

Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Immersion Corporation on February 11, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain mobile electronic devices incorporating haptics (including smartphones and smartwatches) and components thereof. The complaint names as respondents Apple Inc. of Cupertino, CA; AT&T Inc. of Dallas, TX; and AT&T Mobility LLC of Atlanta, GA. The complainant requests that the Commission issue a limited exclusion order and cease and desist orders.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3120") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures).⁴ Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.⁵

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: February 12, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016-03344 Filed 2-17-16; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14-20]

Hatem M. Ataya, M.D.; Decision and Order; Introduction and Procedural History

On July 23, 2014, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Hatem M. Ataya (Respondent), of Lapeer, Michigan. ALJ Ex. 1, at 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificates of Registration, pursuant to which he is authorized to dispense controlled substances in schedules II through V, as a practitioner, at the registered address of 971 Baldwin Road, Lapeer, Michigan (FA2278201), and at the registered address of 3217 W. M-55 Suite B, West Branch, Michigan (BA7776353), on the ground that he has committed acts which render his registration inconsistent with the public interest.¹ *Id.* (citing 21 U.S.C. 824(a)(4)). The Order also proposed the denial of Respondent's applications for two additional registrations,² on the ground that "it is not consistent with the public interest . . . for [him] to be registered with the [Agency] to handle controlled substances." *Id.* (citing 21 U.S.C. 823(f)).

The Show Cause Order alleged that from 2010 through 2013, Respondent "repeatedly violated [his] obligation under federal law by prescribing controlled substances to [his] patients outside of the normal course of professional medical practice." *Id.* at 2 (citing 21 CFR 1306.04(a)). Continuing, the Order specifically alleged that Respondent's "practice of regularly prescribing controlled substances to five patients [who were identified by the initials R.E.H., J.W., R.K., R.J.H., and J.H.] despite numerous and repeated red flags of drug abuse and diversion, [his] repeated failures to take appropriate steps to monitor [his] patients' use of controlled substances, and numerous other actions [he] took in the course of treating these patients all indicate that [he] violated [his] obligations under federal law by 'prescribing [controlled substances] as much and as frequently as the patient demanded' so that '[in] practical effect, [he] acted as a large-scale "pusher" not as a physician.'" *Id.*

¹ The Order alleged that Respondent's registration number FA2278201 expires on June 30, 2016, and that his registration number BA7776353 expires on June 30, 2017. ALJ Ex. 1, at 1.

² The applications are for proposed registered locations in Davidson and Flint, Michigan. ALJ Ex. 1, at 1.

⁴ Handbook for Electronic Filing Procedures: http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.

⁵ Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

(quoting *U.S. v. Moore*, 423 U.S. 122, 143 (1975)). The Show Cause Order then set forth detailed allegations regarding Respondent's prescribing to each of these patients.³ See *id.* at 2–6.

In addition, the Show Cause Order alleged that on March 26, 2013, Respondent was interviewed by a DEA Diversion Investigator and a local Detective. *Id.* at 6. The Show Cause Order further alleged that during the interview, Respondent made multiple false statements regarding his controlled substance prescribing practices.⁴ *Id.* at 6–7.

Following service of the Show Cause Order, Respondent timely requested a hearing on the allegations. ALJ Ex. 2. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to Administrative Law Judge (ALJ) Christopher B. McNeil, who commenced to conduct pre-hearing procedures and ordered the parties to submit their respective pre-hearing statements. GX 3. Thereafter, the parties submitted their pre-hearing and supplemental pre-hearing statements. The parties also filed various motions, the most significant of these being (given the issues raised by the Parties in their Exceptions), the Government's Motion to Exclude Respondent's Witnesses (ALJ Ex. 41).

Also, on September 29, 2014, the ALJ conducted an on-the-record conference with the Parties at which he set the initial date for the evidentiary phase of the proceeding. Tr. 1, 16–17 (Sept. 29, 2014). During the conference, the ALJ authorized the taking of testimony at either the Agency's Arlington, Virginia hearing facility or "by video-teleconferencing in the Detroit DEA Office." *Id.* at 19. The ALJ also authorized Respondent and his counsel to appear at either the Arlington hearing facility or the "video-teleconferencing site" and "direct[ed] the Government to

make available its DEA District or Field Office for this purpose." *Id.* at 19–20.

On November 3, 2014, the ALJ conducted a further on-the-record conference during which he reviewed the parties' proposed stipulations and ruled on the Government's Motion to Exclude Respondent's Witnesses. See *generally* Tr. (Nov. 3, 2014). The ALJ granted the Government's motion with respect to twelve of Respondent's proposed fact witnesses on the ground that Respondent had not identified with sufficient particularity their proposed testimony because his pre-hearing statements did "not clearly indicate each and every matter Respondent intend[ed] to introduce in opposition to the allegations." *Id.* at 35–36; see also *id.* at 37–38. The ALJ also granted the Government's motion to exclude the testimony of Respondent's six witnesses who were to "either testify or provide testimonials . . . as to [his] character, reputation, and qualifications as a physician," ALJ Ex. 39, at 3; stating his agreement with the Government's contention that their testimony was irrelevant and that Respondent did not proffer that "any of these witnesses plan to testify about his treatment of" the five patients. *Id.*; see also Tr. 38 (Nov. 3, 2014).

The Government also sought to exclude the testimony of Ms. Michelle Ann Richards, who, according to Respondent, would "testify that she is certified in healthcare compliance consulting, coding, and office management," and "that she was retained by Respondent to do risk assessment audit and risk mitigation for his practice." ALJ Ex. 39, at 3. Respondent also stated that Ms. Richards would testify that she had "provided compliance training to Respondent's staff [and] that she is continuing to monitor and implement changes to ensure [his] medical practice with all State and Federal laws." Tr. 39. In addition to the ground that Respondent had not adequately summarized Ms. Richards' testimony, the Government also argued that the testimony should be barred because Respondent had represented that he "intend[ed] to testify that he has never been out of compliance with such laws," and that his "care and treatment [of the five patients] at all times comported with reasonable and minimally accepted standards and that all prescriptions were issued for a legitimate medical purpose by a registered physician within the course of professional practice." ALJ Ex. 42, at 4–5 (Gov. Mot.) (quoting Resp. Pre-Hearing Statement, at 3–4 (Sept. 15, 2014)). Continuing, the Government

reasoned that under agency precedent, "mitigation' evidence is not admissible unless and until the registrant fully and unequivocally accepts responsibility for the wrongful or unlawful conduct on which registration consequences are sought." *Id.* at 5.

The ALJ granted the Government's motion, agreeing with both of the Government's arguments. Specifically, the ALJ agreed that Respondent had failed to describe Ms. Richards' testimony "with sufficient particularity" and thus had not complied with his prehearing order. Tr. 39 (Nov. 3, 2014). Also, the ALJ explained that because Respondent intended to testify that in prescribing to the five patients he had "at all times comported with reasonable and minimally accepted standards" and that all of the prescriptions were issued within the usual course of professional practice and for a legitimate medical purpose, this "compels the conclusion that Respondent does not accept responsibility for any failure to conform to the requirements of the" CSA. *Id.* at 40–41. The ALJ thus concluded that there was "no need to address whether the remedial measures that [Respondent] claims to have instituted are adequate to protect the public interest." *Id.* at 41.

Notably, during the conference, the ALJ did not address Respondent's contention that the ALJ had misinterpreted the Agency's precedents, and that if the case law actually required him to admit to misconduct which he did not engage in, "then that precedent is inconsistent with procedural due process." ALJ Ex. 45, at 1 (Resp.'s Response in Opposition to Govt's Mot. to Exclude Resp.'s Witnesses). Nor did the ALJ address Respondent's suggestion that he "defer" his ruling "until the hearing itself," at which time the ALJ and the parties would be in "a better position to determine whether" he "ha[d] sufficiently titrated his contrition to permit the introduction of such testimony." *Id.*

Finally, the Government moved to exclude the testimony of two physicians who Respondent proposed would testify on his behalf as experts. While Respondent identified some eight areas on which he "anticipated" that the experts would testify, ALJ Ex. 39, at 3–5; the Government argued that the disclosure was inadequate because "Respondent has not disclosed any conclusions that the witnesses have actually reached regarding the prescribing conduct at issue." ALJ Ex. 42, at 6. The Government further argued that "[i]t remains a mystery if these doctors have actually reached any

³ The patient-specific allegations will be set forth in discussing the evidence pertinent to each patient.

⁴ The Show Cause Order specifically alleged that Respondent attempted to mislead investigators in an interview on March 26, 2013, when he told a DEA Diversion Investigator and a Lapeer City Detective that he was not aware of any prescription pads being stolen, that patient R.E.H.'s fraudulent practices were in the past and he was no longer a patient, that no controlled substance prescriptions are phoned in, that he attempted to taper patients off of methadone over time, that chronic pain patients must have some diagnostic finding to support their pain and are required to see a specific psychiatrist and attend physical therapy, that each chronic pain patient must sign and annually renew a pain management contract, that MAPS searches are usually run for chronic pain patients on every visit, and that he was unaware of any of his patients dying. *Id.* at 6–7. The Government alleged that Respondent's patient files and its investigation indicated that these statements and others were false. *Id.* at 7.

opinions, to which they will subscribe under oath, to support Respondent's view that his prescribing was entirely legitimate." *Id.*

The ALJ granted the Government's motion, reasoning that he could not "tell from the supplemental prehearing statement which witness will espouse each of the opinions presented in the supplemental prehearing statement" and "whether either of the witnesses has a sufficient foundation, obtained through the review of patient records, or otherwise, to express the opinions presented in the supplemental prehearing statement." Tr. 42. The ALJ also explained that he could not tell which professional standards the witnesses were relying on to reach their opinions. *Id.* at 42–43. Finally, while the ALJ noted that Respondent proposed that one of the doctors (who was also from Flint, Michigan) would testify that this area "is infested with drug-seeking addicts, who employ sophisticated tricks to deceive and frustrate the most vigilant anti-diversion efforts of healthcare providers," the ALJ reasoned that this evidence was irrelevant because Respondent "intends to establish that his prescription practice complied fully with the requirements of the" CSA. *Id.* at 43. Subsequently, the ALJ issued a Journal Entry and Order memorializing his various rulings as well as the various stipulations agreed to by the parties.

On November 17–18, 2015, the ALJ presided over the evidentiary phase of the proceeding, conducting a video-teleconference with he and the reporter being present in Arlington, Virginia, and the witnesses (including Respondent) and the parties' counsels present at the DEA Detroit, Michigan Field Division Office. *Id.* at 73–74; *id.* at 423. Notably, from the outset, the proceeding was marked by telephonic interference and interruptions of the transmission, with interruptions occurring nearly 60 times over the course of a day and half of testimony. *See id.* at 72 *et seq.*

At the hearing, the Government called four witnesses to testify, including Dr. Eugene O. Mitchell, who was accepted as an expert in pain medicine. The Government also submitted for the record an extensive amount of documentary evidence including, *inter alia*, the medical records of the five patients identified in the Show Cause Order, copies of various prescriptions issued to the patients, and copies of reports obtained from the Michigan Automated Prescription System (MAPS) showing the controlled substance prescriptions obtained and filled by each of the five patients.

Respondent testified on his own behalf. He also submitted several exhibits for the record. After the hearing, both parties submitted briefs containing their proposed findings of fact and conclusions of law.⁵

Thereafter, the ALJ issued his Recommended Decision (hereinafter cited as R.D.). Therein, the ALJ found that the Government's evidence with respect to Factors Two (Respondent's experience in dispensing controlled substances) and Four (compliance with applicable laws related to controlled substances) supported the conclusion that "Respondent's continued registration would be inconsistent with the public interest." R.D. 66–68.

More specifically, with respect to Factor Two, the ALJ found that "Respondent demonstrated a material lack of . . . experience regarding a prescribing source's responsibilities to resolve red flags when prescribing controlled substances for persons presenting with symptoms of chronic pain and terminate from his practice patients whose drug-seeking behavior indicates the potential for abuse or diversion (or both) of controlled substances." *Id.* at 67. And with respect to Factor Four, the ALJ found that "[a] preponderance of the evidence establishes that Respondent issued controlled substance prescriptions for the five patients identified [in the Show Cause Order], in a manner that was not in the ordinary course of professional medical practice and was not based upon legitimate medical justification." *Id.* (citing 21 CFR 1306.04(a)). The ALJ also found that Respondent violated Michigan law by post-dating controlled substance prescriptions and failing to include "the patient's full name and address" on the prescription. *Id.* at 67–68 (citing Mich. Comp. Laws §§ 333.7333(7), 338.3161(1)(a)); *see also id.* at 64 (Finding of Fact (FoF) # 3). Finally, the ALJ found that Respondent violated state and federal law by issuing prescriptions for schedule IV controlled substances which authorized more than five refills. *Id.* at 68 (citing 21 U.S.C. § 829(b); Mich. Comp. Laws § 333.7333(4)); *see also id.* at 64–65 (FoF#s 3, 5).⁶

⁵ These briefs will be referred to as Post-hearing Briefs.

⁶ Noting that "the record is silent with respect to the recommendation of the . . . state licensing board," the ALJ found that this factor "neither supports nor contradicts a finding that Respondent's continued . . . registration is inconsistent with the public interest." R.D. 66. The ALJ also found that the Government had neither alleged nor provided evidence that Respondent was convicted of a federal or state offense related to the manufacture, distribution, or dispensing of controlled substances, and thus, Factor Three does

The ALJ thus concluded that "the Government has established its *prima facie* case by at least a preponderance of the evidence." *Id.* at 69. The ALJ explained that "[w]hen responding to the Government's *prima facie* case . . . Respondent has the opportunity to demonstrate that he recognizes any noncompliance with controlled substance laws and has taken steps to ensure against future noncompliance." *Id.* at 68–69. The ALJ then reasoned that under the Agency's case law, "in the absence of evidence of 'sincere[] remorse[],' a 'generalized acceptance of responsibility to the allegations' is not enough to open the hearing so as to permit evidence of remediation." *Id.* (citing Govt's Post-Hrng. Br. 48). Finding that "Respondent has not provided substantial evidence meeting this standard," the ALJ concluded that he "failed to establish a basis that would permit him to rebut the Government's *prima facie* case." *Id.* The ALJ thus recommended that I revoke Respondent registrations and deny his pending applications. *Id.*

Both parties filed Exceptions to the ALJ's Recommended Decision. Thereafter, the record was forwarded to my Office for Final Agency Action.

On review of the record, I noted that it contained no evidence as to whether Respondent is currently authorized under Michigan law to dispense controlled substances. Order at 1 (Nov. 10, 2015). Accordingly, I directed the parties to address whether Respondent currently possesses authority under Michigan law to dispense controlled substances and if Respondent does not possess such authority, to address what consequence attaches for this proceeding. *Id.*

On November 17, 2015, the Government submitted its Response. Therein, the Government noted that on July 6, 2015, the Michigan Department of Licensing and Regulatory Affairs had filed an Administrative Complaint with the Board of Medicine Disciplinary Subcommittee. Govt's Resp., at 7–8; Govt's Resp. Ex. 3, at 8–14

not support the revocation of his registrations and denial of his pending applications. *Id.* at 67.

As for Factor Five—such other conduct which may threaten public health or safety—the ALJ found that the Government had not proved the allegation that Respondent made various false statements to the Diversion Investigator and Detective. *Id.* at 68. The ALJ based his conclusion on the fact that "the written record of that interview was not present" and "the questions presented and answers given were not sufficiently established in the record so as to permit a determination of Respondent's candor during [the] interview." *Id.* Because the Government did not take exception to the ALJ's findings on the issue of Respondent's candor during the interview, I deem it unnecessary to make any findings related to the allegation.

(Administrative Complaint, *In re Ataya*, No. 43–15–137995 (Mich. Bd. of Med. July 6, 2015)). When Respondent failed to respond to the allegations of the complaint, the allegations were deemed admitted, and on October 30, 2015, the Board revoked his medical license. Gov. Resp. Ex. 3, at 2–3, 5. In his Response to my Order, Respondent states that he does not dispute that the Board has revoked his medical license and that he “no longer has any legal authority to dispense controlled substances, which, as a practical matter, he could not accomplish for the jail cell he has occupied for the past several months anyway.” Respondent’s Resp., at 1.

Having considered the record in its entirety, including the parties’ Exceptions, as well as the recent action taken by the Michigan Board of Medicine, I issue this Decision and Final Order. I agree with the ALJ that the record supports findings that Respondent ignored multiple red flags of abuse and/or diversion with respect to each of the five patients (FoF #2). I also agree that the record supports the ALJ’s factual findings specific to Respondent’s prescribing of controlled substances to each of the five patients (FOF#s 3, 4, 5, 6, and 7), as well as his legal conclusions that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to each of the five patients in violation of 21 CFR 1306.04(a). See R.D. at 66–67. I further agree with the ALJ that Respondent violated federal and state law when he issued prescriptions authorizing more than five refills of schedule IV controlled substances, as well as when he post-dated a prescription and failed to include the patients’ names and addresses on numerous prescriptions. Finally, I agree with the ALJ’s conclusion that the Government made out a *prima facie* case that Respondent’s registration is inconsistent with the public interest.

