he observed when watching the video recordings of treatment.[376]

During the visit on January 29, 2013, Agent Moses presented as having left knee stiffness, which he indicated to Dr. Zaidi was dull and aching, and which he said was at worst four on a ten point scale, and was presently two on that same scale.[377] He told Dr. Zaidi he had no prior trauma to the knee, and thus far treated it with ''a couple of aspirin'' but nothing more.[378] Based on this history and examination, Dr. Zaidi suggested Agent Moses get a cortisone shot, which Agent Moses deferred, indicating ''I'll get back to you.'' [379] In response, Dr. Zaidi prescribed Vicoprofen, a controlled substance that is a mixture of Vicodin and ibuprofen.[380]

When asked on cross examination whether a physician acting within the standard of care must decline to provide medical services to a patient who lacks records of prior medical treatment, Dr. Severyn said if there are no prior records then it would not be a breach of the standard of care, nor would it be unusual, as ''[t]here will always be a case in which a physician is seeing a patient for the patient's first event of a condition associated with pain.'' [381] He also opined that physicians ''are reasonably entitled to approach a patient as being truthful and representing true facts, as they are described.'' [382]

Central to Dr. Severyn's analysis were reports of examination contained in the typed notes appearing in the ''History and Physical Examination'' report found in the patient's medical records.[383] Dr. Severyn compared what appears in this written report of examination with what he saw in the video recording of the office visit, and reported inaccuracies in the report.

Included in these inaccuracies were notations that the patient was ''oriented times three,'' which Dr. Severyn explained meant that the patient was oriented as to person, place and time.[384] Dr. Severyn stated these were not formally evaluated during the examination conducted by Dr. Zaidi.[385] He said blood pressure was formally evaluated, but the pupil reaction to light test was not performed, nor was there any examination of the oral mucosa nor the cranial nerves—all of which were reported as being performed in Dr. Zaidi's written report.[386]

As Dr. Severyn noted, Dr. Zaidi's written report of the physical examination states the patient's thyroid gland is not enlarged and there is no cervical or axillary lymphadenopathy, but at no time did Dr. Zaidi palpate the lymph or thyroid glands.[387] Dr. Zaidi wrote that there was ''no tenderness in his cervical, parathoracic, or paralumbar muscles'' yet there was no touching of the area superficial to the cervical spine and no testing of the paraspinal lumbar muscles.[388] Dr. Zaidi wrote that the ''upper extremity examination is normal to sensory and motor testing with normal range of motion at the upper extremity joints,'' but testing of those nerves did not take place.[389] Similarly, although Dr. Zaidi did palpate the knee area, he reported ''lower extremity examination otherwise is normal to sensory and motor testing,'' but did not perform a lower extremity sensory and motor examination.[390]

Having reviewed the video recording, including the time Agent Moses spent with the medical assistant Christy Barrett and the time spent with Dr. Zaidi, I find Dr. Severyn's observations to be supported by substantial evidence. It is clear that Dr. Zaidi instructed Agent Moses to raise his left pant leg, and that he palpated the patellar area of the left leg; and we see Agent Moses extending his leg and, when standing, rise on his toes and then on his heels.[391] This, however, is the extent of the physical examination.

While there is evidence that Dr. Zaidi tested Agent Moses' gait, finding good balance and coordination, and that Agent Moses performed normal heel and toe walking, Dr. Zaidi also indicated finding a ''soft and nontender'' abdomen, but never palpated the abdomen.[392] Dr. Zaidi indicated ''good air entry bilaterally in both longs with normal S1 and S2 heart sounds,'' but such testing, according to Dr. Severyn, requires the use of a stethoscope, which did not take place.[393]

When stating the impressions formed from this examination, Dr. Zaidi indicated ''knee pain, limb pain, and possible early osteoarthritis of knee.'' [394] According to Dr. Severyn, given the examination and history present, the impression of possible early

[366] *Id.* at 513.
[367] *Id.* at 514.
[368] *Id.* at 475–76.
[369] *Id.* at 476–82.
[370] *Id.* at 482–85.
[371] *Id.* at 491–92.
[372] *Id.* at 492.
[373] *Id.* at 495.
[374] *Id.* at 498.
[375] *Id.* at 140.
[376] *Id.*
[377] Gov't Ex. Fourteen at 17.
[378] Gov't Ex. Eleven at 9.
[379] Tr. at 494.
[380] *Id.*
[381] *Id.* at 264–65.
[382] *Id.* at 265.
[383] Gov't Ex. Fourteen at 7–8.
[384] Tr. at 140.
[385] *Id.*
[386] *Id.* at 140–41; Gov't Ex. Fourteen at 7–8.
[387] Tr. at 141; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01–29–13, file 2013–01–29 at 13:42:48 to 13:48:21.
[388] Tr. at 141; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01–29–13, file 2013–01–29 at 13:41:55 to 13:48:21.
[389] Tr. at 141; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01–29–13, file 2013–01–29 at 13:42:48 to 13:48:21.
[390] Tr. at 142; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01–29–13, file 2013–01–29 at 13:42:48 to 13:48:21.
[391] Gov't Ex. 5A, folder AudioVideo 01–29–13, file 2013–01–29 at 13:42:48 to 13:48:21.
[392] Tr. at 142; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01–29–13, file 2013–01–29 at 13:42:48 to 13:48:21.
[393] Tr. at 142–43; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01–29–13, file 2013–01–29 at 13:42:48 to 13:48:21.
[394] Gov't Ex. Fourteen at 8.

osteoarthritis ''cannot be substantiated.'' [395] He explained:

> Early arthritis does cause knee pain, but so do many other things in young, healthy patients. Most common are ligament strains, followed by inflammation of the cartilage behind the knee cap, which is different than cartilage between the bones, between the tibia and the femur, which is the real communicated message, when we use the term osteoarthritis of the knee.[396]

Also of concern to Dr. Severyn was the plan of treatment that Dr. Zaidi based on this examination and history. Dr. Zaidi prescribed Vicoprofen, which is a combination of ibuprofen, a non-steroidal anti-inflammatory, and hydrocodone (or Vicodin), a controlled substance pain medication.[397] ''[A] more justifiable approach,'' according to Dr. Severyn, ''would have been to use a non-controlled substance analgesic medication, such as Tramadol.'' [398] Missing from the plan, according to Dr. Severyn, is any mention of the role the patient's daily activities should play in the treatment plan: ''[T]here is no reference to a change in daily activities, periods of rest, possibly work modification, use of physical therapy or the providing of a home exercise program'' with the result that the treatment plan is ''very controlled-substance focused, as its initial approach to care.'' [399] In Dr. Severyn's opinion, ''what has been presented in the portions of the record that did take place in the examination room does not justify prescribing a controlled substance, not at that time of the patient's care, for those conditions.'' [400]

Agent Moses returned for an office visit on February 12, 2013, which was preserved in an audio-video recording, the contents of which have been transcribed.[401] During this visit, Dr. Zaidi spent approximately 140 seconds in the room with Agent Moses.[402] At no time during this visit did Dr. Zaidi touch Agent Moses, nor did he have Agent Moses perform any diagnostic actions.[403] As Dr. Severyn indicated, there was no physical examination performed during this visit.[404] Nevertheless, Dr. Zaidi prepared a report of physical examination that included findings that could not be supported by his examination of this patient. Dr. Severyn stated that unsupported findings appearing in Dr. Zaidi's report of this examination included pupil reactivity to light, tenderness in the joint, the absence of redness and swelling, range of motion, and normal motor and sensory testing of the leg.[405] Similarly, while the plan of treatment for this visit indicated home exercise as a feature of treatment, no home exercise program had been provided.[406] Agent Moses confirmed that throughout his visits there was never any discussion of physical therapy, no discussion about doing exercises at home, nor was he ever given any written materials relating to home exercise.[407]

Dr. Severyn also noted with some concern the subjective report for this visit, where Dr. Zaidi states that Agent Moses was complaining of both knee and leg pain, and that the pain level he was experiencing was between four and five.[408] While the record supports a complaint of knee pain, there is nothing in the record that supported a complaint of leg pain. Further, as Dr. Severyn correctly observed, Agent Moses reported pain levels only to the office assistant, not to Dr. Zaidi on this visit, and the assistant accurately reported that the pain levels described by Agent Moses were between two and three.[409] There is nothing in the record that would support an examination report of pain level five that Dr. Zaidi reported in his medical history for this visit, Agent Moses stated the written report by Dr. Zaidi, indicating a reported pain level of four or five, was not accurate.[410]

Agent Moses' third visit to Dr. Zaidi's office, on March 11, 2013, lasted two minutes and 25 seconds [411] and was recorded by audio and audio-video recordings.[412] According to Dr. Severyn, objective findings that could not be supported by the actual examination of Agent Moses in the visit on March 11, 2013 included:

> [T]he reactivity of the pupils to light, the diffuse tenderness of the left knee, when the left knee is touched. The absence of redness or swelling being reported in here requires a physical examination to be performed, which was not. Range of motion testing requires a classic evaluation, or at least flexion and extension, and it was not [done]. The lower extremity examination being normal with both motor and sensory testing is reported here, and that did not occur.[413]

Here again, Dr. Severyn noted that although it appears as a term of the treatment plan, there is no evidence suggesting Dr. Zaidi provided Agent Moses with information about a home exercise program.[414] Having seen the audio-video recording of this office visit, I find there is substantial evidence to support Dr. Severyn's finding that Dr. Zaidi did not examine Agent Moses sufficiently to support the findings appearing in this history and examination report.