With respect to Respondent’s rebuttal case, for reasons explained below, I find troubling the ALJ’s handling of the issue of whether Respondent has adequately accepted responsibility for his misconduct. And as for the ALJ’s ruling barring Respondent from presenting evidence of his remedial measures, I agree with the ALJ that Respondent did not sufficiently disclose the scope of the proposed testimony. While this alone is sufficient reason to reject Respondent’s exception, the ALJ further reasoned that under the Agency’s precedent, Respondent is barred from introducing evidence of his remedial measures absent his admission to the allegations

before the Government was even required to put on its evidence. Contrary to the ALJ’s understanding, while a respondent’s failure to acknowledge his misconduct renders evidence of his remedial measures irrelevant, the Agency has never held that a respondent must admit to his misconduct prior to even being able to test the Government’s evidence at the hearing.

I reject, however, Respondent’s contention that a remand is warranted for multiple reasons. First, as explained above, I agree with the ALJ’s conclusion that Respondent did not adequately disclose the scope of the proposed testimony on the adequacy of his remedial measures. Second, even were I to credit Respondent’s admissions at the hearing and give weight to his testimony regarding the remedial measures he has undertaken, I would nonetheless find that his conduct was so egregious that the protection of the public interest warrants the revocation of his registrations and the denial of his pending applications. Finally, because of the recent action of the Michigan Board of Medicine, Respondent is precluded from being registered because he no longer holds authority under state law to dispense controlled substances, and thus evidence of his acceptance of responsibility and remedial measures is irrelevant. See 21 U.S.C. 802(21), 823(f).

Findings of Fact

Respondent’s Licensure and Registration Status

Respondent was formerly licensed as a physician by the Michigan Board of Medicine. However, on July 6, 2015, the Bureau of Professional Licensing, acting on behalf of the Michigan Department of Professional Licensing and Regulatory Affairs, filed a complaint against Respondent. Administrative Complaint, *In re Ataya*, No. 43–15–137995 (Mich. Bd. of Med. July 6, 2015). The Department also ordered that Respondent’s medical license be summarily suspended. Order of Summary Suspension, *In re Ataya*. Thereafter, on October 30, 2015, the Board of Medicine revoked Respondent’s medical license. Final Order, *In re Ataya*.

Respondent currently holds two DEA practitioner’s registrations, pursuant to which he is authorized to dispense controlled substances in schedules II through V. GX 4, at 1–2. The first of these (BA7776353) is for the registered location of 5097 Miller Road, Flint, Michigan and does not expire until June 30, 2017. *Id.* at 1. The second (FA2278201) is for the registered

location of 971 Baldwin Road, Lapeer, Michigan and does not expire until June 30, 2016. GX 3, at 1. Respondent has also applied for two additional registrations: One at the address of 3390 N. State Road, Davison, Michigan; the other at the address of 3400 Fleckenstein, Flint, Michigan.

The Investigation of Respondent

Respondent first came to the attention of law enforcement on January 5, 2012, when a Detective with the City of Lapeer Police Department responded to the death of R.J.H., one of the patients identified in the Show Cause Order. Tr. 90; ALJ Ex. 1, at 1–2. According to the Detective, he knew R.J.H. from his experience in law enforcement and knew him to be an abuser of both “prescription drugs [and] illegal drugs.” Tr. 93. The Detective testified that R.J.H. bore no signs of external injuries and there was no evidence that injuries had led to his death. *Id.* The police did, however, find three empty prescription vials, including a vial bearing a label for 120 methadone 10⁷ and clonazepam (Klonopin), as well as a syringe, on a nightstand in R.J.H.’s bedroom. *Id.* The Detective subsequently obtained a report from the Michigan Automated Prescription System (MAPS) and found that both the methadone and Klonopin had been prescribed to R.J.H. by Respondent on January 3, 2012. *Id.* According to the detective, toxicology testing led to the conclusion that R.J.H. had died of an overdose. *Id.* at 95. The Detective also learned that R.J.H. had overdosed on heroin two days before and was taken to the hospital. *Id.* at 107; GX 5, at 1.

On January 22, 2012, the Detective responded to the death of J.W. Tr. 95. The authorities found two pill bottles in J.W.’s coat, as well as marijuana. *Id.* at 96, 108. One vial, which bore a label for 120 methadone, contained only nine methadone pills; however, the vial also included four Klonopin pills and two diazepam. *Id.* The second vial, which bore a label for 120 Klonopin, contained only 91 pills. *Id.* According to the Detective, J.W.’s body bore possible needle marks. *Id.* at 112.

During his investigation, the Detective determined that on January 19 (three days earlier), J.W. had obtained prescriptions from Respondent for 120 methadone 10 and 120 clonazepam 1. *Id.* at 96. According to the Detective, the investigation and toxicology test results led to the conclusion that J.W. had died of an overdose. *Id.* at 96–97.

⁷ All numbers which follow the name of a drug refer to the dose per pill in milligrams.

During the course of his investigation, the Detective spoke with both J.W.'s mother and niece. The Detective testified that J.W.'s mother said that J.W. did not like methadone and usually sold it to buy other drugs. *Id.* at 112. According to the Detective, J.S. (J.W.'s niece) told him that J.W. had been released from jail only "a week or two prior to his death." *Id.* at 98. J.S.'s niece also told the Detective that she had contacted Respondent's office and told him that her uncle "had a problem" with controlled substances "and asked him not to prescribe any controlled substances" to her uncle. *Id.*

J.S. subsequently testified that her uncle's drug problem "was obvious" and that "[e]verybody knew." *Id.* at 125. She testified that she spoke with Respondent on the phone a couple of weeks before her uncle was released and told Respondent that her uncle "was sick and he didn't need the medications because he wasn't taking them" and "was selling them." *Id.* at 128–29. According to J.S., Respondent initially "blew [her] off." *Id.* at 129. However, when J.S. told Respondent that the police "wanted to know why [J.W.] had two prescriptions for Methadone" which he had not filled, Respondent asked for J.W.'s name, address and date of birth. *Id.* J.S. also told Respondent that J.W. had "nearly died from withdrawal" and asked Respondent not to "give him these strong medications." *Id.* While Respondent said that "he wouldn't do it anymore," *id.* at 130, as found above, Respondent subsequently issued the methadone and clonazepam prescriptions to J.W.⁸ *Id.* at 96.

The Detective also testified regarding an investigation conducted by a subordinate into the death of R.K. on or about July 21, 2012. *Id.* at 98–100. According to the Detective, there was no evidence that R.K. had died of injuries and upon arriving at the scene, the police found a prescription vial which, according to the label, had been issued by Respondent four days earlier for 90 Xanax. *Id.* at 100. However, the vial was empty. *Id.*

The Detective also obtained a MAPS report for R.K. *Id.* The MAPS report

⁸ Respondent testified that he does not recall the phone conversation about which J.S. testified, explaining that he would not remember what patient the conversation involved because he has 7,500 patients. Tr. 485. He also testified that if someone calls and wants to speak to him about a patient, his assistants ask the person "to come with the patient and discuss the matter." *Id.* The ALJ did not make a finding as to whether J.S.'s testimony was credible. R.D. at 9–10. I find her testimony credible, noting that while it may be that Respondent would not recall the conversation given the large number of patients he treated, one would recall a conversation she had with a doctor about a family member.

shows that on July 17, Respondent issued to R.K. a prescription for 90 tablets of methadone 10, which R.K. filled the next day. GX 22, at 16. The cause of R.K.'s death was a drug overdose. *Id.* at 101. According to a police report, a person with Community Mental Health stated that R.K. was known to abuse heroin, Tramadol, and other prescription medications. GX 5, at 17.

The Detective testified that because his agency did not have a lot of experience in prescription drug investigations, after R.K.'s death, he sought the assistance of DEA, and on August 13, 2012, met with a DEA Diversion Investigator (DI). Tr. 102. Two days after the meeting, the mother of another of Respondent's patients (J.L.H.) contacted the Lapeer Police and reported that she had taken her daughter to see Respondent the day before and that he had issued her prescriptions for methadone, tramadol and clonazepam. *Id.* at 102–03. However, the day after J.L.H. saw Respondent, her mother reported that she was unable to contact J.L.H. at her residence and could not get her to answer the door; she thus requested the assistance of the police. *Id.* at 103. The Detective testified that "[a] neighbor had climbed up on the roof and looked through a second story window and observed [J.L.H.] on the couch unresponsive." *Id.* A police officer entered J.L.H.'s home and found her "blue in color and unresponsive." *Id.* J.L.H. was taken to the hospital. *Id.*

Several months later, the Detective obtained a warrant to search Respondent's Lapeer office for several patient charts, and on March 26, 2013, the Lapeer Police Department, DEA, and members of the Thumb Narcotics Unit (a local multijurisdictional task force) executed the warrant. *Id.* at 104. However, the Detective and the DI decided to interview Respondent, who was at his Davidson office, prior to searching his Lapeer office. *Id.*

During the search of the Lapeer office, the Detective determined that several of the patient files that were being sought under the warrant were not at that office. *Id.* at 105. Accordingly, the Detective obtained an amended warrant, which authorized searches of Respondent's Flint and Davidson offices. *Id.* The records were subsequently seized and provided to the DI, who had them scanned. *Id.*

The Government also called the DI who worked with the Detective on the investigation. The DI testified that she obtained MAPS reports for Respondent and found that they showed that he prescribed "a lot of combinations of prescriptions for [m]ethadone,

[h]ydrocodone, and . . . [a]lprazolam" and that the patients were "getting them on a regular basis." *Id.* at 146. The DI also testified that when alprazolam is taken with methadone or hydrocodone, "it enhances the effect of the narcotic causing somewhat of a heroin-type high." *Id.* at 147. The DI further testified that she participated in the execution of the search warrant and that she assisted in the seizure of patient charts and conducted employee interviews. *Id.* at 149. According to the DI, she determined what charts to seize by reviewing MAPS data and conducting "criminal history searches to determine what patients were known to be drug seekers or had a positive criminal history." *Id.*

The DI testified that "many of the charts contained information that [showed] that the patients were not taking the controlled substances as they had been prescribed, or that they had drug addiction issues, or they were narcotic dependent, or any of a number of red flags that were indicated in the charts, and then we sent the patient charts out for expert review." *Id.* at 156–57. The DI explained that there were "instances where the patient was coming [back] before the 30-day[s] had expired, and were [sic] obtaining additional prescriptions for the same medication or," the patients were "obtaining refills of a prescription that had refills written on [it] prior to the time [that] they should have used [] the medication up if they were taking it as directed." *Id.* at 157.

The DI testified that the patient records included evidence that pharmacies had called Respondent raising issues of whether the patients "were doctor shopping or obtaining refills early." *Id.* at 158. The DI also testified that the files contained "reports from the State alerting [Respondent] about medication issues that they wanted him to be aware of" regarding "his prescribing of certain drugs," as well as "police reports" and "hospital reports on several patients indicating that they had a history of drug abuse or they had been admitted for a drug-related issue." *Id.* The DI testified that she provided Dr. Eugene Mitchell, Jr., with the files of the five patients at issue in this proceeding and asked him to review the files and identify examples of Respondent's issuance of controlled substance prescriptions outside of "the usual course of medical practice" and which lacked a legitimate medical purpose. *Id.* at 160. According to the DI, these specific charts were selected for review by Dr. Mitchell because "the findings in these files . . . were

egregious” and four of the five patients were deceased. *Id.* at 160–61.⁹

The DI further testified that in reviewing the patient files she found evidence of other violations of the Controlled Substance Act and DEA regulations. Tr. 172–73. These included instances in which Respondent authorized more than five refills on a prescription; instances in which he issued early refills; instances in which he failed to include a patient’s address, which is required information on a prescription; and instances in which Respondent post-dated prescriptions. *Id.* at 173–74. The DI then testified as to the following examples: (1) A Xanax prescription dated Feb. 9, 2013 issued to R.E.H. authorizing six refills (GX 8, at 23); (2) a Klonopin prescription dated August 14, 2012 issued to J.H. authorizing six refills (GX 19, at 117); and (3) a Xanax prescription dated April 10, 2012 issued to R.K. authorizing six refills (GX 17, at 49). Tr. 184–86.¹⁰ The DI also discussed two examples of prescriptions which Respondent issued to Patient R.E.H. without including his address, and did so even after Respondent had received information that R.E.H., who shared the same first name as his father, had attempted to fill a methadone prescription using his father’s name and date of birth. Tr. 182–84; *see also* GX 8, at 42 (methadone and Xanax prescriptions dated April 19, 2012 with patient’s address left blank).

The Government Expert’s Testimony

The Government called Dr. Eugene O. Mitchell, Jr., who testified as an expert on pain management. Dr. Mitchell received a Bachelor of Science in Biochemistry in 1975 from the University of Florida and a Bachelor of Science in Medicine in 1979 from the University of Florida’s Physician’s Assistant Program. GX 25, at 1. Dr. Mitchell subsequently obtained a Doctor of Medicine in 1985 from the Wayne State University School of Medicine. *Id.* His post-doctoral training includes an internship in internal medicine and a residency in anesthesiology (both at the University of Illinois), and a fellowship in pain medicine at the University of Michigan. *Id.*

⁹In addition to obtaining each patient’s medical file, the DI used the MAPS data to obtain copies of the original prescriptions from the various pharmacies.

¹⁰The DI also testified regarding two methadone prescriptions Respondent issued to R.E.H. in October 2012, including one which was issued notwithstanding that R.E.H. was a week early, and on which the date of the copy in R.E.H.’s file appears to have been altered. Tr. 175–80. These prescriptions are discussed more fully in the findings regarding Respondent’s prescribing to R.E.H.

Dr. Mitchell holds a medical license issued by the State of Michigan and is board certified in both anesthesiology and pain medicine. *Id.* at 2. He is also a member of numerous professional societies including the American Academy of Pain Medicine and the American Society of Regional Anesthesia and Pain Medicine. *Id.*

Since February 2001, Dr. Mitchell has held the position of Clinical Assistant Professor in the Department of Anesthesiology, Division of Interventional Pain Medicine, at the University of Michigan Medical Center. *Id.* In this position, he lectures medical students on pain medicine and trains fellows in pain medicine as well as residents, interns, and nursing staff. *Id.* at 3, Tr. 234. He also is active in practice. *Id.* Dr. Mitchell was qualified as an expert. *Id.* at 239.

Dr. Mitchell testified “all controlled substances have the risk of significant morbidities including death from overdose,” “withdrawal from their use,” and “addiction.”¹¹ *Id.* He testified that to reduce the risks associated with the abuse and diversion of controlled substances, a physician must “be familiar with the patient’s medical history” and review the patient’s records so that the physician has “a clear understanding” of the patient’s diagnosis. *Id.* at 240. Also, the physician must review the patient’s “history of abuse” and “[a]ny issue of addictive illness,” whether it involves tobacco, alcohol, and both “licit” and “illicit” drugs. *Id.*

Dr. Mitchell further testified that there are various compliance tools that he uses to determine whether patients are abusing or diverting controlled substances. The first of these is a “medication agreement” between the physician and the patient which sets forth the “criteria that [the patient] will adhere to” while “being prescribed controlled substances.” *Id.* Dr. Mitchell testified that an essential part of the agreement is “a clause that allows the physician to ask the patient” to provide “a random body fluid sample,” whether of blood or urine, “on demand to verify what is or isn’t present in” the patient’s body. *Id.* at 241. Dr. Mitchell explained that a further compliance tool is to use the MAPS, Michigan’s controlled substance prescription monitoring program, which allows a physician to obtain a list of the controlled substance prescriptions filled by a patient in the State. *Id.*

¹¹He also testified that the use of controlled substances presents a risk of developing both renal and hepatic disease. Tr. 239.

Dr. Mitchell also testified that in Michigan, a task force of physicians developed Guidelines for the “appropriate prescribing” of controlled substances for the treatment of pain. *Id.* at 243; GX 26. These Guidelines have been issued by both the Board of Medicine and the Board of Osteopathic Medicine & Surgery. GX 26, at 1. The Guidelines “recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins.” *Id.* However, the Guidelines caution “that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use” and that “[p]hysicians should be diligent in preventing the diversion of drugs for illegitimate purposes.” *Id.* According to the Guidelines, they “are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.” *Id.* at 2.

Dr. Mitchell then testified regarding the “typical steps taken by doctors in treating patients who suffer from chronic pain.” Tr. 247. Dr. Mitchell testified that when a new patient seeks treatment, a physician “take[s] a detailed history” and asks the patient “to bring [his/her] records” including imaging findings. Tr. 247; *see also* GX 26, at 3–4. Dr. Mitchell explained that a physician “document[s] what [his/her] chief complaint is” and why the patient is seeking “to begin care.” Tr. 247.