In his review of Agent Moses' fourth office visit, on April 9, 2013, Dr. Severyn noted many of the same concerns—that Dr. Zaidi's written history and report of physical examination reported conditions that could be legitimately entered only if a physical examination had been performed. Having reviewed the recording of the visit on April 9, 2013 (which lasted three minutes and 33 seconds),[415] I concur with Dr. Severyn's conclusion that Dr. Zaidi did not conduct a physical examination that would support the written findings in his report.[416]

In his review of the fifth and final visit by Agent Moses on May 6, 2013, Dr. Severyn noted the same concerns as were presented in his discussion of the fourth visit.[417] Again, after reviewing the audio-video recording of this visit, I find substantial evidence to support Dr. Severyn's findings based on a demonstration that Dr. Zaidi performed

[395] Tr. at 143.

[396] *Id.*

[397] *Id.* at 144; Gov't Ex. Fourteen at 8.

[398] *Id.* at 144.

[399] *Id.* at 144–45.

[400] *Id.* at 145.

[401] Gov't Ex. 5b; Gov't Ex. Fourteen at 11–15; Gov't Ex. Eleven at 14–18.

[402] Gov't Ex. 5b, folder Moses UC 2, subfolder AudioVideo 02–12–13, file 2013–02–12 at 14:43:30 to 14:45:49.

[403] *Id.*

[404] Tr. at 145.

[405] *Id.* at 145–46.

[406] *Id.* at 149; Gov't Ex. Fourteen at 12.

[407] Tr. at 546.

[408] *Id.* at 148; Gov't Ex. Fourteen at 12.

[409] Tr. at 148; Gov't Ex. Eleven at 14–15; Gov't Ex. Fourteen at 16.

[410] Tr. at 499.

[411] Gov't Ex. 5c, folder Moses UC Visit, subfolder AudioVideo, file 03–11–2013 at 14:43:15–14:45:37.

[412] Gov't Ex. 5c; Gov't Ex. Eleven at 19–22; Gov't Ex. Fourteen at 11. Note the audio-video recording includes Christy Barrett preparing Agent Moses for his visit with Dr. Zaidi. Some of the video images of this exchange were obscured, as the recording device apparently became improperly positioned. These limitations did not materially affect my ability to discern the nature of Ms. Barrett's preparation, as the audio portion of this interview was intact. Similarly, approximately five seconds of Dr. Zaidi's visit with Agent Moses was obscured either by Agent Moses' hand or his clothing. Immediately before and after this period of obstructed view, Dr. Zaidi was seated away from Agent Moses, mostly facing the wall while reading and writing notes, while Officer Moses was seated on the other side of the office. Notwithstanding this brief period of obstruction, the recording is sufficiently intact to permit me to conclude, as I do, that at no time during this office visit did Dr. Zaidi come into close proximity to or contact with Agent Moses.

[413] Tr. at 149–50.

[414] *Id.* at 150; Gov't Ex. Fourteen at 11.

[415] Gov't Ex. 5d, folder AudioVideo, file SM–04–09–13 at 9:37:25 to 9:40:58; Gov't Ex. Eleven at 23–27. As was the case with the recording of March 11, 2013, a portion of the time Christy Barrett spent with Agent Moses lacks a video picture, but the audio portion is unaffected.

[416] Tr. at 151.

[417] *Id.* at 151–53.

no physical examination of Agent Moses during this visit.[418] Dr. Zaidi conducted the visit, which lasted 80 seconds,[419] while standing at the head of the examination table, while Agent Moses remained seated at all times, without any physical contact between the two.[420]

I also concur with Dr. Severyn's observation that although his treatment plan indicates he prescribed a home exercise program, Dr. Zaidi failed to propose a home exercise plan for this patient.[421] Further, Dr. Severyn stated that there was no evidence Dr. Zaidi attempted to determine whether Agent Moses' pain interfered with his daily activities, with his quality of family life, or with social activities.[422]

Dr. Severyn also expressed the opinion that Dr. Zaidi failed to resolve red flags that arose when Agent Moses sought to increase his medication during the fourth visit.[423] The specific exchange noted here began when Dr. Zaidi asked if Agent Moses had experienced any changes since the last office visit. After stating that there was stiffness in the knee, Agent Moses told Dr. Zaidi, ''I was talking to a guy I work with [who] had like a similar issue, and he said that he tried Percocet and that like knocked it out . . . .'' Without hesitating, Dr. Zaidi responded, ''Well, that's a dramatic statement. I will write you Percocet but it will not knock it out.'' [424] After warning that Percocet was ''a little stronger'' and stating that he thought ''the main thing that will come close to knocking it out is [a] cortisone injection in there,'' Dr. Zaidi noted that Agent Moses has ''been going pretty fast here on the medications'' during these four visits.[425] He warned that ''you are going to not get advice from too many friends'' regarding what medication is appropriate for the next step, explaining ''[t]his is how people get in trouble.'' [426] Dr. Severyn said Dr. Zaidi's warning that the patient is heading for trouble and should not be getting advice from friends about what medication to take was appropriate.[427]

According to Dr. Severyn, however, prescribing Percocet four times daily at this point was not a reasonable solution, and that decision in the face of these red flags ''is one that I don't find to be medically in keeping with . . . prevailing standards of care.'' [428] He said he could find no medical reason for changing Agent Moses' prescription from Vicodin to Percocet.[429] Similarly, when asked whether it appears Dr. Zaidi took into account the risk of addiction and the risk of diversion of controlled substances, Dr. Severyn opined that while the milligram levels prescribed were primarily in the low range,[430] he believed Dr. Zaidi did not take into account the risk of addiction ''to an adequate degree,'' [431] and did not focus attention on the risk of diversion, focusing instead ''on the risk of consumption.'' [432] Dr. Severyn stated that there needed to be interaction between the patient and physician in order to determine whether changes in medication have to be made, and confirmed there was some interaction between Agent Moses and Dr. Zaidi.[433] Such interaction would need to reflect the patient explaining whether the existing medication is helping or not—something Dr. Severyn said did take place, but only to a ''limited'' degree.[434] Dr. Severyn expressed concern, however, that the only reason for changing Agent Moses' prescription for controlled substances was that ''a friend tried Percocet for similar symptoms and that it improved.'' [435] In Dr. Severyn's opinion, changing the prescription upon this history was not at all medically appropriate.[436]

From this review of Dr. Zaidi's prescription practice concerning Agent Moses, Dr. Severyn stated that in his opinion, ''the prescribing of controlled substances in this patient's treatment was not prescribing medication for a legitimate purpose or in the usual course of professional practice.'' [437]

Analysis

Four core facts compel my determination that it would be inconsistent with the public interest for the Administrator to permit Dr. Zaidi to continue prescribing controlled substances. First, the evidence establishes that Dr. Zaidi repeatedly prescribed controlled substances under conditions that warranted further investigation and, in the absence of such investigation, were not for a legitimate medical purpose. His decision to prescribe narcotic pain medication to three undercover agents despite the presence of numerous red flags constituted a material breach of the duties owed by physicians practicing under the Controlled Substances Act, and his prescription practice in these three cases did not meet Ohio's requirements for the distribution of controlled substances.

Second, the evidence establishes that Dr. Zaidi lacks the experience and insight needed to participate in the controlled substance distribution system. His decision to manage a pain clinic using a protocol that permitted the issuance of prescriptions for controlled substances without conducting physical examinations threatens the public safety. Either through ignorance or deliberate indifference, Dr. Zaidi's decision to establish such operations indicates he lacks sufficient insight and experience to be trusted to participate in the controlled substance distribution process.

Third, the evidence establishes that Dr. Zaidi misrepresented the scope and character of both the physical examinations he performed and medical histories obtained during office visits with three DEA undercover agents. While such a practice may well constitute fraud, the Government made no claim of fraud here. Instead, it asserts that this feature of Dr. Zaidi's prescription practice constitutes conduct that is not otherwise addressed by the enumerated factors found in 21 U.S.C. 823(f)(1–4) but which nonetheless is conduct that ''may threaten the public health and safety.'' [438]

Fourth, after the Government presented evidence sufficient to establish that his continued DEA registration would be inconsistent with the public interest, Dr. Zaidi failed to present evidence of an acknowledgement of wrongdoing and a proposal for meaningful remediation. Accordingly, I will recommend that the Administrator revoke Dr. Zaidi's DEA registration and deny any pending application for renewal of the same.