Dr. Mitchell testified that the “standard medical doctoring for a new patient encounter” includes a “review of [the patient’s] systems” and “[a]n appropriately detailed physical examination.” *Id.* The physician then makes a diagnosis and creates a treatment plan. *Id.* The physician also “modulates the treatment plan” in accordance with the patient’s disease process.¹² *Id.* at 248.

¹²With respect to the initial evaluation of the patient, the Michigan Guidelines state:

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

GX 26, at 3. With respect to the creation of a treatment plan, the Guidelines state:

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical

Re-emphasizing his earlier testimony, Dr. Mitchell testified that as part of the process of formulating a plan involving the long term prescribing of controlled substances, the physician reviews the medication agreement/opioid contract with the patient and explains that if the patient violates the agreement, the patient will be discharged from the practice.¹³ *Id.* at 249. Dr. Mitchell further explained that the first time a patient presents with a red flag, regardless of whether the patient has a history of addiction, the red flag should be documented and the patient should be brought in and given the “opportunity to explain what’s going on.” *Id.* at 249–50. Dr. Mitchell explained that there is a spectrum of red flags which runs from such incidents as a patient claiming to have lost a prescription but having “no other infractions,” to a patient whose “urine screens are inappropriate” or whose MAPS report shows they are “multi sourcing.” *Id.* at 250.

Regarding the five patients identified in the Show Cause Order, Dr. Mitchell testified that he reviewed the patient files including the visit notes, MAPS reports, and copies of the prescriptions which included the pharmacy labels. *Id.* at 251. Dr. Mitchell testified that he had identified specific prescriptions which he believed were issued outside of the usual course of professional medical practice. *Id.* at 252. Dr. Mitchell further explained that he has been “practicing medicine for nearly 30 years,” and that he is “familiar with what constitutes general[ly] appropriate behavior regarding prescribing controlled substances.” *Id.*

and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Id.

¹³ Relevant to this testimony, the Guidelines state that:

[i]f the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including . . . urine/serum medication levels screening when requested; . . . number and frequency of all prescriptions, refills; and . . . reasons for which drug therapy may be discontinued (*i.e.*, violation of agreement).

GX 26, at 3. The Guidelines further advise physicians to periodically “monitor patient compliance in medication usage and related treatment plans.” *Id.* at 4.

The Patient Specific Evidence

R.E.H.

The Allegations

With respect to R.E.H., the Government alleged that from August 5, 2010 through at least March 13, 2013, Respondent repeatedly prescribed controlled substances to the patient even after Respondent knew that R.E.H. “was engaged in the abuse and/or diversion of controlled substances, as well as prescription fraud.” ALJ Ex. 1, at 2. Specifically, the Government alleged that Respondent repeatedly prescribed methadone, a schedule II narcotic controlled substance, and other controlled substances to R.E.H., notwithstanding that he presented “numerous red flags of diversion and/or abuse.” *Id.* The allegations included that:

- R.E.H. repeatedly sought early refills;
 - R.E.H. repeatedly claimed that his prescriptions were lost or stolen;
 - pharmacists repeatedly contacted Respondent’s office to report suspicious behavior by R.E.H.;
 - MAPS reports in R.E.H.’s file corroborated reports that R.E.H. and his wife were committing prescription fraud;
 - R.E.H. had been recently released from jail; and
 - hospital records in his file showed that R.E.H. was using illegal drugs.
- Id.* at 2.

The Show Cause Order also alleged that R.E.H.’s patient file and the prescriptions issued to him show that Respondent prescribed methadone on R.E.H.’s “first visit without undertaking other actions typical of medical professionals[,] such as conducting and documenting a complete medical history and physical examination, requiring that R.E.H. (a self-identified addict) sign a pain management contract or undergo a drug test, running a MAPS search on R.E.H., or creating a written treatment plan.” *Id.* at 2–3. The Show Cause Order then alleged that Respondent:

- Never subsequently required R.E.H. to sign a pain management contract;
- “repeatedly issued prescriptions to [him] with instructions to take his methadone ‘PRN’—thus directing that this self-identified addict should take this powerful opioid analgesic (properly used in scheduled dosages) on an ‘as needed’ basis”;
- issued at least one prescription on a date when R.E.H.’s patient file indicates that he did not have an appointment;
- notwithstanding that he knew that R.E.H. was attempting to fill the

prescriptions using his father’s birthdate to avoid being detected, Respondent did not take the minimal preventative step of including R.E.H.’s address on his methadone prescriptions as required by state and federal law;

- issued a prescription for Xanax to be refilled six times, in violation of state and federal law; and
- falsified records to post-date a methadone prescription in order to provide R.E.H. with an early refill in violation of state and federal law, circumventing the efforts by his staff noting that an early refill should not be issued.

Id. at 3.

The Evidence

On August 5, 2010, R.E.H. made his first visit to Respondent. Tr. 254; GX 8, at 143. According to his medical record, R.E.H.’s chief complaint was back pain. Tr. 256; GX 8, at 143. R.E.H. also reported a history of abusing heroin, which is a “significant addictive illness history,” Tr. 257, as well as tobacco abuse and that he was taking methadone; however, there is no indication that Respondent determined how much methadone R.E.H. was taking, which according to Dr. Mitchell was “a critical bit of information . . . because methadone . . . is approximately five times as potent as morphine.” *Id.* at 256. Dr. Mitchell also explained that Respondent did not determine if R.E.H.’s heroin abuse, which he characterized as a “significant addictive illness history” was “currently active” and whether he had gone (or was going to rehabilitation) for it. *Id.* at 257.

Dr. Mitchell further found that Respondent’s physical examination was “very cursory for a new patient” as he did not conduct neurological and spinal examinations. *Id.* at 256. He also did not require that R.E.H. sign a medication contract, *id.* at 257–58, even though he prescribed 30 tablets of methadone 10, with a dosing instruction of TID or one tablet, to be taken three times per day. *Id.* at 255. Dr. Mitchell opined that this prescription was not issued in the usual course of medical practice. *Id.* I agree.

Even though the prescription should have lasted for ten days, R.E.H. returned to Respondent only six days later and obtained a new prescription, which was for 90 tablets of methadone, TID (three times a day). *Id.* at 258–59. Dr. Mitchell testified that this was an early refill and thus required that Respondent ask R.E.H. why he needed to refill his prescription four days early and document the reason he needed the early refill. Tr. 259–60. Dr. Mitchell thus found that the prescription was not

issued in the usual course of medical practice. *Id.* at 259. He further explained that R.E.H.'s seeking of the refill was a matter of concern because of R.E.H.'s history of drug abuse.¹⁴ *Id.* at 260.

R.E.H.'s third visit occurred on September 21, 2010. Tr. 262. The progress note documents, however, that R.E.H. was "just release [sic] from jail" and that he had been in jail "15 days." GX 8, at 141; Tr. 262. The note further states that R.E.H.'s methadone dose was increased to 10 mg five times a day for two weeks, suggesting that this had occurred when he was in jail. *Id.* The note also states: "methadone x 6 months Heroin addiction." GX 8, at 141.

Respondent issued R.E.H. a prescription for 90 pills of methadone 10, TID. *Id.* While this should have provided a 30-day supply and thus lasted until October 21, R.E.H. returned to Respondent on October 13, eight days early, and obtained a new prescription for 90 tablets of methadone 10. Tr. 263–64. Dr. Mitchell testified that R.E.H. was manifesting a pattern of seeking early refills and Respondent's issuance of the prescriptions was not within the usual course of medical practice because there was "no documentation" that Respondent engaged R.E.H. "as to why this is going on." *Id.* at 265. Moreover, Respondent did not attempt to determine if R.E.H. was "even taking the medication" by demanding that he provide "a urine sample." *Id.* He also did not obtain a MAPS report. *Id.*

R.E.H. returned to Respondent on November 1, 2010. GX 8, at 139. While R.E.H. was 11 days early, Respondent issued him another prescription for 90 tablets of methadone 10 with the same dosing instruction. GX 8, at 139; Tr. 266. While R.E.H. was not early at his next visit (November 30), when he again obtained a prescription for 90 methadone 10 (one tablet TID, or three times per day), he returned to Respondent on December 23, and obtained a new prescription, which he increased to 120 tablets (TID) even though he was a week early. Tr. 266–67; GX 8, at 137–38; GX 15, at 15–16. According to Dr. Mitchell, none of the prescriptions Respondent issued in November–December 2010 were issued in the usual course of professional practice. Tr. 268. However, Respondent did not require that R.E.H. sign a pain

contract until apparently December 23, 2010.¹⁵ Tr. 270–71; GX 8, at 242.

R.E.H. returned on January 4, 2011. GX 8, at 136; GX 15, at 17. Even though R.E.H. was 18 days early, and notwithstanding that the pain contract required him to use his "medicine at a rate no greater than the prescribed rate" and stated that if he used it at a greater rate, he would be "without medication for a period of time," GX 8, at 242; Respondent issued him another prescription for 90 tablets of methadone 10 with a dosing instruction of TID and PRN (take as needed). GX 8, at 136; GX 15, at 17. Dr. Mitchell testified that this prescription was not issued in the usual course of professional practice and that the usual course of professional practice would be to discharge a patient seeking a prescription two weeks early. Tr. 269. He also testified that it is not in the usual course of medical practice to prescribe methadone with a dosing instruction of PRN because the drug "has [a] very long half-life" and "takes a while . . . to enter the blood" stream, and the reason the drug is used for pain is to provide "a stable blood level" of medication. *Id.* at 274.

Respondent did not, however, discharge R.E.H., who returned on January 26, 2011. GX 8, at 135. Notwithstanding that R.E.H. was eight days early, Respondent issued him a new prescription and increased the quantity to 120 pills and the dosing to four tablets per day. GX 15, at 19–20. Dr. Mitchell testified that this prescription was also not issued within the usual course of medical practice. Tr. 270.

An entry in R.E.H.'s medical record documents that on February 15, 2011, a pharmacy called and reported that R.E.H. had tried to fill three prescriptions for 120 tablets of methadone in less than one month. GX 8, at 18. The note documented that on January 26, 2011, R.E.H. had filled one such prescription at a different pharmacy using insurance, and that on February 1, 2011, he had filled the second prescription at a second pharmacy paying cash. *Id.* Moreover, on February 15, R.E.H. had attempted to fill a third prescription at still another pharmacy but was denied, after which he took it to the pharmacy that called Respondent's office. *Id.*

Dr. Mitchell testified that "this is obviously very concerning behavior" and that a doctor acting the usual course of medical practice would summon the patient and ask for an explanation. Tr. 276–77. He further testified that it would "[a]bsolutely not" be within the

usual course of professional practice to issue a new prescription for a controlled substance in these circumstances. *Id.* at 277.

R.E.H.'s file includes a MAPS report which was obtained on the morning of February 17, 2011, two days after the Respondent's office was notified that R.E.H. had filled two prescriptions since January 26 and had attempted to fill a third. GX 8, 236. The MAPS report corroborated the pharmacy's report and showed that R.E.H. had managed to fill Respondent's January 26 prescription on both that date and on February 1, 2011 at two different pharmacies. *Id.* Of further note, various entries for these two dispensings are circled, thus indicating that someone reviewed them. *Id.* Dr. Mitchell testified that this raised "another obvious problem with [R.E.H.'s] compliance," and that given his "known history of heroin abuse . . . appropriate medical care would dictate engaging the patient in this behavior," followed by "discharging" him and urging him "to go to rehabilitation." Tr. 279.

While R.E.H. saw Respondent on both February 17 and 22, 2011, there is no evidence that Respondent even addressed R.E.H.'s drug-seeking behavior, let alone discharged him. *Id.* at 280–81; see GX 8, at 132–33. While Respondent did not prescribe methadone to R.E.H. at any of his three visits in February 2011, Tr. 281, on March 2, he issued R.E.H. a new prescription for 120 methadone 10, a 30-day supply based on the dosing instruction (QID and PRN). GX 8, at 131; GX 15, at 25. Yet only 21 days later on March 23, Respondent issued to R.E.H. another prescription for 120 methadone 10 (also QID and PRN), and only six days later on March 29, Respondent issued him a prescription for 90 more methadone 10 (TID). Tr. 282; GX 15, at 27–30.

Dr. Mitchell testified that there was no justification in R.E.H.'s chart for Respondent's issuance of prescriptions, which authorized the dispensing of a three-month supply of the drug. Tr. 283. He also testified that these prescriptions were not issued in the usual course of professional practice. *Id.*

The evidence further shows that on June 2, 2011,¹⁶ Respondent issued to

¹⁴ The transcript includes a question by Government's counsel which suggests that R.E.H.'s second visit occurred on October 11, 2010. See Tr. 260, at Ls 5–6. However, R.E.H.'s medical record includes a progress note for August 11, 2010 and contains no note for an October 11, 2010 visit. See GX 8, at 140–42 (progress notes for visits of Aug. 11, Sept., 21, and Oct. 13, 2010).

¹⁵ The date does not, however, include the year. GX 8, at 242.

¹⁶ While the Government did not ask Dr. Mitchell about the methadone prescriptions issued in April and May 2011, the pattern of early refills continued, as on April 20, 2011, Respondent issued R.E.H. a new prescription for 90 methadone 10 TID, this being eight days early (ignoring that R.E.H. had also obtained methadone on March 23). GX 15, at 31–32. Thereafter, on May 10, 2011, Respondent issued R.E.H. a prescription for 120 methadone QID, this being 10 days early. *Id.* at 33–34. Thus, the June 2 prescription was one week early.

R.E.H. a prescription for 100 tablets of methadone 10 QID. GX 15, at 37–38. This was followed by additional prescriptions for 120 tablets of methadone 10 QID on June 16, July 12, July 14, August 9, and August 23, 2011. *Id.* at 41–42, 45–46, 47–48, 51–52, 53–54. The June 16 prescription was 11 days early, and while the July 12 prescription was only four days early, as Dr. Mitchell testified, the July 14 prescription was 28 days early. Tr. 284–85. Moreover, the August 9 prescription was also early, and the August 23 prescription was 16 days early. *Id.* at 286. Yet there is no progress note for the August 23 prescription and no entry in the log used to document various activities. GX 8, at 15–20 (log entries); *id.* at 120–21 (progress notes for Aug. 9 and Sept. 13, 2011, but not Aug. 23). Dr. Mitchell testified that Respondent's issuance of the early methadone refills during the June through August period was not within the usual course of professional practice. *Id.* at 287.

R.E.H.'s patient file also includes copies of two prescriptions for 120 Vicodin ES (QID), which were dated November 17 and 22, 2011. GX 8, at 191–92. The document bearing the November 17 prescription includes the notation: "Please verify—just filled this RX on 11/17 for 30 day supply—then the follow[ing] RX was brought in 11/23/11." *Id.* at 192. The document further asked: "please call Walmart" and included the notation of "suspicious RX." *Id.*

Dr. Mitchell testified that "as a stand-alone incident it's very concerning" because "[i]t smacks of prescription forgery." Tr. 288. However, in R.E.H.'s case, it was "just another incident . . . in his history that just masked a horrible addictive illness, diversion or both." *Id.* at 288–89. Dr. Mitchell then explained that a physician's "primary concern" is the welfare of his/her patients, and a physician "need[s] to protect them from their addictive illness and document it and refer them to a" detoxification facility and not just "feed" their addiction "by continuing to write medications." *Id.* at 289.

R.E.H.'s patient file also includes a MAPS report which Respondent obtained on December 9, 2011. GX 8, at 185–90. The report showed that during the months of October and November 2011, R.E.H. had filled six prescriptions for 120 methadone 10 (with four of the prescriptions having been filled between Nov. 10 and 29) and that R.E.H. had used four different pharmacies. *Id.* at 185–86. However, R.E.H.'s patient file includes progress notes only for visits on October 10 and November 11. *Id.* at 116–119. Notably, each of the

prescriptions listed on the first page of the report has check marks and Respondent's initial/signature¹⁷ is on the page, thus establishing that Respondent reviewed the document. *Id.* at 185.

Dr. Mitchell testified that the report would indicate "[g]reat concern for what's going on" to a doctor acting in the usual course of medical practice as it showed that R.E.H. was "[o]btaining hundreds of tablets of methadone." Tr. 291. The report also showed that R.E.H. had obtained other controlled substances (alprazolam and hydrocodone) from two additional pharmacies during these two months. GX 8, at 185–86. Thus, R.E.H. had used a total of six pharmacies. *Id.*; Tr. 291–92.

The evidence also showed that Respondent was prescribing methadone and other controlled substances (alprazolam and hydrocodone) to R.S.H., who was R.E.H.'s wife, and that he obtained a MAPS report on her only minutes after obtaining the MAPS report on R.E.H. GX 13, at 161–68. The MAPS report showed that between October 11, 2011 and November 28, 2011, R.S.H. filled seven prescriptions for 120 methadone 10, four prescriptions for 90 alprazolam (in either .5 or 1 mg dose), and prescriptions for 90 and 120 hydrocodone 7.5. *Id.* at 161–63. Notably, the MAPS reports listed the same address for R.S.H. and R.E.H. *Compare* GX 13, at 161; *with* GX 8, at 185.

Regarding this information, Dr. Mitchell testified that "the concerns speak[] for itself [sic]. There's something very troublesome and potentially life threatening going on here with multitudes of refills, repeated incidents," given "there's some indication that they're cohabiting together and have the same last name." Tr. 294–95. Dr. Mitchell then testified that it was not within the usual course of professional practice to continue writing methadone and other controlled substance prescriptions given these circumstances. *Id.* at 295. However, Respondent did not stop issuing methadone and other controlled substance prescriptions to R.E.H. after he learned of this. *Id.* at 295. Instead, on both December 21 and 22, 2011, Respondent issued R.E.H. two more prescriptions for 120 methadone 10, and he continued issuing methadone prescriptions to R.E.H. for another 15 months. GX 15, at 87–90, 155–56.

Moreover, on February 29, 2012, Respondent's office received a phone

call from a pharmacy, which reported that R.E.H. was using his father's birthdate to fill the prescriptions. GX 8, at 43. The pharmacy also reported that it had called R.E.H.'s father who stated that "he doesn't receive [sic] this script." *Id.* As Dr. Mitchell testified, this was evidence that R.E.H. was forging prescriptions. Tr. 296; *see also* 21 U.S.C. 843(a)(3) (rendering it unlawful to "knowingly or intentionally . . . acquire . . . a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge"). Asked whether it was appropriate for Respondent to continue to issue controlled substance prescriptions to R.E.H., Dr. Mitchell answered: "[a]bsolutely no." Tr. 297. Yet, on March 6, 2012, Respondent issued another prescription to R.E.H. for 120 methadone 10.¹⁸ GX 15, at 107.

On July 12, 2012 (in the interim, Respondent had continued issuing prescriptions for 120 methadone 10 to R.E.H., several of which were early¹⁹), Respondent obtained another MAPS report showing the controlled substance prescriptions filled by R.E.H. GX 8, at 204–12. The report includes the handwritten notation of "was not seen on this day" in 14 separate entries for methadone prescriptions which list Respondent as the authorizing practitioner.²⁰ *See id.* at 204–09. The report also bears Respondent's signature on the first page. *Id.* at 204. Dr. Mitchell explained that these entries "typically mean[]" either that Respondent was issuing the prescriptions without seeing R.E.H. or that R.E.H. had stolen a prescription pad. Tr. 299. Yet Respondent issued R.E.H. still more prescriptions for 120 methadone 10 on July 24, August 15, September 18, and October 8, 2012, as well as a prescription for 60 methadone 10 on September 4; each of the last four prescriptions was early. GX 15, at 125–36.

The evidence further shows that even when Respondent's nurse noted in R.E.H.'s file that R.E.H. was seeking an early refill, Respondent nonetheless issued a post-dated prescription to him. As found above, the evidence shows that on October 8, 2012, Respondent

¹⁸ There is, however, no progress note for this visit. *See* GX 8, at 113–14 (notes for visits of Mar. 22 and Feb. 28, 2012 but not for Mar. 6).

¹⁹ The prescriptions were issued on March 22, April 19, May 15, June 6, and June 26. GX 15, at 109–24. Each of the prescriptions was for a 30-day supply, and thus the March 22, June 6, and June 26 prescriptions were early.

²⁰ The "was not seen on this day" notations are also written in entries for an alprazolam prescription (filled on 1/3/12) and for two hydrocodone prescriptions (filled on 12/30/11 and 11/19/11). GX 8, at 207, 209.

¹⁷ This initial/signature is the same as that used on the numerous prescriptions contained in the record.

issued R.E.H. a prescription for 120 methadone 10.²¹ GX 8, at 32. However, a progress note for an October 29, 2012 visit includes a nurse's note stating: "med refills—Ibuprophen—asked for methadone, last refill 10/8/12." *Id.* at 100. Also, a note in a log dated October 30, 2012 states: "Pt requests a refill on methadone—and last refill was 10/8/12—not time yet." *Id.* at 15. A MAPS report obtained by the Government shows that R.E.H. filled two methadone prescriptions with an issue date of October 8, 2012—one on October 8th, the other on October 30th. GX 20, at 14; *see also* GX 15, at 135–36 (Rx filled on Oct. 8); *id.* at 137–38 (Rx filled on Oct. 30). Not only was the second prescription post-dated—a violation of 21 CFR 1306.05(a) which requires that "[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued"—it was also another early refill which should not have been filled. Tr. 301 (testimony of Dr. Mitchell).

On December 12, 2012, R.E.H. was admitted to a hospital after he overdosed on Seroquel. GX 8, at 158. While in the hospital, R.E.H. provided a urine drug test which was positive for cocaine. *Id.* He also was diagnosed as "polysubstance dependen[t]." *Id.* at 159. A copy of the hospital report was provided to Respondent and bears his signature. *Id.* at 158.

Dr. Mitchell testified that upon learning that R.E.H. was using cocaine, the appropriate response was to refer him to inpatient drug rehabilitation as R.E.H. "obviously" had "a life threatening illness manifested by his addicting behavior" as well as to cease prescribing controlled substances to him. Tr. 303. Asked by the Government whether there ever was a point at which Respondent should have stopped writing controlled substance prescriptions to R.E.H., Dr. Mitchell testified:

The short answer is yes. But the whole format of the care is so appalling that he never had a drug contract in the beginning and it's just one infraction after another.

So if you had started from the very beginning, the patient already told you that he has a history of heroin abuse. So if you were to make the decision to treat his . . . back pain . . . there has to be documentation.

Discussing with the patient about concerns regarding his illness, contract agreed upon and . . . random urine samples as well as MAPS surveys being pulled.

In my opinion, in this case, after the second early refill, he'd be discharged from

the practice. With the option to go to rehabilitation.

You can't just let him go off and not have some kind of aftercare. I mean—he's a very sick individual . . . regarding his addictive illness. *Id.* at 303–04. Yet even after the December 12, 2012 hospitalization, Respondent continued to issue more methadone prescriptions to R.E.H. *See* GX 15, at 143 (Rx of 12/27/12); 145 (Rx of 1/22/13); 149 (Rx 2/19/13); 155 (Rx 3/13/13). Moreover, on February 19, 2013, Respondent issued R.E.H. a prescription for 90 Xanax with six refills.²² GX 15, at 151.

Following Dr. Mitchell's testimony, Respondent testified on his own behalf. After acknowledging that he had listened to all of Dr. Mitchell's testimony, Respondent was asked by his counsel if Dr. Mitchell is "right or wrong about you ignoring the red flags about patients who are or could be abusing or diverting drugs?" Tr. 484. Respondent answered: "He's right." *Id.* Subsequently, the ALJ asked Respondent if he (the ALJ) was "correct in understanding that you've read the order to show cause?" *Id.* 535. Respondent answered: "I did." *Id.* The ALJ then asked Respondent: "Do you agree that the facts that they allege there are all true?" Respondent answered: "I did." *Id.* The ALJ followed up by asking: "Your answer was yes you do?" *Id.* Respondent answered: "Yes." *Id.*

I find (as did the ALJ) that Dr. Mitchell provided credible testimony that Respondent ignored multiple red flags that R.E.H. was abusing and diverting controlled substances and that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he continued to prescribe methadone and other drugs in the face of the red flags. While this alone constitutes substantial evidence to support a finding that Respondent violated 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1) in prescribing to J.E.H., this conclusion is buttressed by Respondent's testimony that Dr. Mitchell was "right" when he testified that Respondent ignored multiple red flags.

J.W.

The Allegations

The Show Cause Order alleged that from December 23, 2010 through January 4, 2012, Respondent "repeatedly prescribed controlled substances after [he] came to know that

J.W. was engaged in the abuse and/or diversion of controlled substances." ALJ Ex. 1, at 3. Specifically, the Show Cause Order alleged that Respondent repeatedly prescribed controlled substances to J.W. notwithstanding numerous red flags of diversion and/or abuse. *Id.* These included that:

- J.W. repeatedly sought early refills;
- the Michigan Medicaid program notified Respondent that J.W. was doctor-shopping;
- a pharmacy also notified Respondent that J.W. was doctor-shopping;
- J.W. was incarcerated;
- J.W. exhibited withdrawal symptoms; and
- a MAPS report obtained by Respondent in October of 2011 showed that J.W. was engaged in a persistent pattern of doctor and pharmacy shopping.

Id.

The Show Cause Order also alleged that J.W.'s patient file and the prescriptions issued to him show that Respondent:

- Prescribed Adderall, a schedule II stimulant, to J.W. on his first visit without diagnosing him with Attention Deficit Disorder (ADD), and that he prescribed other controlled substances without taking actions typical of medical professionals such as conducting and documenting a complete medical history and physical examination, or creating a written treatment plan;
 - prescribed numerous controlled substances to J.W. without conducting a MAPS search "that a typical Michigan doctor would have conducted," and that such a search would have shown that J.W. was engaged in "a dangerous pattern of doctor and pharmacy shopping (through which J.W. obtained 11 monthly prescriptions for Adderall within the first six months of 2011)";
 - prescribed methadone to J.W. with a PRN (take as needed) dosing instruction "within a week of meeting him and repeatedly thereafter";
 - "never subjected J.W. to any drug tests"; and
 - "took no action to enforce the pain management contract that J.W. signed on his first visit, in which [J.W.] committed (among other things) to obtain controlled medications from only one provider (Respondent), fill them at one pharmacy, and take them at the prescribed dosages."
- Id.* at 3–4.

The Evidence

J.W. first saw Respondent on December 23, 2010. GX 9, at 42.

²¹ Here again, there is no progress note for this visit. *See* GX 8, at 100–101 (progress noted for visits on Oct. 3 and 29, 2012). However, a copy of the prescription is in R.E.H.'s patient file.

²² However, the pharmacy apparently caught the fact that Respondent had provided too many refills, and noted that only five refills were authorized. GX 15, at 152.

According to a nurse's notation on the progress note, J.W. was seeking treatment for pain. *Id.* Respondent prescribed to J.W. 60 tablets of Adderall 20, with a dosing instruction of BID or one tablet to be taken twice a day. GX 16, at 1. One week later, J.W. returned to Respondent, who wrote him a prescription for 90 tablets of methadone 5, with a dosing of TID and PRN. *Id.* at 3.

Dr. Mitchell testified that neither prescription was issued in the usual course of professional practice. Tr. 308. As for the Adderall prescription, Dr. Mitchell explained that the drug is "typically" prescribed to treat ADD (Attention Deficit Disorder) or ADHD (Attention Deficit Hyperactivity Disorder). *Id.* Dr. Mitchell explained that neither J.W.'s chief complaint nor history "would indicate an appropriate diagnosis for the prescribing of Adderall." *Id.* Dr. Mitchell also observed that Respondent's assessment and plan also contained "no indication of any appropriate diagnosis for" Adderall. *Id.* Reviewing the notes for the first visit, Dr. Mitchell also questioned whether Respondent had performed a physical exam, as in the space on the progress note for listing the exam findings, Respondent had scribbled "an S." GX 9, at 42. Regarding the notation, Dr. Mitchell testified that "I don't know what that signifies." *Id.* at 309. While Dr. Mitchell also noted that the margin of the progress note included a listing of various areas with boxes in which Respondent wrote either plus or minus signs, he further testified that he was "not sure what they're trying to communicate." *Id.*

Dr. Mitchell testified that it was inappropriate for Respondent to issue the methadone prescription at J.W.'s second visit. *Id.* Asked to explain why, Dr. Mitchell testified that:

There's no documentation that the patient is having any findings based on physical examination that would serve as a foundation for prescribing [me]thadone. Even though the records are reviewed, I don't see any documentation where it states the patient had previously taken [m]ethadone or was on any analgesics whatsoever.

And then there's some notation that's very hard to make out, it says something Vicodin. I can't really read it, but it's in the middle of the HPI box.

I'm not really sure what it's trying to communicate. Whether it's regarding prior Vicodin prescription or what. So it's really not legible.

Id. at 309–10. As he testified regarding Respondent's prescribing to R.E.H., Dr. Mitchell re-iterated that it was not appropriate to prescribe methadone for pain on a PRN basis. *Id.*

J.W.'s file includes a fax of a "Notice of Prior Authorization Determination," which Respondent received from the Michigan Medicaid program on or about January 21, 2011. GX 9, at 69. The form noted that a prior authorization request had been received and provided the name of another physician (Dr. M.) who had prescribed Adderall to J.W.; it also listed a pharmacy other than the one which J.W. had listed on the Pain Management Agreement he entered into at his first visit with Respondent. *Compare* GX 9, at 69; *with id.* at 70. As Dr. Mitchell explained, this is "evidence that . . . J.W. [wa]s multi-sourcing for amphetamine from another physician." Tr. 311. However, in the Pain Management Agreement, J.W. had agreed that he would "not attempt to obtain controlled medicine, including . . . stimulants . . . from any other doctor, provider or facility." GX 9, at 70; *see also* Tr. 312. While the Pain Management Agreement also stated that if J.W. broke the agreement, Respondent would stop prescribing controlled substances and discharge him, Respondent did not do so. *See* GX 9, at 70.

Dr. Mitchell further explained that upon learning that J.W. was obtaining Adderall from another doctor, Respondent should have engaged J.W. and obtained an explanation for why he was obtaining prescriptions from two different doctors and documented the encounter. Tr. 313. Respondent, however, did not do this. *Id.* at 314 (GX 9, at 39). Instead, he issued J.W. another prescription for 60 Adderall. Tr. 314; ALJ Ex. 50, at 2; GX 16, at 7–8. Asked whether Respondent's issuance of the prescription was within the usual course of professional practice, Dr. Mitchell answered "no" and added that "[t]he whole beginning for the prescriptions of Adderall were not issued in the course of legitimate methods of practice." Tr. 314–15.

On February 16, 2011 (22 days later), J.W. again saw Respondent. GX 9, at 38. Respondent wrote J.W. a new prescription for 60 Adderall even though he was eight days early. Tr. 315. Respondent also wrote J.W. a prescription for 120 methadone 10. GX 16, at 11.

However, only two days later (Feb. 18), Respondent's office received a phone call from a pharmacy reporting that insurance would not cover J.W.'s methadone prescriptions and that he was seeing Dr. M. who was prescribing Suboxone to him—Dr. M. being the same doctor listed as the medical provider on the prior authorization request form Respondent had received from the Michigan Medicaid program.

Compare GX 9, at 4; *with id.* at 69. Thus, J.W. was simultaneously obtaining prescriptions for both methadone and Suboxone, which according to Dr. Mitchell "is not done." Tr. 316.

Dr. Mitchell testified that in response to this information, the appropriate course would be to discharge the patient and recommend that he go to inpatient drug rehabilitation. *Id.* at 316. Dr. Mitchell testified that he would "have called the other physician" to tell him/her that J.W. was engaged in "potentially . . . life threatening" behavior. *Id.* Yet there is no evidence in J.W.'s file that Respondent did this. *Id.*

On both March 16 and April 6, 2011, Respondent wrote J.W. additional prescriptions for 60 Adderall. GX 16, at 21–22; *id.* at 25–26. According to Dr. Mitchell, J.W. was a week early when he received the April 6 prescription.²³ Tr. 317. Dr. Mitchell explained that J.W.'s early refills and doctor shopping was "a continued obvious flag to the physician that there's something going on here that can potentially put the patient's life at risk." *Id.*

The evidence also shows that in the first six months of 2011, Respondent wrote J.W. six prescriptions for 60 Adderall.²⁴ GX 21, at 19–25. Dr. Mitchell testified that these prescriptions were not issued in the usual course of professional practice. Tr. 317–18.

The evidence further shows that Respondent issued to J.W. prescriptions for 60 Adderall 30 (BID) and 120 Klonopin (QID) on both July 6 and 26. GX 16, at 41–52. According to Dr. Mitchell, both of the July 26 prescriptions were "approximately a week early" (actually, they were 10 days early), and there was no justification in the patient file for issuing the prescription when Respondent did. Tr. 318.

On October 25, 2011, Respondent received a fax from the Medical Department of the Lapeer County Jail. The fax stated that J.W. was an inmate and requested information as to his prescriptions and diagnosis. GX 9, at 47. Respondent reported that J.W. was on methadone for chronic pain and Adderall for EDS and ADD. *Id.* at 47.

The same day, Respondent obtained a MAPS report on J.W. GX 9, at 48–51; 79–83. The report showed that J.W. was still obtaining controlled substance prescriptions for Suboxone and Adderall from Dr. M., while also

²³ Actually, he was nine days early.

²⁴ While Dr. Mitchell testified that 10 prescriptions were issued to J.W. in this period, three of them were issued by Dr. M., the other by a Dr. R. GX 21, at 19–25.

obtaining prescriptions for methadone, hydrocodone and Adderall from Respondent. *See id.* As found above, while J.W. was incarcerated, his niece contacted Respondent and told him that J.W. had “nearly died from withdrawal” and that he was selling his medications; she also asked him to stop prescribing controlled substances to J.W. Tr. 128–29. Dr. Mitchell explained that under these circumstances, he would confront the patient regarding whatever the family reported and “let the patient react and respond.” Tr. 323.