Elements of a *Prima Facie* Case

This administrative action began when the DEA's Administrator through her Deputy Administrator issued an order proposing to revoke Dr. Zaidi's DEA Certificate of Registration and ordering him to show cause why that

[418] Gov't Ex. 5e, folder Sept 05 2013, subfolder AudioVideo, file 05–06–2013 at 09:55:14–09:56:46 (vital signs and history taken by Ms. Barrett), 09:58:50–10:00:10 (visit with Dr. Zaidi).

[419] Gov't Ex. 5e, folder Sept 05 2013, subfolder AudioVideo, file 05–06–2013 at 09:58:50–10:00:10.

[420] *Id.*

[421] Tr. at 153.

[422] *Id.* at 155.

[423] *Id.* at 156–57.

[424] Gov't Ex. Eleven at 25.

[425] *Id.*

[426] *Id.*

[427] Tr. at 275.

[428] *Id.* at 159–60.

[429] *Id.* at 276–67.

[430] *Id.* at 202.

[431] *Id.* at 160.

[432] *Id.* at 161.

[433] *Id.* at 202.

[434] *Id.* at 203.

[435] *Id.* at 277.

[436] *Id.*

[437] *Id.*at 153.

[438] 21 U.S.C. 823(f)(5).

registration should not be revoked.[439] The order alleged that Dr. Zaidi distributed controlled substances by issuing prescriptions under conditions that violated provisions in sections 823(f) and 824(a)(4) of Chapter 21 of the United States Code.[440] Thus, in order to revoke Dr. Zaidi's Certificate of Registration, the Government has the burden of establishing, by at least a preponderance of the evidence, that allowing Dr. Zaidi to continue to issue prescriptions for controlled substances is contrary to the public interest.[441]

While the burden of establishing that Dr. Zaidi's certification contravenes the public interest never shifts from the Government, once the Government meets this burden, Dr. Zaidi has the opportunity to present evidence that he accepts responsibility for his misconduct, and has taken appropriate steps to prevent misconduct in the future.[442]

Under the registration requirements found in 21 U.S.C. 823(f), the Administrator is expected to consider five factors in determining the public interest when presented with the actions of a physician engaged in prescribing controlled substances. These factors are:

(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.[443]

Any one of these factors may constitute a sufficient basis for taking action with respect to a Certificate of Registration.[444] 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 a registration should be rejected.[445] Moreover, although the Administrator is obliged to consider all five of the public interest factors, she is ''not required to make findings as to all of the factors.'' [446] The Administrator is not required to discuss each factor in equal detail, or even every factor in any given level of detail.[447] 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.'' [448]

In making a medical judgment concerning the right treatment for an individual patient, physicians require a certain degree of latitude. Hence, ''[w]hat constitutes bona fide medical practice must be determined upon consideration of evidence and attending circumstances.'' [449]

Factor One—Recommendations of the State Licensing Board

In its post-hearing brief, the Government does not propose to use Factor One as a basis for arguing that the continued registration of Dr. Zaidi is contrary to the public interest.[450] Factor One considers ''[t]he recommendation of the appropriate State licensing board or professional disciplinary authority.'' Although the recommendation of the applicable state medical board is probative to Factor One, the Administrator possesses ''a separate oversight responsibility with respect to the handling of controlled substances'' and therefore must make an ''independent determination as to whether the granting [or revocation] of [a registration] would be in the public interest.'' [451]

We do not have an express recommendation by the applicable regulators in Ohio. This may be a factor to consider when evaluating the weight to be given to Dr. Severyn's analysis. There is, however, no substantial evidence of a ''recommendation'' in support of Dr. Zaidi's continued practice in Ohio; nor is there evidence that the state's medical board elected to evaluate any of Dr. Zaidi's treatment records (or even that it is currently aware of this administrative action).

From the record before me I cannot discern a reason for the Board's inaction, and as such I cannot conclude that its inaction establishes that Dr. Zaidi's prescription practice conformed to Ohio law. Such evidence, standing alone, cannot support a finding under Factor One.

Deleted Discussion (Factor Two)

Factor Three

Under Factor Three the Administrator is to consider an applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.[452] Neither the Government nor Respondent has raised any claims pertaining to Factor Three, and there is no evidence that Dr. Zaidi has been convicted of any laws related to dispensing controlled substances. Accordingly Factor Three does not serve as a basis for revoking Respondent's DEA Certificate of Registration.

Factor Four

Under Factor Four the Administrator is required to consider Respondent's ''compliance with applicable State, Federal, or local laws relating to controlled substances.'' [453] ''A prescription for a controlled substance is unlawful unless it has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.'' [454] Departing from the usual course of professional practice can have profound negative consequences. Here, a preponderance of the evidence establishes that with respect to the three undercover agents, Dr. Zaidi prescribed controlled substances without having a legitimate medical purpose and under conditions that fell outside of the usual course of professional practice.

As the Government aptly notes in its post-hearing brief, when she determines whether a practitioner's conduct ''exceeds the bounds of professional practice when prescribing controlled substances,'' [455] the Administrator

[439] ALJ Ex. One.

[440] *Id.* at 1.

[441] 21 U.S.C. 823(f); 21 U.S.C. 824(a); 21 CFR 1301.44(d)–(e); see also *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981).

[442] *Marc G. Medinnus, D.D.S.,* 78 FR 62683–01, 62691–93 (DEA October 22, 2013).

[443] 21 U.S.C. 823(f).

[444] *Robert A. Leslie, M.D.,* 68 FR 15227–01, 15230 (DEA March 28, 2003).

[445] *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs,* 53 FR 43945–02, 43947 (DEA October 31, 1988); see also *David E. Trawick, D.D.S.,* 53 FR 5326–01, 5327 (DEA February 23, 1988).

[446] *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall* v. *DEA,* 412 F.3d at 173–74 (D.C. Cir. 2005).

[447] *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988).

[448] *Jayam Krishna-Iyer, M.D.,* 74 FR 459–01, 462 (DEA January 6, 2009).

[449] *United States* v. *Collier,* 478 F.2d 268, 272 (5th Cir. 1973).

[450] Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 21.

[451] *Mortimer B. Levin, D.O.,* 55 FR 8209–01, 8210 (DEA March 7, 1990).

[452] 21 U.S.C. 823(f)(3).

[453] 21 U.S.C. 823(f)(4).

[454] *Sun & Lake Pharmacy, Inc., D.B.A. The Medicine Shoppe,* 76 FR 24523–02, 23530 (DEA May 2, 2011).

[455] Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 22 (quoting *United States* v. *Moore,* 423 U.S. 122, 142–43 (1975)).

''generally looks to state law.'' [456] The Government points out that Ohio regulations prohibit a physician from prescribing controlled substances without first ''taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for non-therapeutic use or to distribute to others, and the possibility of an illicit market for the drug.'' [457]

There is evidence, aptly noted in Respondent's post-hearing brief, that Dr. Zaidi did to some extent take into account the risks of abuse and diversion associated with the drugs he was prescribing. Dr. Zaidi, for example, screened all cases using the OARRS protocol, required urine drug screening at the initial visit, prescribed low doses of the narcotics (at least initially), required check-ins every two weeks, warned against taking medication that had been prescribed to others, and described the risks of moving quickly to ever stronger narcotic medication.[458]

No one distinct set of circumstances permits me to determine the extent to which Dr. Zaidi recognized the potential for abuse or diversion when treating the undercover agents. All of the foregoing office protocols may have been instituted to reflect Dr. Zaidi's concern for the potential misuse or diversion of controlled substances. Given Respondent's decision to not testify, however, our record is silent with respect to Dr. Zaidi's mental assessment of these cases. I am thus left to discern what factors Dr. Zaidi took into account when prescribing these drugs based on the contents of the written medical records and on what I heard and saw in reviewing the recordings of the undercover agents' office visits. In doing so, I cannot help but be influenced by the evidence of falsification present in these records. Knowing now what actually occurred during the office visits and comparing that to what Dr. Zaidi wrote in the patient records, I find little reason to believe these protocols were instituted to reduce the risk of abuse or diversion, but were instead instituted to provide some degree of cover for Dr. Zaidi against regulatory action by the DEA, should his records ever by subject to audit.

As the Government correctly points out, in its prehearing statement the Government put Dr. Zaidi on notice well before the hearing that it intended to question him about his response to these red flags.[459] As a matter of law, the Government is entitled to an inference that had he testified, Dr. Zaidi would have acknowledged fabricating much of the information in the officers' medical records and failing to resolve the red flags identified by Dr. Severyn, and would have acknowledged that his treatment of the undercover agents fell below accepted medical standards.[460] With such an inference occasioned by his silence in the face of independent evidence showing that his practice fell below accepted medical standards, Dr. Zaidi cannot now be understood to have conformed to those standards.

Independent of such an inference, however, the same result is warranted. I have considered the steps taken to resolve red flags identified by Dr. Severyn. As the Government has suggested, Dr. Severyn's conclusion is supported by evidence that Dr. Zaidi failed to resolve numerous red flags the agents presented during their office visits.[461]

Testimony from Dr. Severyn helps to identify what red flags were presented to Dr. Zaidi during these visits. These include, for example, being presented by a patient's request for OxyContin by brand name.[462] Dr. Severyn explained why this conduct needs to be addressed by the prescribing physician, as it indicates that the patient was relying on outside sources (here either friends or family) to chart the course of medication, ''instead of relying on my expertise to introduce a specific medication.'' [463]

I give great weight to Dr. Severyn's assessment of circumstances that constitute red flags, given his substantial relevant experience in prescribing controlled substances for treating pain, his understanding of the pressures facing pain medicine physicians, and his familiarity with Ohio's pain management regulations. Thus, when he relates that a pain management patient's request for OxyContin by name has been a red flag for pain management physicians for ''a decade or more'' I attribute great weight to that opinion. The same was true when Officer Leonard requested Opana, which both Officer Leonard and Dr. Severyn stated was now becoming increasingly diverted and abused.[464] While our record shows that Dr. Zaidi did not actually prescribe Opana, it is silent with respect to whether Dr. Zaidi recognized this as a red flag needing resolution.

Similarly, Dr. Severyn considered Agent Moses' request for an increase in medication at the fourth office visit to be a red flag, where the request was based solely on the recommendation of ''a guy [Agent Moses] work[s] with'' [465] who reported successful treatment using Percocet.[466] I attribute great weight to Dr. Severyn's opinion that these all were unresolved red flags.

To much the same effect was Dr. Zaidi's apparent complacence when a patient sought an increase in the amount of OxyContin being prescribed. Again, there was no evidence that Dr. Zaidi engaged Officer Parkison in any inquiry that would probe why existing levels of pain medication were inadequate.[467] According to Dr. Severyn, given that OxyContin has been so ''largely diverted and abused,'' the failure to make such an inquiry constituted the failure to resolve a relevant red flag.[468]

Respondent in his post-hearing brief correctly points out that resolving red flags can take time—a point with which Dr. Severyn concurred.[469] Specifically, Dr. Severyn opined that a treating source generally will not sufficiently observe and evaluate a patient in one or two visits, but that instead will address red flags over time, with the length of time dependent on the circumstances.[470]

Dr. Severyn added, however, that depending on the indicators presenting as red flags, the physician may have to do more than just wait.[471] There is, however, no evidence that Dr. Zaidi took any action when confronted with these red flags, other than to accede to the requests of his patients to increase the amount of pain medication being prescribed.

Another red flag was the refusal of a patient to obtain an MRI despite the treating physician's order for such imaging.[472] While I agree with Respondent's proposition that MRIs are expensive and cost may have been a factor Dr. Zaidi took into account when faced with this particular red flag, I agree with the opinion expressed by Dr. Severyn in this regard. We have three

[456] *Id.* (citing *Kamir Garces-Mejias,* 72 FR 54931–02, 54935 (DEA September 27, 2007) *& United Prescription Services, Inc.,* 72 FR 50397–01, 50407 (DEA August 31, 2007)).

[457] Ohio Admin. Code 4731–11–02(C).

[458] Post-Hearing Brief of Respondent at 14–19 and citations to the record therein.

[459] Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 28 and citations therein.

[460] *Id.*

[461] *Id.* at 23.

[462] Tr. at 95–96.

[463] *Id.* at 96.

[464] *Id.* at 134, 578.

[465] Gov't Ex. Eleven at 25.

[466] Tr. at 156–57.

[467] *Id.* at 113.

[468] *Id.* at 113–14.

[469] Post-Hearing Brief of Respondent at 5 and citations therein.

[470] Tr. at 173–74.

[471] *Id.* at 174–75.

[472] *Id.* at 185, 266–67.

patients who demonstrated the ability to pay $300 for their initial visits and $95 for each of four or five subsequent visits. The refusal of Agent Moses to comply with Dr. Zaidi's recommendation that he pay $200 for a cortisone shot, and the refusal of Agent Parkison to pay $350 for an MRI ''is very suspicious, and it is a red flag.'' [473] What I saw in the video recordings of the office visits where Dr. Zaidi made these recommendations leads me to conclude that Dr. Zaidi saw no significance in the undercover agents' refusal to procure these treatments and diagnostic tools. He was indifferent—the patients could comply with his orders or not—but he would continue prescribing controlled substances regardless.

While a patient's request for brand name opiates does not in and of itself compel a conclusion that the patient is seeking to divert or abuse pain medication, the request must be addressed by the treating physician. There is, however, nothing in the record suggesting that Dr. Zaidi regarded these requests for brand-name pain-killers as anomalous or requiring further inquiry. Similarly, a patient's decision not to pursue more conservative treatment (such as cortisone injections) or obtain diagnostic information (such as is available with an MRI) by itself is not conclusive of an intent to abuse or divert narcotics, but such decisions have to be taken into account by the prescribing source. To the extent Dr. Zaidi elected to not dispute Dr. Severyn's thoroughly documented observations, I am entitled to infer that Dr. Zaidi failed to consider the possibility that the undercover agents sought drugs for non-therapeutic reasons or that the drugs he prescribed could have led to dependence. To the extent such a failure indicates a lack of experience, Dr. Zaidi's failure to resolve red flags—standing alone—has been addressed in the Factor Two discussion above. To the extent it led to the issuance of actual prescriptions for controlled substances, Dr. Zaidi's practice violated Ohio law relating to the prescription of controlled substances.[474] In turn, this violation of Ohio law leads to my finding that Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Four.[475]

Independent of Dr. Zaidi's failure to resolve red flags is evidence that the diagnoses upon which controlled substances were prescribed cannot withstand scrutiny. I find substantial evidence supports Dr. Severyn's opinion that Dr. Zaidi had no basis for diagnosing either Agent Parkison or Detective Leonard with lumbar radiculitis, given the examinations that supported those diagnoses and given that neither officer complained of pain radiating into the leg.[476] I find uncontroverted and persuasive Dr. Severyn's description of the steps needed to establish such a diagnosis; and I find that the examinations of record would not permit such a diagnosis in the ordinary course of professional practice, for the reasons presented by Dr. Severyn. I believe Dr. Zaidi purposely included more serious diagnoses to support prescribing more controlled substances than were medically necessary and to insulate him from DEA investigations, perhaps not realizing that the DEA performs undercover operations that include surreptitious audio-video recordings of patient visits.

I find the evidence establishes that by prescribing controlled substances based on a diagnosis of radiculitis, Dr. Zaidi did so without a legitimate medical purpose. As such, Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Four.[477]

There is a third basis under Factor Four that warrants evaluation. Apart from failing to resolve red flags and basing controlled substance prescriptions upon an unsustainable diagnosis of radiculitis, Dr. Zaidi failed to comply with Ohio law in the maintenance of his medical records. Under Ohio law a physician prescribing controlled substances must ''complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients.'' [478] Note that this requirement applies to *all* prescriptions involving controlled substances, regardless of whether the diagnosed condition relates to pain, and regardless of the duration of treatment.[479] Thus, it is a requirement arising from the very start of the patient-physician relationship, once the physician determines the need to prescribe controlled substances.

In addition, under this regulation, a medical record of treatment involving controlled substances must ''accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized, and any additional information upon which the diagnosis is based.'' [480] As the Government correctly observed in its post-hearing brief, ''Respondent repeatedly fabricated the officers' medical records by exaggerating their pain levels and falsely stating that his 'Plan of Treatment' included 'home exercise' which was never proposed, suggested, nor discussed at any visit.'' [481]

I found this part of the record particularly troubling. Had I before me only Dr. Zaidi's written medical records of the officers' treatment, I would have reasonably concluded that Dr. Zaidi was responding to complaints of pain that were significantly more severe than what was actually presented during these office visits. Dr. Zaidi's assistant accurately recorded pain levels as they were presented to her by the undercover officers, generally noting pain in the range of two, three, or four on a ten-point scale. In his typewritten chart, however, Dr. Zaidi indicates pain levels of five, which could not be substantiated by either what the patients said to the assistant or what they said to Dr. Zaidi. The evidence shows Dr. Zaidi misrepresented and exaggerated the patients' complaints of pain.