J.W. did not see Respondent again until December 21, 2011. GX 9, at 25. Regarding the progress note for the visit, Dr. Mitchell testified that “the physical exam is really nothing, it says awake and stable.” Tr. 324. As for J.W.’s chief complaint, Dr. Mitchell testified that Respondent’s writing was illegible. *Id.*; *see also* GX 9, at 25. Respondent did not issue any prescriptions to J.W. on this day.²⁵ ALJ Ex 50, at 3.

J.W. returned on January 4, 2012. On the progress note, Respondent lined through a box next to the words stating “substance abuse +, reviewed w/ patie[nt].” GX 9, at 24. However, the progress note is otherwise illegible. *See id.* Also, Respondent resumed prescribing controlled substances to J.W., issuing him prescriptions for 30 tablets of Valium 10 mg and 120 tablets of Tylenol with Codeine No. 4. ALJ Ex 50, at 3.

On January 19, 2012, J.W. made his final visit to Respondent and obtained a prescription for 120 tablets of methadone 10 with a dosing instruction of QID and PRN. Tr. 325; GX 16, at 59–60. Asked whether the prescription was issued in the usual course of professional practice, Dr. Mitchell answered “no.” Tr. 325. Asked “why not,” Dr. Mitchell explained: “[w]ell again, the same basis. Where is the justification, based on the patient[’s] clinical complaints, a detailed examination, a clear diagnosis that [m]ethadone was justified.” *Id.* As for at what point during his treatment of J.W. Respondent should have refused to prescribe controlled substance and discharged him, Dr. Mitchell answered:

Again, it would be early on with the early refills. The behavior that is an obvious flag by the patient for addiction illness. Which he has a history of. History of drug abuse is documented in the chart.

Id. at 326.

As found above, Respondent testified that he had listened to all of Dr. Mitchell’s testimony. Respondent was

then asked by his counsel if Dr. Mitchell is “right or wrong about you ignoring the red flags about patients who are or could be abusing or diverting drugs?” Tr. 484. Respondent answered: “He’s right.” *Id.*

Based on Dr. Mitchell’s credible testimony, I find that the controlled substance prescriptions Respondent provided to J.W. lacked a legitimate medical purpose and were issued outside of the usual course of professional practice and violated the CSA. 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1). This finding is buttressed by Respondent’s admission that Dr. Mitchell was correct in his criticism that he ignored red flags.

R.K.

The Allegations

The Show Cause Order alleged that from January 27, 2011 through July 17, 2012, Respondent repeatedly prescribed controlled substances to R.K. after Respondent knew that R.K. was engaged in the abuse and/or diversion of controlled substances. ALJ Ex. 1, at 4. The Show Cause Order specifically alleged that Respondent repeatedly prescribed to R.K. controlled substances despite the numerous red flags of diversion and/or abuse R.K. presented. *Id.* These included that:

- R.K. repeatedly sought early refills;
- Respondent was notified by the Michigan Department of Community Health Drug Utilization Review that R.K. was doctor shopping;
- a pharmacist contacted [his] office reporting suspicious conduct by R.K.; and
- two consecutive drug tests on April 10, 2012 and May 8, 2012 showed that R.K. was not taking the methadone that Respondent had prescribed to him.

Id.

The Show Cause Order also alleged that R.K.’s patient file and the prescriptions issued to him show that Respondent:

- Prescribed controlled substances to R.K. on his first visit without taking actions typical of medical professionals, such as conducting and documenting a complete medical history and physical examination, or creating a written treatment plan;
- never required R.K. to sign a pain management contract or ran a MAPS report on him;
- engaged in a pattern of issuing Xanax prescriptions to R.K. on a near monthly basis that authorized multiple refills, and that while the dosing instructions directed R.K. to take 690 tablets in the 10-month period preceding his death, the prescriptions

allowed R.K. to obtain up to 2,250 tablets of Xanax;

- issued a prescription for Xanax to be refilled six times, in violation of state and federal law; and

- stopped testing R.K. to determine if he was taking the methadone Respondent prescribed after R.K. tested negative on two consecutive monthly drug tests.

Id. at 4–5.

The Evidence

At the beginning of the Government’s examination of Dr. Mitchell about Respondent’s prescribing to R.K., the ALJ raised his “concern about evidence that becomes cumulative at some point in a preceding [sic].”²⁶ Tr. 326. The Government thus did not ask Dr. Mitchell about the prescriptions Respondent issued to R.K. from his first visit (January 27, 2011), through and

²⁶ According to the ALJ, “[t]hat can happen in two ways in this particular preceding [sic]. And one way is that you [the Government] present evidence of many patients and the other way is to present evidence of many forms of failure to treat in a manner that’s required in the ordinary course of medical practice.” Tr. 326–27. Continuing, the ALJ explained that:

So far I’ve heard more than one instance. In fact, multiple instances of prescribing [m]ethadone on a PRN basis, which the witness has told me is inconsistent with medical practice.

Not having a complete medical history, not having a physical examination noted in the file, not writing a treatment plan, diagnosing controlled substances without sufficient support in the medical record through objected[sic] testing, imagining [sic] or other data, prescribing controlled substances prematurely before the expiration of the prior prescription, concurrent prescriptions from more than one prescribing source, filling those prescriptions in more than one pharmacy, failure to properly utilize the MAPS data in the record, failure to discharge and failure to enforce the pain medication treatment plan and contract.

Id. The ALJ then announced that “[t]o the extent that proposed testimony is redundant in these fields, I will be sensitive to an objection that the evidence does not have an informative role and becomes less useful to me as it is cumulative at that point.” *Id.* The ALJ thus directed the Government to “tailor your questions appropriately” and advised Respondent’s counsel that “I will be listening to you for your concern as well.” *Id.* at 328.

Contrary to the ALJ’s understanding, the Government was entitled to put on evidence regarding each and every allegation it had raised in the Order to Show Cause and its pre-hearing statements. That the Government had previously shown that Respondent failed to obtain a complete history and conduct an adequate physical exam, or that he failed to address red flags such as repeated early refill requests or ignored evidence of doctor shopping and the use of multiple pharmacies, etc., with respect to patients R.E.H. and J.W., does not render evidence as to whether he acted in the same manner with respect to the other three patients redundant. Furthermore, notwithstanding that evidence of a single act of diversion can, in appropriate circumstances, support an order of revocation, it is for the Government to decide, in the exercise of its prosecutorial discretion, on the number of patients (and prescriptions) that are necessary to prove its case.

²⁵ However, on October 18, 2011, J.W. had filled an Adderall prescription which Respondent had written for him on the same day. GX 16, at 57–58.

including R.K.'s visit of October 4, 2011. See *id.* at 330–36; GX 10, at 52–65.

On October 20, 2011, Respondent issued R.K. a prescription for 60 tablets of Xanax .5 mg, with a dosing instruction of BID or PRN. ALJ Ex. 50, at 3; Tr. 330. The prescription authorized three refills, ALJ Ex. 50, at 3; and based on the dosing instruction, the prescription provided R.K. with a four-month supply of the drug. However, Dr. Mitchell testified that there was nothing in the progress note for this visit which justified providing R.K. with a four-month supply of the drug. Tr. 330.

Yet, not even six weeks later on November 29, 2011, Respondent issued R.K. an additional prescription for 60 Xanax .5 mg (BID or PRN), with three refills. ALJ Ex. 50, at 3; Tr. 330. Here again, Dr. Mitchell testified that there was no medical justification in the visit's progress note for providing R.K. with another four-month supply of Xanax. Tr. 330–31.

On January 17, 2012, Respondent provided R.K. with another prescription for 60 Xanax (BID and PRN), with three refills. ALJ Ex. 50, at 3. Moreover, Respondent increased the strength of the drug to 1 mg. *Id.* While this prescription alone again provided R.K. with a four-month supply, on February 15, 2012, Respondent provided R.K. with another prescription for 60 Xanax 1(BID and PRN) with three refills. *Id.*

On April 10, 2012, Respondent provided R.K. with another prescription for Xanax 1, increasing the quantity to 90 tablets and the dosing to TID (and PRN). *Id.* Moreover, Respondent authorized six refills, this being a separate violation of the Controlled Substances Act, which, with respect to a schedule IV drug, prohibits refilling a prescription “more than five times” unless the practitioner renews the prescription. See 21 U.S.C. 829(b).

Notwithstanding the numerous refills R.K. had remaining on both the February 15 and April 10 prescriptions (not to mention the supply R.K. had likely obtained from the earlier prescriptions), Respondent provided him with new prescriptions for 90 Xanax 1 (TID or PRN) on May 8 and May 30, 2012. ALJ Ex. 50, at 4. While these two prescriptions did not authorize any refills, on June 21, 2012, Respondent provided R.K. with another prescription for 90 Xanax 1(TID or PRN), which authorized three refills. *Id.* Finally, at R.K.'s last visit, Respondent provided him with another prescription for 90 Xanax 1 (TID or PRN). *Id.*

According to Dr. Mitchell, from October 20, 2011 through July 17, 2012, R.K. “obtained 1950 tablets of alprazolam,” an amount far in excess

(by more than 1,000 pills) of what was necessary based on Respondent's dosing instructions.²⁷ Tr. 331. Dr. Mitchell further testified that Respondent pattern of issuing multi-month prescriptions on top of one another is “not a customary, legitimate medical practice behavior.” *Id.* at 332.

The Government also questioned Dr. Mitchell about Respondent's prescribing of methadone to R.K. On March 13, 2012, Respondent first prescribed 90 methadone 5 mg (TID + PRN), a 30-day supply, to R.K. GX 17, at 45–46. However, on April 10, 2012, R.K. tested negative for methadone. GX 10, at 31. A note in the entry states: “ran out week ago.” *Id.*

Regarding this incident, Dr. Mitchell testified that “[i]f a patient was truly taking [m]ethadone . . . and they abruptly ran out, they would go through significant medical withdrawal.” Tr. 333. Dr. Mitchell further explained that a physician “would engage the patient, are you taking, what's the problem here? Find out why the chaotic pattern in your lab results, when you are prescribing the medication for them and give them a chance to respond.” *Id.* Dr. Mitchell also stated that even if he believed in giving the benefit of the doubt to the patient he would still ask the patient why the patient “never bothered to contact” him and would also express his “concern[] about what's going on with [the patient's] behavior.” *Id.* at 334.

At the April 10 visit, Respondent issued R.K. a new prescription for 90 methadone 10 mg (TID), which was double the strength of what he had previously prescribed. GX 17, at 47–48. Moreover, while Respondent subjected R.K. to another drug test during his next visit (May 8, 2012), R.K. again tested negative for methadone claiming that he had run out several days earlier.²⁸ GX 10, at 31. Yet here again, Respondent issued R.K. a new prescription for 90 methadone 10 TID. GX 17, at 51–52.

Dr. Mitchell testified that “[t]here is no legitimate foundation for” the prescription. Tr. 335. And when asked what the appropriate response was to R.K.'s having provided a second negative urine test for methadone, Dr. Mitchell answered: “[d]ischarge.” *Id.*

On May 30, 2012, R.K. again saw Respondent, who provided him with a

²⁷ A review of the MAPS data suggests that the actual figure was 1890 tablets, as one dispensing which occurred on January 15, 2012 is listed twice. GX 22, at 11. Either way, the amount of alprazolam R.K. was able to obtain based on Respondent's prescriptions far exceeded what was necessary based on the dosing instructions.

²⁸ The actual notation in R.K. drug screening record states: “last pill Saturday.” GX 10, at 31. In May 2012, May 8 was a Tuesday.

new prescription for 90 methadone 10. GX 10, at 6, 43; GX 17, at 55–56. Notwithstanding that R.K. had provided negative urine samples on his two previous visits, there is no evidence that Respondent required R.K. to provide a new urine sample. Tr. 335. And while Respondent put a slash mark through the box next to the entry “Substance Abuse +, reviewed w/patient,” GX 10, at 43; as Dr. Mitchell explained: “There's no detail, it's just merely a swipe of the pen.” Tr. 336. Continuing, Dr. Mitchell noted that there is “[n]o documentation of, I discussed with the patient two negative urines samples, so forth and so . . . my plan was so forth and so on.” *Id.*

Asked by the Government whether there was ever a point when Respondent should have discharged R.K., Dr. Mitchell answered “[y]es.” *Id.* While Dr. Mitchell explained that he would give the patient the benefit of the doubt, after the second negative urine test, “he would definitely be discharged.” *Id.* Dr. Mitchell further agreed that every controlled substance prescription Respondent issued to R.K.'s after the second negative urine test was issued outside of the usual course of professional practice. *Id.* at 336–37.

During cross examination, Dr. Mitchell agreed that by referring R.K. to a physical therapist to treat the patient's back pain, Respondent was employing a multifaceted treatment plan. *Id.* at 446. However, Dr. Mitchell found that there was no medical evidence to support Respondent's prescribing of methadone, and there was no evidence that Respondent ever tested R.K. to determine if he was using the medication as prescribed. *Id.* at 335.

Based on the above, I find that all of the controlled substance prescriptions issued by Respondent to R.K. on and after October 20, 2011 lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a).

R.J.H.

The Allegations

The Show Cause Order alleged that from March 10, 2011 through November 30, 2011, Respondent repeatedly prescribed controlled substances to R.J.H. after he knew that R.J.H. was engaged in the abuse and/or diversion of controlled substances. *Id.* at 5. Specifically, the Government alleged that Respondent prescribed controlled substances to R.J.H., notwithstanding numerous red flags of diversion and/or abuse, including:

- R.J.H. repeatedly sought early refills;
- R.J.H. repeatedly reported lost or stolen prescriptions;
- another patient reported that R.J.H. was selling his prescription of methadone and taking his girlfriend's prescription as his own; and
- R.J.H. was requesting controlled substances by name.

Id. at 5.

The Government also alleged that R.J.H.'s patient file and the prescriptions issued to him show that Respondent:

- Prescribed controlled substances to R.J.H. on his initial visit without taking actions typical of medical professionals such as conducting and documenting a complete medical history and physical examination, requiring that R.J.H. (a self-identified addict) sign a pain management contract or submit to a drug test, running a MAPS search on R.J.H., and creating a written treatment plan, which was periodically re-evaluated;
- never subjected R.J.H. to drug tests;
- never ran a MAPS report on R.J.H.;
- never required R.J.H. to sign a pain management agreement; and
- repeatedly prescribed methadone to R.J.H. to be taken "PRN."

Id. at 5.

The Evidence

The Government's presentation with respect to R.J.H. focused primarily on the manner in which Respondent escalated the amount of methadone he prescribed and ignored various red flags. R.J.H. first saw Respondent on March 10, 2011, at which time Respondent documented that R.J.H. had a history of narcotic abuse. GX 11, at 3, 57; *see also* Tr. 341. At the visit, Respondent issued to R.J.H. a prescription for 30 tablets of methadone 5 to be taken twice a day, providing a 15-day supply. GX 18, at 1–2; ALJ Ex. 50, at 4. Thereafter, on a March 24, 2011, Respondent issued to R.J.H. a prescription for 90 tablets of methadone TID, providing a 30-day supply, and on April 5, 2011, he issued to R.J.H. a prescription for 40 tablets of methadone 10 (QID and PRN). GX 18, at 5–6, 9–10; ALJ Ex. 50, at 4. Moreover, on April 19, 2011, Respondent issued to R.J.H. a prescription for 120 tablets of Methadone 10 (QID and PRN). GX 18, at 11–12; ALJ Ex. 50, at 4. Thus, between the March 10 and April 19 prescriptions, Respondent had quadrupled R.J.H.'s daily methadone dose from 10 to 40 milligrams.

Dr. Mitchell testified that this was "a significant escalation in" the total "24 hour dose" of R.J.H.'s methadone

regimen. Tr. 338. Dr. Mitchell further explained there was "no" justification for Respondent's having quadrupled R.J.H.'s daily dose. *Id.*

Progress notes in R.J.H.'s file show that R.J.H. had appointments with Respondent on both May 18 and May 26, 2011. GX 11, at 52–53. Moreover, on May 17, 2011, Respondent wrote R.J.H. a new prescription for 120 tablets of methadone 10 QID and PRN), and on May 26, 2011, he wrote R.J.H. another prescription for 120 tablets of methadone 10 (QID and PRN). GX 18, at 15–16, 19–20. Attempting to interpret Respondent's handwriting on the May 26 progress note, Dr. Mitchell thought that R.J.H. had reported "that the prescription was stolen," Tr. 339, and according to a notation on the May 26 prescription, R.J.H. told the pharmacist that "he was beat[en] up and his meds were stolen." GX 18, at 20. A further notation on the prescription states: "Early refill Ok'd by Dr. Ataya Police Report on file. Per Christina @Dr. Ataya's." *Id.*

Dr. Mitchell testified that when a patient claims that his medication has been stolen, "there needs to be some action on the patient[s]" part. Tr. 339. According to Dr. Mitchell, "part of the opioid contract [is] that if medications are stolen, you have to make a police report." *Id.* There is, however, no police report in R.J.H.'s file. *See generally* GX 11. Nor is there an opioid contract. *See also generally id.*; Tr. 341.

On June 8, R.J.H. again saw Respondent. GX 11, at 51. A nurse's note on the progress note states: "meds (stolen)." *Id.* Dr. Mitchell testified that the appropriate response to this information would be to discharge the patient. Tr. 340–41. Dr. Mitchell subsequently explained that the point at which Respondent should have discharged R.J.H. was "after the second report of medications being stolen" without verification "of that event happening." *Id.* at 342. Dr. Mitchell further noted that while Respondent documented that R.J.H. "has a history of narcotic abuse," there is no evidence that Respondent required him to sign a pain management contract. *Id.* at 341. Dr. Mitchell also found no evidence that Respondent conducted any drug tests on R.J.H. and there were no MAPS reports in R.J.H.'s file. *Id.* at 341–42.

The evidence also shows that on June 7, 2011, an employee of Respondent documented that he/she "was told by another patient that [R.J.H.] was selling his prescription of methadone, and taking his girlfriend[']s prescription as his own." GX 11, at 9. While Respondent did not prescribe

methadone to R.J.H. at the June 8 visit,²⁹ on June 15, 2011, he issued R.J.H. another prescription for 60 tablets of methadone 5 to be taken twice a day or PRN. GX 18, at 21–24.

While this prescription should have lasted R.J.H. for 30 days, only six days later on June 21, 2011, Respondent issued to R.J.H. a prescription for 60 tablets of methadone 10, thereby doubling the daily dose. *Id.* at 25–26. Thus, this refill was early by 24 days.

Moreover, Respondent continued to provide R.J.H. with additional early refills. Specifically, only 15 days later on July 6, Respondent issued to R.J.H. a prescription for 60 methadone 10 (BID/PRN). *Id.* at 27–28. Even ignoring the June 15 prescription, this refill was early by 15 days.

Only 13 days later on July 19, 2011, Respondent issued to R.J.H. a prescription for 120 of methadone 10 (QID, or four times a day), thereby doubling the daily dose and quantity. *Id.* at 29–30. And on August 11, 2011, he issued to R.J.H. another prescription for 120 tablets of methadone 10 to be taken four times a day or PRN. *Id.* at 31–32. Even ignoring the prescriptions prior to July 19, this prescription was still one week early.³⁰

As Dr. Mitchell testified, there was no justification for Respondent's rapid escalation of R.J.H.'s daily dose. Also, Respondent ignored red flags such as R.J.H.'s claim on two occasions that his prescription had been stolen, the report that he was selling his methadone and using his girlfriend's, and R.J.H.'s repeated seeking of early refills, some of which were weeks early. Moreover, while Respondent knew that R.J.H. had a history of narcotic abuse he did not require him to sign a pain contract, never conducted a drug test on him, and never obtained a MAPS report. Based on the above, I find that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice when prescribed methadone to R.J.H. 21 CFR 1306.04(a).

J.H.

The Allegations

The Show Cause Order alleged that from June 10, 2010 through August 12, 2012, Respondent repeatedly prescribed controlled substances to J.H. even after he knew that she was engaged in the

²⁹ Rather, he prescribed 30 tablets of Tylenol with Codeine No. 3 ("Tylenol 3").

³⁰ Thereafter, Respondent issued additional methadone prescriptions to R.J.H. on an approximately monthly basis up until January 3, 2012, the same day he overdosed on heroin and was hospitalized. GX 23, at 6–8. As found above, R.J.H. died of an overdose on or about January 5, 2012. GX 5, at 1.

abuse and/or diversion of controlled substances. ALJ Ex. 1, at 5. Specifically, the Government alleged that Respondent repeatedly prescribed controlled substances to her notwithstanding numerous red flags of diversion and/or abuse, including that:

- J.H. repeatedly sought early refills;
- J.H. requested controlled medications by name;
- J.H. was in frequent contact with Respondent's office regarding her pain medications;
- J.H. tested negative for controlled substances that Respondent had prescribed to her;
- Respondent diagnosed J.H. as narcotic dependent;
- hospital records in Respondent's file show that J.H. tested positive for illegal drugs; and
- J.H. exhibited symptoms of withdrawal.

Id. at 5–6.

The Show Cause Order also alleged that J.H.'s patient files and the prescriptions Respondent issued to her show that he:

- Issued controlled substance prescriptions to J.H. on her initial visit without taking actions typical of medical professionals such as conducting and documenting a complete medical history and physical examination, and creating a written treatment plan;
- diagnosed J.H. as being narcotic dependent but took no actions such as referring her to rehabilitation or a specialist, or even minimal precautionary steps such as requiring her to sign a pain management contract, subjecting her to comprehensive drug tests, or even running MAPS reports on her, and that MAPS reports would have shown that she was engaged in doctor and pharmacy shopping;
- prescribed two different benzodiazepines—Klonopin and Xanax—to J.H. even after she reported that she would not be using Xanax but using Klonopin instead;
- repeatedly prescribed methadone to J.H. to be taken “PRN”; and
- prescribed Adderall to J.H. without any basis for doing so, continued to prescribe Adderall after drug tests showed that she was not taking the drug, stopped conducting drug tests to determine if J.H. was taking the Adderall he prescribed, and only stopped prescribing the drug when the Michigan Medicaid program asked him to substantiate his prescriptions.

Id. at 6.

The Evidence

The progress note for J.H.'s November 10, 2010 visit shows that on that date,

Respondent diagnosed J.H. as “narcotic dependent.” GX 12, at 125; Tr. 343. While Dr. Mitchell stated that he did not know if Respondent was “trying to indicate a history of abuse by that statement or he wasn't familiar with the definitions of addiction versus dependence,” he explained that the decision to start a patient on methadone “depends on the history you gleaned from the patient and what the old medical records showed,” because “you're essentially becoming their addictionologist and beginning treatment for them.” *Id.* at 346. However, according to Dr. Mitchell, when a physician determines that a patient is narcotic dependent, it is not appropriate to prescribe methadone without requiring the patient to sign an opioid agreement, conduct drug tests, and obtain a prescription monitoring program report. *Id.* at 346–47.

There is, however, no evidence that Respondent required J.H. to enter an opioid agreement. Tr. 347; *see also* GX 12 (J.H.'s patient file). Moreover, while Respondent did eventually obtain a MAPS report, he did not do so until November 30, 2012, more than two years after he diagnosed her as narcotic dependent.³¹ *See* GX 12, at 8–13.

The evidence shows that on November 26, 2010, Respondent issued to J.H. a prescription for 90 methadone 5 (TID), a 30-day supply. GX 19, at 21–22. Yet, according to J.H.'s file, on December 1, 2010, she was suffering from narcotic withdrawal. Tr. 349. Dr. Mitchell testified that when confronted with this situation, the appropriate response of a physician acting within the bounds of professional practice is to send the patient “to the hospital.” *Id.* When then asked if it was an appropriate response to continue to issue controlled substance medication to the patient, Dr. Mitchell testified “absolutely not.”³² *Id.* at 349–50. At this

³¹ The report shows prescriptions beginning only on August 31, 2011. GX 12, at 8–13. The report shows several instances in which J.H. obtained small amounts of hydrocodone and acetaminophen with codeine from a dentist in the May 2012 time period, and a further prescription for a small amount of hydrocodone from another dentist on September 14, 2011. GX 12, at 8, 13. However, every other prescription listed in this report was issued by Respondent.

Of note, the Government also submitted a MAPS report it obtained showing J.H.'s prescriptions from January 8, 2010 through February 2013. However, the questioning regarding the MAPS reports was interrupted by telephonic interference seven times and is not clear what the precise questions were and which of the MAPS reports the Government was referring to in its questions. Tr. 348–49.

³² A DEA regulation, however, expressly authorizes a physician to administer (but not prescribe) a “narcotic drug [] to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made

point, the ALJ declared the line of questioning “redundant” and no further clarification was obtained as to whether Dr. Mitchell was referring to prescribing or administering. Yet the evidence shows that Respondent continued to prescribe methadone and other controlled substances to her. GX 24.

The evidence further shows that on September 8, 2010, J.H. called Respondent's office “and stated that she stopped Xanax³³ and went back to Klonopin b/c she didn't like the way it made her feel.” GX 12, at 7. Respondent provided J.H. with prescriptions for 60 clonazepam on September 15, October 13, November 10, and a prescription for 30 tablets on November 30, 2010. GX 24, at 5–8.

However, on December 1, 2010, he issued J.H. a prescription for 60 alprazolam 1.³⁴ *Id.* at 8. Moreover, only one week later on December 8, Respondent issued J.H. a prescription for 90 clonazepam. *Id.* While on January 4, 2011, Respondent issued her another prescription for 90 clonazepam, on January 13, he issued her a prescription for 30 alprazolam 1. *Id.* In the ensuing months, Respondent continued to provide J.H. with both clonazepam and alprazolam prescriptions, even though both drugs are benzodiazepines.³⁵ According to Dr. Mitchell, there was “[n]o” medical reason for Respondent to prescribe both drugs after J.H. stated that she did not like how the alprazolam made her feel. Tr. 351.

The evidence also shows that on August 3, 2011, Respondent issued J.H.

for referral for treatment.” 21 CFR 1306.07(b). This is so even when the physician “is not specifically registered to conduct a narcotic treatment program.” *Id.* However, the physician may not administer “more than one day's medication” at a time and may not do this for “more than three days.” *Id.*

³³ Respondent had prescribed 30 alprazolam .25 mg to J.H. on August 31, 2010. GX 24, at 4.

³⁴ J.H. filled the Nov. 30 clonazepam prescription and the December 1 alprazolam prescription on the days they were they were issued.

³⁵ The evidence shows that during 2011, Respondent issued J.H. prescriptions for 90 clonazepam on Feb. 2, Mar. 1, April 5, May 3, June 1, June 28, July 26, August 25 (with three refills which were filled on Sept. 21, Oct. 15, and Nov. 10), and Dec. 13. GX 24, at 9–12. During 2011, he also issued J.H. prescriptions for 90 alprazolam 1 on Mar. 15, for 30 alprazolam .5 on April 20, and for 30 alprazolam .25 on June 21. *Id.* at 9–11.

During 2012, Respondent issued J.H. a prescription for 90 clonazepam on Jan. 5, with three refills that were filled on Feb. 1, Feb. 19, and Mar. 10; a prescription for 90 clonazepam on Mar. 28; a prescription for 120 clonazepam on April 25, with three refills, two of which were filled on May 15 and June 6; a second prescription for 120 clonazepam on April 25, which was filled on July 4; and two prescriptions for 90 clonazepam on August 14, one of which was filled the same date, the other being filled on December 8. *Id.* at 14–17. Respondent also issued her a prescription for 15 alprazolam .5 on May 22, 2012. *Id.* at 15–16.

a prescription for 30 Adderall 10, with a dosing instruction to take one tablet daily. GX 19, at 71–72. However, at J.H.'s August 31, 2011 appointment, J.H. tested negative for the drug; a note on the drug screening results sheet states: "last Adderall 2 days ago." GX 12, at 61. Respondent, however, issued her a new prescription for 30 Adderall 10 at the visit. GX 19, at 77–78.

Dr. Mitchell testified that J.H.'s clean urine tests raised the same concerns (*i.e.*, that the patient was either abusing or diverting the drug to others) as he testified to when asked about the significance of a negative test for methadone. Tr. 352. He also testified that Respondent's issuance of a new Adderall prescription after the negative test result raised the same concern that the prescription was "outside the typical practice of medicine." *Id.*

Finally, the Government questioned Dr. Mitchell as to whether there was a point at which Respondent should have stopped prescribing controlled substances to J.H. *Id.* at 355. According to Dr. Mitchell, "in the face of [J.H.'s] history of drug abuse . . . [a]fter the second negative urine that would be a [sic] unavoidable, irrevocable sign to discharge her from the practice." *Id.* However, while the Patient Drug Screening Results form states that J.H. was negative for amphetamine on October 11, 2011 and includes the notation "Ran out 8 days ago," GX 12, at 61; on the date of this test, Respondent had last issued her an Adderall prescription on August 31, 2011, and that prescription provided her with a 30-day supply.³⁶ As there is no evidence as to how long amphetamines would still be present in a patient's urine after the last use, no weight can be given to this testimony. What is notable, however, is that over the entire course of Respondent's prescribing to J.H., which lasted from June 10, 2010 through August 12, 2012, Respondent conducted only three urine tests, with the last one being done on November 15, 2011. GX 12, at 61.

Notwithstanding that no weight can be given to Dr. Mitchell's testimony regarding the October 11, 2011 drug tests, I find that the evidence otherwise supports a finding that Respondent provided J.H. with controlled substance prescriptions which lacked a legitimate

³⁶ According to the ALJ, the parties stipulated that Respondent issued a prescription for 60 Adderall 10 on October 1, 2011. ALJ Ex. 50, at 5. However, the patient file does not contain a prescription for this date (as opposed to October 11, 2011) and the MAPS report which the Government obtained does not list any Adderall/amphetamine prescription as having been issued between August 31 and October 11, 2011. GX 24, at 12–13.

medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a). As the evidence shows, while Respondent knew that J.H. was dependent on narcotics, he: (1) Did not require her to sign an opioid agreement; (2) did not obtain a MAPS report on her until two years after he determined that she was dependent; (3) conducted only three drug tests over the course of the 26 months that he prescribed to her; (4), did not refer her to treatment when she was suffering from withdrawal even though he had given her a 30-day methadone prescription only five days earlier and continued to prescribe methadone to her; and (5) repeatedly prescribed both alprazolam and clonazepam to her, even after she had told him that she did not like the way the Xanax (alprazolam) made her feel.

Concluding its direct examination, the Government asked Dr. Mitchell: "Of the prescriptions that we have discussed today, are there any that you've found to be legitimate, issued for [a] legitimate purpose or within the usual practice of medicine?" Tr. 356. Dr. Mitchell answered: "Not for the controlled substances." *Id.*

Respondent's Testimony

Respondent testified on his own behalf. According to Respondent, he graduated from medical school in Damascus, Syria in 1993, and after moving to the United States, he did an internal medicine residency which he completed in 2002. Tr. 469. Thereafter, Respondent started practicing at nursing homes and assisted living facilities and also worked as an urgent care and ER physician. *Id.*; see also RX J. Respondent did this until 2009 when he purchased a "very small practice" of 120 patients in Davidson, Michigan from a retired physician. Tr. 470. Respondent testified that in the meantime he studied hospice and palliative medicine and became board certified in 2012. *Id.* at 469. On some date which Respondent did not specify, Respondent also began working at a medical practice in Lapeer, Michigan, which had 150 patients. *Id.* at 471.

According to Respondent, when he started his internal medicine practice, he "did not expect this influx of chronic pain patient[s], and . . . was not planning to have a clinic for chronic pain patients." *Id.* at 482. While addressing the DI's testimony regarding the statements he made in the 2013 interview, Respondent offered various statements regarding the "general" "way" in which he practices medicine. *Id.* at 484. Specifically, he testified that in 2011 and 2012, "we start to do it [*i.e.*,

obtain MAPS reports] more often, but definitely not in every visit." *Id.* at 482. He further asserted that "we do referral [of] patients for diagnostic, for another specialty, depends on their need." *Id.* He also asserted that he attempts to control his patients' symptoms, while "try[ing] to taper them off the medication, if possible, while they are getting another treatment like the physical therapy or going to the pain management, some going to counseling." *Id.* at 484.

As found above, Respondent acknowledged that he had "listened to all of" Dr. Mitchell's testimony. *Id.* Respondent then testified that Dr. Mitchell was "right" about his having ignored the red flags that the five patients were diverting or abusing drugs. *Id.*

Respondent further testified that he had reviewed multiple online Continuing Medical Education courses,³⁷ and that the week before the hearing, he attended a three-day "course about prescribing medication and dealing with the addicted patients." *Id.* at 486, 495. He also stated that he was referring his patients who have chronic pain to "pain management." *Id.* at 496. However, he then testified that it takes six to twelve weeks for a patient to obtain an appointment with pain management in the Lapeer, Michigan area and that in the meantime, he has "to continue the patient's treatment." ³⁸ *Id.*

Respondent further asserted that "[s]ince the interview on the show cause, it came to [his] attention some wrong way in doing and dealing with patients" and he "went back and review[ed] what he's been doing and inquire[d]." *Id.* at 495. He also testified that he had invested in electronic medical records because with three offices, it was a "major problem . . . following the patients." *Id.* He also

³⁷ However, it is unclear the extent to which these courses actually addressed the prescribing of controlled substances and the monitoring of patients for abuse and diversion. While Respondent also testified that he has subscribed to Audio Digest, a CME program which provides lessons on a CD with a questionnaire, he then acknowledged that this program "[h]as nothing to do with" his prescribing practices and involves "medical education in general internal medicine." Tr. 504–05.