As Dr. Severyn noted with some concern, once it became clear that Dr. Zaidi exaggerated the patients' reports of pain, and once it became clear that Dr. Zaidi's diagnoses for radiculitis could not be substantiated by the actual physical examinations he performed, ''the entire validity of the record becomes subject to extreme doubt and questioning.'' [482] Similarly, Dr. Zaidi's report of leg pain and early osteoarthritis of the knee in Agent Moses was exaggerated, and the patient never reported limb or leg pain.[483]

Beyond exaggerating the patients' complaints of pain, Dr. Zaidi falsely reported results from tests that were never performed. From my review of the recordings of the undercover officers' visits, I find Dr. Zaidi falsely reported their pupils' reactivity to light, their heart and chest sounds, the condition of their abdomens, their lower extremity sensory and motor condition, and their limbs' range of motion. Further, I find Dr. Zaidi falsely described prescribing conservative measures (including home exercise programs) in their medical

[473] *Id.* at 278.

[474] Ohio Admin. Code 4731–11–02(C).

[475] 21 U.S.C. 823(f)(4).

[476] Tr. at 77–78, 118.

[477] 21 U.S.C. 823(f)(4).

[478] Ohio Admin. Code 4731–11–02(D).

[479] Ohio Admin. Code 4731–11–02(A) (''A physician shall not utilize a controlled substance other than in accordance with all of the provisions of this chapter of the Administrative Code'').

[480] Ohio Admin. Code 4731–11–02(D).

[481] Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 23, and citations to the record therein.

[482] Tr. at 121.

[483] Gov't Ex. Fourteen at 8–9.

records, when instead he prescribed controlled substances as the first course of treatment.

Respondent in his post-hearing brief notes that Dr. Severyn offered no statutory or other authority ''which sets forth mandatory requirements for a physical examination and diagnosis.'' [484] Given the requirement under Ohio law for all physicians to maintain accurate medical records, I find Dr. Zaidi's medical records documenting the visits and treatment of the three undercover officers violated Ohio law.[485] Accordingly, this constitutes evidence that Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Four.[486]

Respondent also describes at length the attention Dr. Severyn gave to practice requirements that arise after a patient has been receiving pain medication for more than twelve weeks.[487] Before I address Respondent's concerns, I note that the foregoing analysis depended not upon regulations cited by Respondent regarding chronic or intractable pain, but instead upon regulations relating to the dispensation of controlled substances generally. Thus, whether Ohio's regulations regarding intractable pain do or do not apply here has no bearing on Dr. Zaidi's failure to respond to red flags, failure to properly diagnose patient conditions, and failure to maintain accurate records. Under Factor Four, the evidence establishes that it would be inconsistent with the public interest to permit Dr. Zaidi to continue to hold a DEA registration, regardless of whether the conditions described in the officers' history of treatment fell within the scope of Ohio's laws concerning the prescription of controlled substances for persons with intractable pain.

Having said that, I note that I do not interpret Dr. Severyn's testimony as having required Dr. Zaidi to conform to the standards for treating intractable pain from the start of the physician/patient relationship. As Respondent noted in his post-hearing brief, Dr. Severyn acknowledged that the statute and regulation treating chronic pain (Ohio Rev. Code § 4731.052) and intractable pain (Ohio Admin. Code 4731–21–02) do not apply during that phase of treatment where the diagnosis is of acute pain, but apply only after treatment extends past twelve weeks.[488] Respondent proposes that the undercover officers' complaints ''were for acute pain and not for 'intractable' or 'chronic' pain'' and argues that ''[t]he statutes have no application for acute pain.'' [489] He asserts further that each of the undercover agents ''presented with short term, acute pain for which there had been no prior treatment.'' [490]

Our record reflects, however, that upon making his initial diagnoses in these cases, Dr. Zaidi elected not to characterize the patients' conditions (all of which involved potentially chronic conditions) as either chronic or acute. Instead, he prescribed opioid treatment exclusively, and during the first twelve weeks treated the patients as though their symptoms were not likely to change or improve. At no time during the first twelve weeks of treatment, for example, did Dr. Zaidi indicate he expected to reduce the officers' reliance on narcotics. Thus, from all outward appearances, Dr. Zaidi was treating these patients as though their conditions were not acute, but were instead chronic, from the outset of treatment.

I am mindful that Dr. Zaidi in his post-hearing brief notes that he did not diagnose any of the undercover agents with ''chronic'' pain; nor, for that matter, did he describe any of the pain as ''acute.'' [491] I am, however, guided by Ohio statutory language that defines ''chronic pain'' as pain that persists after treatment for longer than three continuous months.[492] As such, by the twelfth week of treatment, Dr. Zaidi's failure to characterize the agents' conditions as chronic is irrelevant.

The distinction regarding chronic or acute designations made by Dr. Severyn, however, did not depend on the patients' condition during the first twelve weeks. My understanding of his testimony is that whether or not a patient is identified as having intractable or chronic pain during the first twelve weeks, the physician must re-assess the patient once the course of treatment enters into its twelfth week. That appears to be what the regulation cited by Respondent calls for. The regulation defines ''intractable pain'' as ''a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.'' [493] It also defines ''protracted basis'' as ''a period in excess of twelve continuous weeks,'' [494] and articulates a standard of care applicable ''[w]hen utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions.'' [495]

From our record, I found no evidence that Dr. Zaidi regarded as clinically significant the twelve-week benchmark in his treatment of the three undercover agents. His actions during the office visits immediately before and after the twelfth week were remarkable only in that they remained essentially the same—they were cursory, involved no physical examinations, and focused almost entirely on the patients' requests for additional or different narcotics.

What is notable in the treatment of chronic pain in Ohio, however, is that once pain ''has persisted after reasonable medical efforts have been made . . . either continuously or episodically, for longer than three continuous months,'' [496] Ohio law requires pain management physicians to include in their written records a ''periodic assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient.'' [497] No such assessment was made, for example, when Officer Leonard appeared on March 21, 2013, either in his interview with Ms. Barrett [498] or during his visit with Dr. Zaidi, twenty-one weeks into treatment.[499]

As noted in the Government's post-hearing brief, Dr. Severyn found that when treatment of the undercover agents extended into the twelfth week, Dr. Zaidi failed to assess the impact of pain on their physical and psychological functions, failed to discuss alternative treatment plans, and failed to document how their pain affected their employment, daily and social activities, and family life.[500] In these respects, the evidence supports, and I find persuasive, Dr. Severyn's opinion that Dr. Zaidi's treatment of the three undercover agents after the twelfth week failed to conform to the applicable

[484] Post-Hearing Brief of Respondent at 10.
[485] Ohio Admin. Code 4731–11–02(D).
[486] 21 U.S.C. 823(f)(4).
[487] Post-Hearing Brief of Respondent at 3–12.
[488] *Id.* at 4.
[489] *Id.*
[490] *Id.* at 5.
[491] *Id.* at 9.
[492] Ohio Rev. Code § 4731.052(A)(1).
[493] Ohio Admin. Code 4731–21–01(G).
[494] Ohio Admin. Code 4731–21–01(L).
[495] Ohio Admin. Code 4731–21–02(A).
[496] Ohio Rev. Code § 4731.052(A)(1).
[497] Ohio Admin. Code 4731–21–02(B)(2).
[498] Gov't Ex. Ten at 32–33.
[499] Gov't Ex. Ten at 33–35.
[500] Government's Recommended Findings of Fact, Conclusions of Law[,] and Argument at 24–25.

standard of care and violated Ohio law regarding the treatment of chronic [501] and intractable pain.[502] Therefore, when Dr. Zaidi prescribed controlled substances based on this treatment, he did so without a legitimate medical purpose and outside the usual course of professional practice in Ohio.[503] As such, his prescription practice regarding the three undercover agents during the period after the twelfth week of treatment constitutes an additional basis for finding his continued DEA registration inconsistent with the public interest under Factor Four.

I note the Government also argues that Respondent violated Ohio law by prescribing a controlled substance to his daughter.[504] Ohio regulations state:

> Accepted and prevailing standards of care require that a physician maintain detached professional judgment when utilizing controlled substances in the treatment of family members.[505] A physician shall utilize controlled substances when treating a family member only in an emergency situation which shall be documented in the patient's record.[506]

Ohio courts have stated that ''utiliz[ing] controlled substances'' includes ''prescribing'' them.[507] Accordingly, if Dr. Zaidi prescribed Vicodin, a Schedule III controlled substance, to his daughter he violated Ohio law. In attempting to prove this allegation, the Government did not, however, present a copy of the prescription Dr. Zaidi allegedly gave to his daughter, nor did it present, as an alterntative, her patient chart. The Government also did not show whether Dr. Zaidi prescribed Vicodin to his daughter in an emergency situation or whether Dr. Zaidi noted the prescription in his daughter's patient chart. The only evidence the Government has offered to support its allegation is the testimony of Diversion Investigator Brinks. Investigator Brinks interviewed Dr. Zaidi ''during the search warrants.'' [508] Apparently, at that time, Dr. Zaidi admitted to Investigator Brinks that ''in the past he had written a prescription for Vicodin to his daughter.'' [509]

Respondent's counsel pointed out that the evidence does not show whether the prescription was filled.[510] However, ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner'' while the ''corresponding responsibility'' for filling the prescription ''rests with the pharmacist.'' [511] Thus, even if a prescription for a controlled substance is not filled, a practitioner may nonetheless violate the Controlled Substances Act by issuing the prescription in the first place.