³⁸ Following his testimony regarding his referring his chronic pain patients to pain management, Respondent's counsel asked him if he had also employed "some outside help to do criminal background checks of [his] existing patients, look at your current policies and procedures as they relate to pharmaceuticals that," at which point the transmission cut out. Tr. 497–98. When, however, the transmission was re-established, Respondent's counsel asked only: "Did you make any efforts to hire outside consultants to come and make some recommendations regarding your office?" *Id.* at 498.

hired a consultancy to review his practice's policies and procedures which met with his employees and discussed issues such as "communicat[ing] with the patients, keeping their records, follow[ing] their records, referring the patients, and talking to the families and patients." ³⁹ *Id.* at 499. Finally, Respondent bought a safe. *Id.*

On cross-examination, Respondent further asserted that after being served with the Show Cause Order, he started doing more frequent drug screening "to identify any problematic patients." *Id.* at 512. However, he also explained that "before we tried to do drug screening but it was very expensive for the patient because [it was] not covered" by a local insurance plan. *Id.* Moreover, he offered no further detail as to how frequent the screenings were.

Asked whether, in the period 2010–2012, he believed that doctors should not prescribe controlled substances to patients who are abusing or diverting them, Respondent testified: "If it is a proof they are abusing or diverting, yes." *Id.* at 520. Asked to explain what he meant by proof of abuse and diversion, Respondent answered:

Well, counseling the patient in the room and talking to them about their pain and their using their pain medication and the way, and what is their answer, for me I will take whatever the patient tell me.

If they said no, they are not abusing the medication, they are not diverting the medication, and I am entitled to treat their symptoms and make sure they are not going in withdrawal and take care of the patient.

Id. at 521. Asked whether he believed this today as much as he did in the 2010–2012 period, Respondent answered: "[y]es." *Id.*

The Government then asked Respondent whether he "believe[s] that doctors should detect when patients are abusing or diverting controlled substances?" *Id.* Respondent's counsel objected, on the ground that it was outside the scope of his direct examination and the ALJ sustained the objection.⁴⁰ *Id.* at 522. So too, when the Government asked Respondent if "[d]octors should respond to red flags of abuse and diversion of controlled substances," Tr. 526, Respondent

objected, and the ALJ sustained the objection. *Id.*

Next, the Government asked Respondent: "[w]hat are the signs for abuse and diversion of controlled substances?" *Id.* Respondent's counsel objected. After the ALJ overruled the objection, Respondent testified: "[w]hat do you mean diversion exactly?" *Id.* This prompted the ALJ to instruct Respondent that "if you don't know how to answer the question, just tell me that you don't know." *Id.* Respondent answered: "I do not." *Id.*

The Government then asked Respondent what signs he looks for to see if a patient is abusing medication. *Id.* at 527–28. Respondent answered:

Well, if they're using, now a patient if he is taking the pain medication and they have extra pain and taking medication, extra pill or extra two, this is a view that what you intend that it is abusing, well, it's still a pain medication they are using to control their symptoms. I don't understand what exactly what answer you want for that.

I'm telling you exactly what I think. If the patient using the pain medication instructed to control their pain medication, now if they come earlier to take medication that's if they have a chronic problem and they need it, somebody can call them abusing, some people calling them they are controlling their pain symptoms.

Id.

After again admitting that he "did not pay attention too much to this [sic] signs with the red flags and things," *id.*, Respondent asserted that in determining whether patients are abusing controlled substances, "[w]e do the drug screen" and "[w]e run a MAP with the electronic medical records if they are taking the medication the right way and taking the other alternative medications." *Id.* at 529. Asked by the ALJ how he is now treating pain management patients, Respondent explained that if patients "ask for more medication or [to] change to a specific medication and . . . looking in the drugs screen, if they are utilizing the medication." *Id.* After apparently more telephonic interference, Respondent added that when patients ask for an early refill or a different medication or to increase their pain medication, "to confirm we'll do the drug screen and we'll run the MAP." *Id.* at 531.⁴¹

After confirming that Respondent was adhering to his earlier testimony that Dr. Mitchell was correct that he had ignored red flags of abuse and diversion, the

Government asked Respondent whether he also agreed with Dr. Mitchell's testimony that he had "issued prescriptions outside of the usual course of practice or for nonlegitimate medical purposes?" *Id.* at 534. Respondent's counsel objected, asserting that "[w]e've said everything Dr. Mitchell has said about prescribing in the face of red flags is correct." *Id.* at 535. The ALJ did not, however, rule on the objection. *See id.* Instead, the ALJ asked Respondent if he had read the Show Cause Order, and after Respondent acknowledged that he had, the ALJ asked if he "agree[d] that the facts that they allege there are all true?" *Id.* Respondent answered "[y]es." *Id.*⁴²

Discussion

As noted above, both parties filed exceptions to the ALJ's Recommended Decision. Having reviewed their briefs, I conclude that some of their exceptions are best addressed prior to discussing whether the Government is entitled to prevail under the public interest standard. These include Respondent's contention that the ALJ committed prejudicial error when he barred him from cross-examining the Diversion Investigator regarding the use of confidential informants. *See Resp. Exceptions*, at 9–12. As for the Government, it argues that the ALJ erred when he allowed Respondent to present his case by VTC. *Gov. Exceptions*, at 3–9.

Respondent's Exception to the ALJ's Ruling Limiting Cross-Examination

As found above, at the hearing, a DEA Diversion Investigator testified regarding the investigation she

⁴² Subsequently, during a colloquy with the ALJ as to whether it could cross-examine Respondent regarding the specific prescriptions discussed by Dr. Mitchell and whether he agreed with Dr. Mitchell's testimony that the prescriptions "were issued illegitimately and outside of the usual course," the Government observed that Respondent was shaking his head; the Government thus argued "that there is some ambiguity as to whether or not he's really admitting that he has actually issued those unlawfully." Tr. 538–39. The ALJ explained: "[n]ot according to my record" and that he had seen "the shaking of the head." *Id.* at 539. The record does not, however, reflect the manner in which Respondent shook his head, and notwithstanding the tenor of the Government's statement, I am not free to speculate as to whether Respondent was disputing or acknowledging that he acted unlawfully.

Notably, in his Post-Hearing Brief, Respondent states that Dr. Mitchell's testimony establishes that he "wrote a substantial number of prescriptions . . . without a legitimate medical purpose and/or in the usual course of a practitioner's professional practice and/or in the face of paradigmatic 'red flags' of diversion or abuse such as repeated requests for early refills, facially-evident documentation of doctor shopping, and testing results inconsistent with use of the prescribed controlled substances." *Resp. Post-Hrgng Br.* at 12.

³⁹ This, however, did not occur until mid-September 2014. Tr. 509.

⁴⁰ When the Government attempted to re-ask the question, Respondent's counsel again objected on the ground that because Respondent has testified that Dr. Mitchell was correct in his criticism of his practice, "how much stronger can we say that we adopt Dr. Mitchell's testimony as to us ignoring those red flags and prescribing in the face of those." Tr. 524. The ALJ against sustained the objection.

⁴¹ The Government then asked Respondent what steps "a doctor should and could take in response to any signs that a patient is abusing their controlled substance medications?" *Id.* at 531–32. The ALJ sustained Respondent's objection stating that he had "a record of that." *Id.* at 532.

conducted of Respondent's prescribing practices. On cross-examination, Respondent's counsel attempted to question the DI about two undercover agents who, according to the proffer, went to Respondent, and while posing as patients, attempted to entice him to prescribe controlled substances in exchange for cash. Tr. 222. The Government objected to this line of questioning, arguing that the evidence "was not offered as part of the basis for the order to show cause." *Id.*

In response to the objection, Respondent argued that the Agency "is required to consider not just the evidence that [the Government] brought in on the direct, but evidence that we can bring out on cross examination." *Id.* Respondent then proffered that Respondent told the undercover agents that "he would not" prescribe to them. *Id.* Respondent argues that this "is exculpatory" because Respondent "had no idea who he was talking to" and this evidence "would be very relevant to [assessing] his state of mind." *Id.* at 222–23.

The ALJ sustained the objection, on the ground that Respondent had failed to disclose in advance of the hearing that he "wanted to cover this subject." *Id.* at 223. Continuing, the ALJ explained that "[i]f you knew about these things, and you wanted me to consider them, then you had a duty and the opportunity to come forward and tell me. And I saw nothing like that in your pre-hearing statements, or that of prior counsel." *Id.* at 223–24.

Respondent then argued that his counsel had not had "the time that the Government had to prepare" for the hearing and that there was no prejudice to the Government, because "these are their witnesses." *Id.* at 224–25. The ALJ rejected the contention, explaining that "you had knowledge of this undercover operation. If you wanted to bring it to my attention, you clearly had it for a while." *Id.* at 226.⁴³

Even assuming that the Government's direct examination of the DI as to what steps she took in investigating Respondent opened the door to this line of inquiry, the ALJ did not abuse his discretion in sustaining the Government's objection. See *Gunderson v. Department of Labor*, 601 F.3d 1013, 1021 (10th Cir. 2010) (applying abuse of discretion standard in reviewing ALJ's exclusion of evidence); *Walter A. Yoder*

& Sons, Inc. v. NLRB, 754 F.2d 531, 534 (4th Cir. 1985) (applying abuse of discretion standard in reviewing ALJ's decision to limit cross-examination). Moreover, the warrant return listed the actual names (as well as the undercover names) of both undercover officers. Thus, Respondent had ample opportunity to present this evidence either through calling the undercover officers to testify or by introducing any documentation he placed in their respective patient files regarding the incidents. See *Randall L. Wolff*, 77 FR 5106, 5120 n.23 (2012).

To be sure, DEA has recognized that in some instances, evidence of "prior good acts" can refute evidence that a registrant knowingly or intentionally diverted controlled substances. See *Jayam Krishna-Iyer*, 74 FR 459, 462 n.6 (2009). Here, however, the Government put forward extensive evidence to show that Respondent acted with the requisite knowledge to support the conclusion that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice and thereby violated the CSA on some 100 occasions when he prescribed to the five patients. See 21 CFR 1306.04(a); see also 21 U.S.C. 841(a)(1). Moreover, even if Respondent's testimony regarding Dr. Mitchell's criticism of his prescribing practices was ambiguous as to whether he was also admitting that he violated 21 CFR 1306.04(a), his post-hearing brief has resolved the issue.

Accordingly, even if I had found that the ALJ abused his discretion in not permitting Respondent to cross-examine the DI about the two undercover visits, I would still conclude that this does not rise to the level of prejudicial error. See *Gunderson*, 601 F.3d at 1021 ("An error is prejudicial only 'if it can be reasonably concluded that with . . . such evidence, there would have been a contrary result.'") (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).

In his Exceptions, Respondent further notes that the ALJ "frames this issue as one 'regarding arguably exculpatory evidence that has been withheld by the Government.'" Exceptions, at 9 (citing R.D. at 60–62). He then states that he adopts and incorporates by reference the ALJ's view, and requests that I consider it as a separate argument.

Therein, the ALJ noted that the Agency has not adopted "[t]he rule from *Brady v. Maryland*," 373 U.S. 83, 87

(1963), which requires the prosecution in a criminal case to disclose material exculpatory evidence to the defendant. R.D. at 61. Citing *MacKay v. DEA*, 664 F.3d 808, 819 (10th Cir. 2011), the ALJ correctly noted that "even if *Brady* did apply in this case, the excluded evidence would have no outcome [sic] on my final recommendation." R.D. at 62. The ALJ nonetheless proceeded to discuss several cases in which other ALJs had either: (1) Ordered the Government to review its files for exculpatory evidence, or (2) suggested that DEA should provide for disclosure of exculpatory evidence because three other federal agencies provide for such disclosure. *Id.* The ALJ noted that the Agency has held that there is "an ongoing duty to ensure that material evidence and argument made to a factfinder is not knowingly contradicted by other material evidence in the Government's possession, but not otherwise disclosed." *Id.* (quoting *Randall L. Wolff*, 77 FR 5106, 5124 (2012)). However, based on an earlier case in which the Agency held that an ALJ did not have authority to require the Government to "disclose any exculpatory information in its possession when such information is timely requested by a respondent," see *Nicholas A. Sychak*, 65 FR 75959, 75960–61 (2000), the ALJ opined "that the DEA's view of releasing exculpatory evidence is 'just trust me.'" R.D. at 62.

Unacknowledged by the ALJ is that several federal appeals courts have held that *Brady* does not apply to administrative proceedings. See *Mister Discount Stockbrokers, Inc. v. SEC*, 768 F.2d 875, 878 (7th Cir. 1985); *NLRB v. Nueva Eng. Inc.*, 761 F.2d 961, 969 (4th Cir. 1985). Cf. *Echostar Comm. Corp. v. FCC*, 292 F.3d 749, 755–56 (D.C. Cir. 2002) (rejecting litigant's claim that "the Agency's decision to deny it discovery . . . denied it due process"); *Silverman v. CFTC*, 549 F.2d 28, 33 (7th Cir. 1977) ("There is no basic constitutional right to pretrial discovery in administrative proceedings.") (citations omitted).

Instead, this Agency follows the holding of *McClelland v. Andrus*, 606 F.2d 1278 (D.C. Cir. 1979). Therein, the D.C. Circuit held that "discovery must be granted [in an administrative proceeding] if in the particular situation a refusal to do so would so prejudice a party as to deny him due process." *Id.* at 1285–86; see also *Margy Temponeras*, 77 FR 45675, 45676 n.4 (2012); *Beau Boshers*, 76 FR 19401, 19403–04 (2011). However, "the party seeking discovery must rely on more than speculation and must show that the evidence is relevant, material, and that the denial of access to the [evidence] is prejudicial." *Boshers*,

⁴³ The record shows that Respondent became aware that two undercover officers had visited Respondent from the return of the state search warrant which listed the two officers' files as being among the items seized. Resp. Ex. A, at 7. However, the return was executed on March 27, 2013, *id.* at 6; which was well in advance of the hearing.

76 FR at 19403 (citing *Echostar*, 292 F.3d at 756; *Silverman v. CFTC*, 549 F.2d 28, 34 (7th Cir. 1977)). As explained previously, while evidence that Respondent refused to prescribe controlled substances to the undercover officers is relevant and material in assessing his experience as a dispenser of controlled substances, in light of his concession that he knowingly diverted controlled substances some 100 times to the five patients, he cannot show prejudice.⁴⁴ I thus reject the exception.⁴⁵

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to “dispense a controlled substance . . . may be suspended or revoked by the Attorney General 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.” 21 U.S.C. 824(a)(4) (emphasis added). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

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

(2) The applicant’s experience in dispensing . . . 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.

Id. 823(f).⁴⁶

⁴⁴ It is noted that Respondent requested that the ALJ provide him with a copy of the Agency’s investigative files on him; the ALJ correctly held that he had no power to compel the Agency to provide Respondent with its investigative files. ALJ Ex. 3, at 5.

⁴⁵ I have considered the Government’s Exception regarding the ALJ’s decision to allow Respondent to present his case by Video Teleconferencing technology. While I acknowledge that technical difficulties caused a number of interruptions during the hearing in this matter, the record nonetheless contains overwhelming evidence supporting my Decision and Order.

⁴⁶ Section 304(a) also provides that a registration to “dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent state authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances.” 21 U.S.C. 824(a)(3). Likewise, the CSA defines “[t]he term ‘practitioner’ [to] mean[] a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to distribute,

“[T]hese factors are . . . considered in the disjunctive.” *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). It is well settled that I “may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.” *Id.*; see also *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I “need not make explicit findings as to each one.” *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222 (quoting *Hoxie*, 419 F.3d at 482)).⁴⁷

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. 824(a) are met. 21 CFR 1301.44(e). However, “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.” *MacKay*, 664 F.3d at 817 (citing *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (citing cases)).

In this matter, the Government’s evidence focused on factors two, four, and five. Having reviewed the record in its entirety and having considered all of the factors, I find that the Government’s evidence with respect to factors two and four satisfies its *prima facie* burden of showing that Respondent has committed acts “which render his registration . . . inconsistent with the public interest.” 21 U.S.C. 824(a)(4).

dispense, [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. 802(21). See also *id.* § 823(f) (“The Attorney General shall register practitioners . . . to dispense . . . controlled substances in schedule II, III, IV, or V . . . if the applicant is authorized to dispense controlled substances under the laws of the State in which he practices.”).

⁴⁷ 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; what matters is the seriousness of the registrant’s misconduct. *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay*, 664 F.3d at 821.

Factors Two and Four—Respondent’s Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is not “effective” unless it is “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). Continuing, the regulation provides that “an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” *Id.*

As the Supreme Court has explained, “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135, 143 (1975)).

Both this Agency and the federal courts have held that establishing a violation of the prescription requirement “requires proof that the practitioner’s conduct went beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence.” *Laurence T. McKinney*, 73 FR 43260, 43266 (2008) (quoting *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006)). See also *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006) (“[T]he *Moore* Court based its decision not merely on the fact that the doctor had committed malpractice, or even intentional malpractice, but rather on the fact that his actions completely betrayed any semblance of legitimate medical treatment.”).