Respondent's counsel also pointed out, however, that Investigator Brinks did not ask whether the prescription was issued during an emergency.[512] Without that information, or any other evidence to support the Government's allegation, I am unable to conclude that the evidence proves Dr. Zaidi violated Ohio law in issuing a controlled substance prescription to his daughter.

The Government also asserts that Dr. Zaidi violated Ohio law by instituting a practice by which he would pre-sign prescriptions at the beginning of a work day, leaving those prescriptions not needed on that day in storage, so that they could be used the following day; and that he failed to require patient addresses be included in each prescription.[513] As the Government correctly points out, federal law provides that ''prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient . . . .'' [514] The evidence supports a finding that Dr. Zaidi's office practice included procedures that would permit Kim Maniglia to receive pre-signed but otherwise blank prescriptions from Dr. Zaidi and retain unused scripts for use the next business day.[515] It also supports a finding that Dr. Zaidi did not require controlled substance prescriptions to include a patient's address.[516] Each of the prescriptions in our record is for a controlled substance, and none include patient address information.[517] Thus, this evidence establishes a violation of federal law relating to controlled substances, and serves as a basis for making an adverse finding under Factor Four.

The record does not, however, include substantial evidence of an actual instance where Ms. Maniglia had pre-signed prescriptions at the end of a work day, and used the carried-over script the following day for purposes of dispensing controlled substances. Accordingly, this is discussed under Factor Five, but does not serve as a basis for making an adverse finding under Factor Four.

While I do not endorse the Government's assertion that it proved Dr. Zaidi violated Ohio law regarding prescribing to family members, I do find substantial and persuasive evidence establishing that Dr. Zaidi otherwise failed to comply with applicable state and federal laws relating to controlled substances, and that this failure warrants a finding that his continued DEA registration would be inconsistent with the public interest under Factor Four.

Factor Five

Under Factor Five, after considering the public interest in the context of the first four factors, the Administrator will consider ''other conduct which may threaten the public health and safety.'' [518] Factor Five thus encompasses the universe of conduct not expressly within the scope of the first four factors, but ''which creates a probable or possible threat (and not only an actual) threat to public health and safety.'' [519] Further, agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the Controlled Substances Act.[520]

In its post-hearing brief, the Government contends that Respondent ''instituted and maintained policies that were contrary to Federal law'' in two respects under Factor Five.[521] First, the Government posits that Dr. Zaidi ''advised [Kim] Maniglia that including a patient address on a prescription for controlled substances was not necessary'' and second, that he ''maintained a policy by which employees were forbidden from contacting law enforcement officers in the event they suspected patients were

[501] Ohio Rev. Code § 4731.052.

[502] Ohio Admin. Code 4731–21–02.

[503] 21 CFR 1306.04(a).

[504] Government's Recommended Findings of Fact, Conclusions of Law[,] and Argument at 25.

[505] ''[F]amily member' means a spouse, parent, child, sibling or other individual in relation to whom a physician's personal or emotional involvement may render that physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.'' Ohio Admin. Code 4731–11–08.

[506] Ohio Admin. Code 4731–11–08(B).

[507] See, *e.g., Harris* v. *State Med. Bd.,* 974 NE.2d 207, 216 (Ohio Ct. App. 2012).

[508] Tr. at 618.

[509] *Id.* at 619.

[510] *Id.* at 620.

[511] 21 CFR 1306.04(a).

[512] Tr. at 620.

[513] Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 25–26.

[514] *Id.* (citing 21 CFR 1306.05(a)).

[515] Tr. at 407.

[516] *Id.* at 429.

[517] Gov't Exs. Fifteen; Eighteen; & 21.

[518] 21 U.S.C. 823(f)(5).

[519] *Roni Dreszer, M.D.,* 76 FR 19434–01, 19434 n.3 (DEA April 7, 2011).

[520] *Terese, Inc., D/B/A Peach Orchard Drugs,* 76 FR 46843–02, 46848 (DEA August 3, 2011).

[521] Government's Findings of Fact, Conclusions of Law[,] and Argument at 26.

obtaining multiple prescriptions for controlled substances.'' [522]

As a matter of procedure, I regard the scope of Factor Five to be limited to those portions of our record that do not establish violations of federal law. ''Because section 823(f)(5) only implicates 'such other conduct,' it necessarily follows that conduct considered in Factors One through Four may not ordinarily be considered at Factor Five.'' [523] Thus, if either office policy violates any laws relating to prescribing controlled substances, then it must be considered in the discussion of Factor Four, rather than Factor Five. Failing to put patient addresses on controlled substance prescriptions is a violation of federal law and thus has been addressed in the Factor Four analysis.

I am not, however persuaded that sufficient evidence has been presented to conclude Dr. Zaidi ''maintained a policy by which employees were forbidden from contacting law enforcement'' [524] when presented with questionable patient conduct. The evidence does tend to establish that Ms. Maniglia felt that laws regarding patient privacy prohibited her from reporting patient activities to law enforcement authorities.[525]

I have carefully reviewed Ms. Maniglia's testimony regarding the reasons she felt constrained in reporting suspicious behavior to law enforcement personnel. Clearly the record indicates that Ms. Maniglia understood patient privacy laws to be very broad in scope. In her understanding of those laws, Ms. Maniglia said, ''I ha[ve] been in the field for 20 years and we're not allowed to talk about any patient confidentiality stuff.'' [526] When asked, however, whether this understanding came from policies instituted by Dr. Zaidi, Ms. Maniglia was clear and consistent in responding in the negative, saying ''we never talked about it.'' [527]

Ms. Maniglia's understanding about federal privacy laws as they pertain to pain management clinics is understandable. Federal law in this area is complex and generally tends to restrict disclosure of medical records, as Ms. Maniglia correctly stated. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of Health and Human Services to create standards for privacy of ''individually identifiable health information.'' [528] In 2001 the Secretary issued the HIPAA Privacy Rule.[529] The rule preempts most state laws affecting medical records to the extent that state laws contradict the Privacy Rule and are less stringent.[530] Under the Rule, a covered entity [531] may not use or disclose protected health information without written authorization from the individual or, alternatively, the opportunity for the individual to agree or object.[532]

However, there are situations in which the covered entity may use or disclose protected health information without the individual's authorization or agreement. These are situations where the entity is obligated by law to disclose information, where the information is requested as part of a judicial or administrative proceeding, or where the information is needed for public health or safety purposes.[533] For example, covered entities may disclose protected health information to health oversight agencies, public health authorities, and to courts or tribunals engaged in judicial or administrative proceedings under circumstances designed to insure that the information is disclosed only to those who need to know.[534]

There are also several circumstances under which covered entities may disclose protected health information to law enforcement agencies or officials.[535] Protected health information may be disclosed pursuant to laws that require reporting of certain types of injuries or in compliance with a court order, warrant, subpoena (including a grand jury subpoena) summons, or administrative request.[536]

Assuming, as I do, that Ms. Maniglia's testimony is accurate, I think a strong argument can be made for the proposition that Dr. Zaidi's failure to correctly understand the law-enforcement exceptions to HIPAA and to discuss with his staff the role law enforcement plays in preventing abuse and diversion is important. If pain management staff members observe evidence of doctor shopping or diversion of prescribed narcotics, those staff members should be familiar with steps they can and must take to alert the relevant authorities of possible illicit action. Dr. Zaidi is responsible for ensuring that his staff understands the practitioner's role in preventing abuse and diversion of controlled substances. The evidence tends to demonstrate Dr. Zaidi failed to meet this responsibility in the management of his medical practice.

To some extent, therefore, there is evidence that Dr. Zaidi's management of his staff was materially deficient and was inconsistent with the public interest.

I cannot, however, agree with the Government's assertion that the evidence establishes Dr. Zaidi ''maintained a policy by which employees were forbidden from contacting law enforcement in the event they suspected patients were obtaining multiple prescriptions for controlled substances from multiple doctors.'' [537] I found Ms. Maniglia's testimony credible throughout, including when she told me she never talked with Dr. Zaidi about limits on disclosing confidential information.[538] I further found credible her explanation that when she was interviewed by the DEA during the execution of the warrant allowing the search of Dr. Zaidi's office, she was misunderstood. She denied telling the interviewing officer that employees who discovered evidence of doctor shopping were not allowed to report that to law enforcement, explaining, ''He misunderstood me. I told him that was [] HIPAA, that we weren't allowed to discuss anything. . . . We were not allowed to call. It was patient confidentiality.'' [539]

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[522] *Id.*

[523] *Joe W. Morgan, D.O.,* 78 FR 61961–01, 61977 (DEA October 8, 2013).

[524] Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 26.

[525] Tr. at 411.

[526] *Id.* at 412.

[527] *Id.*

[528] Health Insurance Portability and Accountability Act, Pub. L. 104–191, § 264, 110 Stat 1936 (1996).

[529] See 45 CFR parts 160 and 164.

The term ''individually identifiable health information'' means any information, including demographic information collected from an individual, that—

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. 42 U.S.C. 1320d.

[530] 45 CFR 160.203-.204.

[531] A covered entity is: ''(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.'' 45 CFR 160.103; see also 45 CFR 164.104. The third category tends to include most healthcare providers since the regulation lists twelve common activities that would subject healthcare providers to HIPAA's requirements. See 45 CFR 160.103.

[532] 45 CFR 164.508, 164.510.

[533] 45 CFR 164.512.

[534] *Id.*

[535] *Id.*

[536] *Id.*

[537] Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 26.

[538] Tr. at 412.

[539] *Id.* at 411.

Accordingly, while I find insufficient evidence establishing that Dr. Zaidi established a policy prohibiting his staff from reporting evidence of diversion or abuse, I find his office practice generally created a risk to the public safety in failing to properly train his staff regarding the role of law enforcement officers in detecting abuse and diversion of controlled substances. In this respect, the Government has met its burden of demonstrating that Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Five.

Evidence of Respondent's Remediation

Once the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must ''present[] sufficient mitigating evidence to assure the Administrator that [the registrant] can be entrusted with the responsibility carried by such a registration.'' [540] In addition, because ''past performance is the best predictor of future performance,'' [541] the Administrator repeatedly has held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct.[542] Further, ''admitting fault'' is ''properly consider[ed]'' by DEA to be an important factor in the public interest determination.[543] The Administrator repeatedly has held that the ''registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' [544] ''Once the [G]overnment establishes a *prima facie* case showing a practitioner has committed acts which render his registration inconsistent with the public interest, the burden shifts to the practitioner to show why his continued registration would be consistent with the public interest.'' [545]

Here the Administrator must proceed without testimony from Dr. Zaidi, and without evidence of remediation or of an admission of fault. I cannot concur with Respondent's claim that ''there is no evidence to suggest that Dr. Zaidi is a threat to the public interest.'' [546] Evidence that Dr. Zaidi persistently misrepresented the extent of his examination of the three undercover agents is but one example of conduct that threatens the public interest. With respect to remediation, Respondent asserted in his post-hearing brief that ''[t]hrough his counsel during the hearing in this matter, there is an acknowledgment of areas Dr. Zaidi could improve. He would take appropriate corrective action to eliminate those errors.'' [547] I cannot find from this representation any substantial evidence of either contrition or remediation. Accordingly, the Government's *prima facie* case is established, and the matter is presented to the Administrator without evidence that would compel any outcome other than the revocation of Dr. Zaidi's DEA registration.

Findings of Fact

1. On October 8, 2013, the Deputy Administrator for the Drug Enforcement Administration issued an order to show cause why the DEA should not revoke its Certificate of Registration BA3842259 issued to Syed Jawed Akhtar-Zaidi, M.D., and should not deny any application for renewal or modification of the same. That certificate authorizes the distribution of controlled substances out of an office located at 34055 Solon Road, Suite 201, Solon, Ohio 44139. The order also immediately suspended this DEA registration, under the authority found in 21 CFR 1301.36(e) and 1301.37(c). By its own terms, Respondent's DEA registration will expire on June 30, 2014.

2. Between September 11, 2012, and May 17, 2013, Respondent prescribed controlled substances to three undercover agents posing as patients. The dates these prescriptions were written; the name, dosage, and quantity of the controlled substances prescribed; and the identity of the agents who received these prescriptions are accurately set forth in paragraphs 2a through 2c in the order to show cause,[548] and are incorporated by reference into this finding.

3. In each of the prescriptions for controlled substances Respondent issued to these agents identified in Finding of Fact Two, Respondent failed to include the patient's address.

4. In the cases of Agent Parkison and Detective Leonard, Respondent based his prescription for controlled substances on a diagnosis of lumbar radiculitis, under conditions where the patients' examination and history did not support such a diagnosis.

5. In the case of Agent Moses, Respondent based his prescription for controlled substances in part on diagnoses of limb pain, leg pain, and osteoarthritis, under conditions where the patient's examination and history did not support such diagnoses.

6. After his initial examination of each undercover officer, Respondent never performed physical examinations in subsequent office visits with these patients, but nonetheless either maintained or increased narcotic prescriptions throughout the course of treatment, generally based on no objective medical findings but instead based on requests by the undercover officers.

7. In the case of each undercover officer, Respondent failed to complete and maintain accurate medical records reflecting his examination of these patients in that he reported exaggerated levels of pain; reported completing examinations that were never performed; falsely stated he had examined the patients to detect pupil response to light, range of motion in the upper or lower extremities, chest and heart sounds, abdominal tenderness, and sensory and motor functions; and based his prescriptions for controlled substances on these false examination reports.

8. In the case of each undercover officer, Respondent treated for pain for a period exceeding twelve weeks, but failed either before or after the twelfth week to indicate in the patient's medical chart a diagnosis of chronic pain (including signs, symptoms, and causes); failed to develop a comprehensive assessment of the patient a description of the patient's response to treatment; failed to fully document his periodic assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the interference with activities of daily living, quality of family life and social activities; failed to fully document his periodic assessment and documentation of the patient's progress toward treatment objectives, including the intended role of controlled substances within the overall plan of treatment; and failed to fully document that he had addressed with the patient the risks associated with protracted treatment with controlled substances, including informing the

[540] *Medicine Shoppe—Jonesborough,* 73 FR 364–01, 387 (DEA January 2, 2008) (quoting *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (DEA May 1, 2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (DEA June 10, 1988)).

[541] *ALRA Labs, Inc.,* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995).

[542] See *Jackson,* 72 FR at 23853; *John H. Kennedy, M.D.,* 71 FR 35705–01, 35709 (DEA June 21, 2006); *Prince George Daniels, D.D.S.,* 60 FR 62884–01, 62887 (DEA December 7, 1995).

[543] *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005).

[544] *Medicine Shoppe—Jonesborough,* 73 FR at 387.

[545] *MacKay* v. *DEA,* 664 F.3d 808, 817 (10th Cir. 2010) (citing *Medicine Shoppe—Jonesborough,* 73 FR at 387).

[546] Post-Hearing Brief of Respondent at 19.

[547] *Id.*

[548] ALJ Ex. One.

patient of the potential for dependence, tolerance, and addiction, and the clinical or monitoring tools the physician may use if signs of addiction, drug abuse, or drug diversion are present.

9. In the course of treating each of the undercover officers, Respondent failed to identify in his medical chart and resolve red flags indicating possible controlled substance abuse or diversion, including solicitation by the patient of specific narcotics by name as an initial course of treatment, particularly where the named drugs were OxyContin, Percocet, or Opana, all of which are recognized as frequently diverted narcotics; solicitation by the patient of increasing amounts of narcotic medication or changes in name-brand narcotics without objective medical reasons justifying the change; a patient presenting to the medical office without a government-issued identity card that included the patient's current address; a patient's use of medication provided by non-authorized sources such as a family member; and persistent patient noncompliance with orders for MRI-based studies and refusal to consider non-narcotic treatments including cortisone injections.

10. Contemporaneous to the execution of a search warrant of Respondent's premises, Respondent told DEA agents he had prescribed Vicodin to his daughter. There is, however, no copy of the prescription nor any evidence that would permit a determination of the circumstances under which this controlled substance was prescribed, including whether such treatment was provided in an emergency situation.

11. Included in Respondent's prescription practice was a protocol by which he would pre-sign prescriptions, many of which were used to prescribe controlled substances. The supply of pre-signed prescriptions would not always be exhausted at the end of the day, and remaining prescriptions would be used the following day. There is, however, insufficient evidence permitting a finding that any left-over prescriptions were used for prescribing controlled substances on a day other than the day the prescription was issued.

12. Respondent was the physician in charge of and the only authorized prescribing source at his pain management clinic. In training his clinical staff, Respondent did not require those who assisted in filling out controlled substance prescriptions to include patient addresses on the prescription. Further, he did not provide training to his staff regarding exceptions to patient privacy laws that apply when the staff members observe behavior relating to controlled substance abuse, misuse, or diversion.

13. Respondent has not provided substantial evidence that he has acknowledged any noncompliance with controlled substance laws, nor that he has undertaken efforts to avoid such noncompliance in the future.

Conclusions of Law

1. When it proposes to revoke a DEA Certificate of Registration or deny any pending applications for such registration, the Government is required to establish by at least a preponderance of the evidence that the holder's continued registration is inconsistent with the public interest.

2. Five factors must be considered when determining the public interest in this case:

(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.[549]

3. Under 21 U.S.C. 823(f)(1) (Factor One), as is the case here, where the record is silent with respect to the recommendation of the appropriate state licensing board or professional disciplinary authority, Factor One neither supports nor contradicts a finding that Respondent's continued DEA registration is inconsistent with the public interest.

4. In order to establish a basis for revoking a Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(2) (Factor Two), and assuming Factor Two applies to Respondent, the Government must present preponderant evidence establishing that the experience of Respondent in dispensing controlled substances is of such character and quality that his continued registration is inconsistent with the public interest. Upon the determinations appearing in Finding of Fact Number Nine (above), where a preponderance of the evidence establishes that Respondent demonstrated a material lack of insight and experience regarding a prescribing source's responsibilities to resolve red flags when prescribing controlled substances for persons presenting with symptoms of chronic pain, the Government has met its burden of proving Respondent's continued DEA registration would be inconsistent with the public interest under Factor Two, warranting the revocation of that registration and the denial of any pending application for registration.

5. In order to establish a basis for revoking a Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(3) (Factor Three), and assuming Factor Three applies to Respondent, the Government must present evidence of Respondent's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances. As this Factor is neither alleged by the Government nor suggested by the evidence, this Factor may not be considered to support the revocation of Respondent's current DEA registration or deny any pending application for registration.

6. Under 21 U.S.C. 823(f)(4) (Factor Four), the Administrator is to consider the Respondent's compliance with applicable state, federal, or local laws relating to controlled substances.

7. Federal law relating to controlled substances includes the requirement that prescriptions for controlled substances include the patient's address.[550] Where the Government establishes by at least a preponderance of the evidence, as is the case here, that Respondent issued prescriptions for controlled substances that did not include any patient address information, the Government has met its burden of establishing Respondent's noncompliance with applicable federal law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

8. Federal law relating to controlled substances include the requirement that all prescriptions for controlled substances must be for a legitimate medical purpose and must be issued in the ordinary course of a professional medical practice.[551] Ohio law includes the requirement that prescriptions for controlled substances must be for legal and legitimate therapeutic purposes.[552] A preponderance of the evidence establishes that Respondent issued controlled substance prescriptions for the three undercover agents described

[549] 21 U.S.C. 823(f).

[550] 21 CFR 1306.05(a).

[551] *Sun & Lake Pharmacy,* 76 FR 24523–02, 24530 (DEA May 2, 2011) (quoting 21 CFR 1306.04(a)); *George C. Aycock, M.D.,* 74 FR 17529–01, 17541 (DEA April 15, 2009).

[552] Ohio Rev. Code § 4731.22(B)(3).

herein without first resolving red flags identified in Finding of Fact Nine (above), in a manner that was not in the ordinary course of professional medical practice and not for legitimate therapeutic purposes. A preponderance of the evidence further establishes that Respondent issued controlled substance prescriptions based on diagnoses of radiculitis (with respect to Agent Parkison and Detective Leonard) and limb pain (with respect to Agent Moses) where the objective findings taken together with the examinations and histories obtained by Respondent do not support such diagnoses. Upon such evidence, the Government has met its burden of establishing these prescriptions were not for a legitimate medical or therapeutic purpose and were not written in the ordinary course of Respondent's professional practice, and has established Respondent's noncompliance with applicable federal and state law relating to controlled substances. Accordingly, the Government has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

9. Ohio law includes the requirement that when prescribing controlled substances for pain, the prescribing source ''shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients.'' [553] A preponderance of the evidence establishes that when Respondent issued controlled substance prescriptions for the three undercover agents described herein, he did so based on records that falsely reported the extent and nature of his examination of the patients and falsely reported the patients' reports of pain, as enumerated in Finding of Fact Seven (above). Upon such evidence, the Government has met its burden of establishing Respondent's noncompliance with applicable state law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

10. Ohio law defines ''chronic pain'' as pain that ''has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months.'' [554] A preponderance of the evidence establishes that each of the three undercover officers presented before Respondent with symptoms of chronic pain. In these cases, Ohio law requires the physician to include in the patient's medical charts a written diagnosis of chronic pain; a plan of treatment that includes documentation that other medically reasonable treatments for relief of the pain have been offered or attempted without adequate or reasonable success; periodic assessments and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities and the patient's physical activities; and periodic documentation of progress towards treatment objectives.[555] Where a preponderance of the evidence establishes that Respondent failed to comply with the requirements of Ohio law applicable to the treatment of chronic pain, on the facts set forth in Finding of Fact Eight (above), the Government has met its burden of establishing Respondent's noncompliance with applicable state law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

11. Ohio law provides that ''intractable pain'' is ''pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.'' [556] It further provides that specific practice standards apply when utilizing any prescription drug for the treatment of intractable pain on a protracted basis, defining ''protracted basis'' as a period in excess of twelve continuous weeks.[557] Where, as here, the evidence establishes by at least a preponderance that Respondent treated each of the three undercover agents as though there were no cure possible for periods exceeding twelve weeks, Ohio law required that he conform to those practice standards applicable in the treatment of intractable pain. Those standards applicable at the initial evaluation include reporting the patient's complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases, or conditions; and an appropriate physical examination.[558] Those standards also more generally require a medical diagnosis documented in the patient's medical record that indicates not only the presence of intractable pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism; and an individualized treatment plan formulated and documented in the patient's medical record specifying the medical justification of the treatment of intractable pain by utilizing prescription drugs, the intended role of prescription drug therapy within the overall plan, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without adequate or reasonable success.[559] Where a preponderance of the evidence establishes that Respondent failed to comply with the requirements of Ohio law for the treatment of intractable pain, as set forth in Finding of Fact Eight (above), the Government has met its burden of establishing Respondent's noncompliance with applicable state law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

12. Ohio law permits a physician to utilize controlled substances when treating a family member only in an emergency situation, and requires the emergency situation to be documented in the patient's medical record.[560] While there is some evidence in our record indicating Respondent prescribed a controlled substance for his daughter, the record does not include the patient's medical record, the prescription, nor sufficient circumstantial facts that would warrant concluding that Respondent violated Ohio law regarding prescribing controlled substances to family members.

13. Under 21 U.S.C. 823(f)(5) (Factor Five), the Administrator is to consider, ''Such other conduct which may threaten the public health and safety.'' Respondent's actions or omissions that threaten the public interest may constitute a basis for revoking a DEA registration under Factor Five, where

[553] Ohio Admin. Code 4731–11–02(D).

[554] Ohio Rev. Code § 4731.052(A)(1).

[555] Ohio Rev. Code § 4731.052(D).

[556] Ohio Admin. Code 4731–21–01(G).

[557] Ohio Admin. Code 4731–21–01(L); Ohio Admin. Code 4731–21–02.

[558] Ohio Admin. Code 4731–21–01(A)(1).

[559] Ohio Admin. Code 4731–21–02(A)(2)–(3).

[560] Ohio Admin. Code 4731–11–08(B).

the conduct is not within the scope of Factors One through Four.[561] Where by at least a preponderance of the evidence the Government establishes, as is the case here, that Respondent failed to provide training to his staff regarding exceptions to patient privacy laws that apply when staff members observe behavior relating to controlled substance abuse, misuse, or diversion, the Government has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Five.

14. Federal law requires prescriptions for controlled substances be signed on the date the prescription is issued.[562] Under this law, an office practice in which Respondent signed but otherwise left incomplete scripts in such quantity as to make it possible for incomplete signed scripts to be used on a later day creates the potential for violating federal law. Without more, however, particularly without evidence corroborating Ms. Maniglia's testimony that left-over scripts may have been used for controlled substance prescriptions on days other than the date signed, there is insufficient evidence to establish a violation of this law. While such evidence does not establish a violation of law so as to fall within the scope of Factor Four, it does demonstrate an office practice that constitutes a threat to the public interest. Accordingly, by this evidence the Government has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Five.

15. When responding to the Government's *prima facie* case establishing cause to find Respondent's continued DEA registration inconsistent with the public interest, Respondent has the opportunity to demonstrate that he recognizes any noncompliance with controlled substance laws and has taken steps to ensure against future noncompliance.[563] Where Respondent has not provided substantial evidence that he has acknowledged any noncompliance with controlled substance laws, nor that he has undertaken efforts to avoid such noncompliance in the future, Respondent has failed to rebut the Government's *prima facie* case.

Recommendation

As the Government has established its *prima facie* case by at least a preponderance of the evidence that Respondent's continued DEA registration would be inconsistent with the public interest, and as Respondent has failed to rebut that case through a demonstration of sufficient remediation, Respondent's DEA Certificate of Registration should be **REVOKED** and any pending application for the renewal or modification of the same should be **DENIED.**

Dated: February 10, 2014.

Christopher B. Mcneil

Administrative Law Judge

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[561] 21 U.S.C. 823(f)(5).

[562] 21 CFR 1306.05(a).

[563] *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *MacKay* v. *DEA,* 664 F.3d 808, 817 (10th Cir. 2010) (citing *Medicine Shoppe—Jonesborough,* 73 FRFR 364–01, 387 (DEA January 2, 2008)).