Thus, in *Moore*, the Supreme Court reinstated the conviction of a physician under 21 U.S.C. 841(a)(1) and what is now 21 CFR 1306.04(a) for prescribing controlled substances outside of the usual course of professional practice. 423 U.S. at 139–43. The Court explained:

The evidence presented at trial was sufficient for the jury to find that respondent’s conduct exceeded the bounds of “professional practice.” As detailed above, he gave inadequate physical examinations or none at all. He ignored the results of the tests

he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patients demanded. . . . In practical effect, he acted as a large scale “pusher”—not as a physician.
Id. at 142–43.

Under the CSA, it is fundamental that a practitioner must establish a bona fide doctor-patient relationship in order to act “in the usual course of . . . professional practice” and to issue a prescription for a “legitimate medical purpose.” *See, e.g., Moore*, 423 U.S. at 142–43; *United States v. Lovern*, 590 F.3d 1095, 1100–01 (10th Cir. 2009); *United States v. Smith*, 573 F.3d 639, 657 (8th Cir. 2009); *Jack A. Danton*, 76 FR 60900, 60904 (2011) (finding violations of 21 CFR 1306.04(a) “where a physician has utterly failed to comply with multiple requirements of state law for evaluating her patients and determining whether controlled substances are medically indicated and thus has “completely betrayed any semblance of legitimate medical treatment””) (quoting *McKinney*, 73 FR at 43266 (quoting *Feingold*, 454 F.3d at 1010)).

However, while the Government frequently relies on a physician’s failure to establish a bona-fide doctor-patient relationship to prove a violation of 21 CFR 1306.04(a), no “specific set of facts ha[s] to be present in order to find that a physician stepped outside of his role and issued prescriptions without a legitimate medical purpose.” *United States v. McKay*, 715 F.3d 807, 823 (10th Cir. 2013). Thus, as the Tenth Circuit explained, the question is whether sufficient evidence “exist[s] for a fact finder to affirmatively determine that the physician issued the drugs for an improper purpose.” *Id.*

As found above, Dr. Mitchell offered extensive and uncontested testimony that included identifying specific acts and omissions by Respondent, which support the conclusion that Respondent acted outside of the usual course of professional practice and without a legitimate medical purpose when he prescribed controlled substances to each of the five patients. He also opined that none of the prescriptions he discussed complied with 21 CFR 1306.04(a). Tr. 356.

In his post-hearing brief, Respondent states that Dr. Mitchell’s testimony establishes that he “wrote a substantial number of prescriptions . . . without a legitimate medical purpose and/or in the usual course of a practitioner’s professional practice and/or in the face of paradigmatic ‘red flags’ of diversion or abuse such as repeated requests for

early refills, facially-evident documentation of doctor shopping, and testing results inconsistent with use of the prescribed controlled substances.” Resp. Proposed Recommended Rulings, Findings of Fact and Conclusions of Law, at 12. Respondent, however, also attempts to portray himself as a soft touch, suggesting that it is “culturally ingrained” that he could “not say no” to patients, and that he prescribed “with some naivety and perhaps even full-blown gullibility,” which was “laid bare when the size of his practice grew exponentially faster than he and his staff” were capable of managing. Respondent’s Post-Hrng. Submission, at 1–2. *See also id.* (“These proceedings have also opened [his] eyes to the fact that his knowledge and experience as a medical practitioner contained gaps that proved easy to exploit.”).

The ALJ embraced this argument. *See* R.D. at 43 (quoting Resp. Post-Hrng. Submission, at 2) (Respondent’s “lack of knowledge, experience, and familiarity with accepted protocols for prescribing controlled substances, combined with some naivety and perhaps full-blown gullibility, where laid bare when the size of his practice great exponentially faster. . . .”); *see also id.* at 43–44 (“Here, it appeared [Respondent] became a very popular weak link used by those seeking to circumvent [controlled substance prescribing] protocols.”). The ALJ also stated his agreement “with the proposition appearing in [his] post-hearing brief that ‘his practice did not consist of a “pill mill” and that *however misguided*, he was nevertheless *treating* his patients, not merely processing their prescriptions in furtherance of a larger criminal enterprise.” R.D. 47 (quoting Resp. Prop. Recommended Rulings, etc., at 12) (first emphasis added; second emphasis in original). *See also id.* at 44 (“I found no evidence to suggest the failures in his practice were the results of avarice or greed . . .”).

Contrary to the ALJ’s understanding, the Government was not required to prove that Respondent was motivated by avarice or greed to establish a violation of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1). Nor did the ALJ reconcile the inconsistency between his findings that that Respondent violated 21 CFR 1306.04(a) with respect to each of the patients—findings which establish that he knowingly diverted drugs—with his embrace of Respondent’s claim that he was merely naïve and gullible. Indeed, Respondent offered no testimony to support the claims made in his brief that he prescribed out of naivety or gullibility,

or that his inability to say no was “culturally ingrained.”

As for the ALJ’s embrace of Respondent’s claim that he was not running a pill mill and was treating his patients, to be sure, there is some evidence that Respondent referred patients for MRIs, a sleep study, and alternative treatments such as a chiropractor and physical therapy. However, the overwhelming weight of the evidence shows that Respondent issued the prescriptions knowing that the patients were either abusing or diverting the drugs.

With respect to R.E.H., Dr. Mitchell found Respondent’s initial evaluation to be inadequate based on Respondent’s failure to adequately develop his substance abuse history and how much methadone he was currently taking. He further found that Respondent did not perform an adequate physical examination. He therefore concluded that Respondent acted outside of the usual course of professional practice in issuing the initial methadone prescriptions. Based on this testimony, I find that Respondent did not establish a bona fide doctor-patient relationship and I further conclude that at no point in the course of his treatment of R.E.H. did Respondent do so.

Dr. Mitchell further described a plethora of instances in which Respondent provided R.E.H. with early refills and failed to document that he had engaged R.E.H. as to why he needed the early refills. Dr. Mitchell pointed out that Respondent failed to enforce his medication contract which required R.E.H. to use his medicine only at the prescribed rate. He also pointed out that Respondent continued to prescribe without obtaining urine samples, and only rarely obtained a MAPS report. Moreover, even when he did obtain and review a MAPS report, the MAPS report showed that R.E.H. had filled the same prescriptions at different pharmacies, and yet Respondent failed to even address R.E.H.’s behavior and continued to prescribe methadone to him. So too, Respondent was notified on multiple occasions that R.E.H. was trying to fill multiple prescriptions and presenting forged prescriptions, and yet did nothing to address this obvious drug-seeking behavior and continued to prescribe to him. Finally, even after he received a report that R.E.H. had tested positive for cocaine and was diagnosed as polysubstance dependent, he continued to prescribe to R.E.H. In short, given the numerous times that R.E.H. sought early refills, coupled with the information Respondent obtained from MAPS reports, pharmacies and the hospital, Respondent cannot credibly

argue that he was merely gullible or naïve. Rather, Respondent knowingly diverted controlled substances to R.E.H.

The same holds true with respect to Respondent's prescribings to J.W. Here too, Dr. Mitchell testified that there was no clinical basis to diagnose J.W. with a condition that would support prescribing both Adderall and methadone. He also testified that it was inappropriate to prescribe methadone on a PRN basis. Moreover, Respondent ignored evidence that J.W. was obtaining Adderall from another physician, in violation of the medication contract, as well as that J.W. was obtaining Suboxone from the other physician. J.W. also sought early refills on multiple occasions, yet Respondent continued to prescribe to him.

Also, the same day that Respondent was informed that J.W. was in the county jail, Respondent obtained a MAPS report which showed that J.W. had continued to obtain controlled substances for Suboxone and Adderall from another doctor at the same time he was obtaining prescriptions from Respondent. Moreover, Respondent was notified by J.W.'s niece that her uncle was selling his medications. Yet notwithstanding this information, after J.W. was released from jail, Respondent eventually resumed prescribing controlled substances to him. Here again, the evidence amply refutes the contention that Respondent was merely gullible or naïve.

With respect to R.K., the evidence showed that Respondent issued multiple prescriptions for Xanax, which frequently authorized multiple refills, resulting in R.K. obtaining, in a nine-month period, approximately 1,000 pills more than were necessary based on Respondent's dosing instructions. Given that R.K.'s chart contained copies of the prescriptions, Respondent cannot credibly argue that he was duped by R.K. into issuing the excessive prescriptions. Also, while Respondent prescribed methadone to R.K., on two occasions, R.K. tested negative for the drug, stating after the first test that he had run out a week earlier, and after the second, stating that he had run out several days earlier. Yet there was no documentation that R.K. had undergone withdrawal, this being a clear indication that R.K. was diverting the drug. Respondent continued to prescribe the drug to R.K. (going so far as to double the strength after the first negative test) and did not subject him to any more drug tests after the second test. The evidence thus shows that Respondent was willfully blind to what R.K. was doing with the drugs. Moreover, Dr. Mitchell testified that there was no

medical evidence to support the methadone prescriptions. Here again, the evidence amply refutes the contention that Respondent issued the prescriptions because he was gullible or naïve.

Respondent knew that R.J.H. had a history of drug abuse. Yet over the course of just six weeks, Respondent quadrupled R.J.H.'s daily dosage of methadone with no medical justification. Moreover, within three months of R.J.H.'s seeing Respondent, R.J.H. had twice claimed that his prescriptions were stolen, and the day before the second such incident, Respondent's office had been told by another patient that R.J.H. was selling his prescription and using his girlfriend's medication. Yet Respondent issued him another prescription and continued to prescribe methadone to him, even though R.J.H. sought early refills. Here again, the evidence refutes Respondent's contention that he issued the prescriptions because he was gullible or naïve.

So too, the evidence with respect to J.H. refutes Respondent's claim that he was gullible or naïve. Here the evidence shows that only five days after Respondent issued her a prescription for a 30-day supply of methadone, she was suffering from narcotic withdrawal. Yet, instead of sending her for treatment, Respondent continuing prescribing controlled substances to her. Moreover, over the course of his treatment of J.H., on multiple occasions, Respondent prescribed either alprazolam or clonazepam to her, both being benzodiazepines, even though he had recently prescribed the other drug to her. Also, even after J.H. reported that she did not like how alprazolam made her feel, he still issued her more prescriptions for the drug. So too, even after J.H. tested negative for Adderall, he issued her a new prescription for the drug. Finally, over the course of the 26 months Respondent treated her, he only drug tested her three times, with all three tests occurring in a three-month period. I thus conclude that Respondent knew or was willfully blind to the fact that J.H. was either abusing or diverting her drugs to others.

In addition to his issuance of numerous unlawful prescriptions, Respondent also violated federal law by writing a methadone prescription for R.E.H. which he dated as having been issued on November 8, 2012, when he likely issued it on October 30, 2012. Notably, the evidence shows that on October 8, 2012, Respondent issued R.E.H. a methadone prescription, which R.E.H. filled the same day. GX 15, at 135–36. The evidence also shows that

on October 30, R.E.H. was seeking more methadone and his medical record states that it was not time yet and includes a copy of a prescription bearing an issue date of November 8, 2012. GX 8, at 15; *id.* at 31. The evidence further shows that a second prescription with an issue date of October 8, 2012 (which appears to have been altered) was filled on October 30, 2012. GX 15, at 137–38; GX 20, at 14. Moreover, there are no notes corresponding to a visit by R.E.H. on November 8, 2012, and the MAPS data contains no entry for a methadone prescription with an issue date of November 8, 2012. *See* GX 8, at 15; *id.* at 99–100; *see also* GX 20.

Under a DEA regulation, “[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued.” 21 CFR 1306.05(a). Based on Respondent's failure to address the DI's testimony regarding this prescription and there being no evidence that R.E.H. saw Respondent on November 8, 2012, I find that Respondent violated this regulation when he post-dated the prescription.⁴⁸

The evidence also shows that Respondent repeatedly failed to include the patients' addresses on their prescriptions. *See, e.g.,* GX 8, at 21, 23, 27–38, 40–42, 52, 54–57, 64, 233, 240, 248–49, 253–54 (Pt. R.E.H.); *see also* GX 9, at 5–6, 45, 54, 57–59, 61–63, 68 (Pt. J.W.). This too is a violation of 21 CFR 1306.05(a).

Finally, the evidence shows that on several occasions, Respondent issued prescriptions that authorized six refills. GX 8, at 23 (Xanax Rx issued to R.E.H.); GX 17, at 49 (Xanax Rx issued to R.K.); GX 19, at 117 (Klonopin Rx issued to J.H.). Respondent violated DEA regulations when he issued the prescriptions because, with respect to schedule III and IV controlled substances, a prescription may not “refilled more than five times.” 21 CFR 1306.22(a).

Accordingly, I find that the Government's evidence with respect to Factors Two and Four conclusively establishes that Respondent has committed such acts as to render his registrations “inconsistent with the public interest.” 21 U.S.C. 824(a)(4); *see also id.* § 823(f). I further conclude that his misconduct is especially egregious and supports the revocation of his

⁴⁸ Even if it was R.E.H. who altered the date to “10/08/12,” if Respondent's intent was to provide R.E.H. with a prescription that he could not fill until November 8, then he should have written on the prescription “the earliest date on which a pharmacy” could fill it. 21 CFR 1306.12(b)(ii). In any event, Respondent was still required to date the prescription as of the date he issued it.

existing registrations and the denial of his pending applications.

Moreover, while the Government put on no evidence as to Factor One—the recommendation of the state licensing board—in response to my November 10, 2015 order, the Parties have acknowledged that on October 30, 2015, the Michigan Board of Medicine revoked Respondent's medical license and that he is longer legally authorized to dispense controlled substances in the State in which he is registered and seeks additional registrations.⁴⁹

Sanction

Under Agency precedent, where, as here, “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 [he] can be entrusted with the responsibility carried by such a registration.’’” *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))). “Moreover, because ‘past performance is the best predictor of future performance,’ *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.” *Medicine Shoppe*, 73 FR at 387; see also *Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). See also *Hoxie v. DEA*, 419 F.3d at 483 (“admitting fault” is “properly consider[ed]” by DEA to be an “important factor[]” in the public interest determination).⁵⁰

⁴⁹No evidence was presented regarding Factor Three—Respondent's conviction record for offenses related to the manufacture, distribution or dispensing of controlled substances. However, the Agency has held that the absence of a conviction is not dispositive of the public interest inquiry. *Dewey C. MacKay*, 75 FR 49956, 49973 (2010), *pet. for rev. denied*, *MacKay v. DEA*, 664 F.3d 808 (10th Cir. 2011). As for Factor Five, as explained above, the Government did not take exception to the ALJ's findings regarding the allegation that Respondent made various false statements in the interview.

⁵⁰However, while a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. See, e.g., *Joseph Gaudio*, 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. See

The ALJ found that Respondent “failed to take the full and unconditional acceptance of responsibility required by” the Agency's case law. R.D. at 55. As support for this conclusion, the ALJ noted that during his cross-examination of Dr. Mitchell, Respondent “challenged multiple aspects of the Government's evidence regarding [his] treatment of the patients that were fundamental to the Government's case against him.” *Id.* The ALJ also found that “Respondent's repeated and persistent pre-hearing assertions that his prescription practice was within the usual course of medical practice stand as compelling evidence that [he] had not accepted responsibility for his actions under the high standard established by the” Agency. *Id.* Thus, the ALJ declined to credit Respondent's testimony that he did not dispute Dr. Mitchell's criticism of his prescribing practices with respect to the five patients, notwithstanding that he characterized Respondent's testimony as “unequivocally stat[ing]” as much. *Id.* The ALJ did not, however, reconcile his finding with his statement during the hearing that “right now I have fairly compelling evidence that [Respondent] has accepted responsibility, even though he didn't tell me he did so or he was going to do so in his prehearing statement.” Tr. 491. Moreover, as discussed previously, because Respondent did not provide notice in his pre-hearing statements that he intended to admit to the truth of the Government's allegations, the ALJ granted the Government's motion to bar him from introducing evidence of his remedial measures.⁵¹

Jacobo Dreszer, 76 FR 19386, 19387–88 (2011) (explaining that a respondent can “argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation”); *Paul H. Volkman*, 73 FR 30630, 30644 (2008); see also *Paul Weir Battershell*, 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and “manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant”); *Gregory D. Owens*, 74 FR 36751, 36757 n.22 (2009).

The Agency has also held that “‘[n]either *Jackson*, nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.’” *Gaudio*, 74 FR at 10094 (quoting *Southwood*, 72 FR at 36504); see also *Robert Raymond Reppy*, 76 FR 61154, 61158 (2011); *Michael S. Moore*, 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. See *Gaudio*, 74 FR at 10095 (quoting *Southwood*, 71 FR at 36503). Cf. *McCarthy v. SEC*, 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of “deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions”).

⁵¹As found above, Respondent did offer extensive testimony of his remedial measures. However,

Respondent takes exception to the ALJ's finding that he did not accept responsibility for his misconduct. Resp. Exceptions, at 2–9. He argues that the ALJ misapplied Agency precedent, “in effect penaliz[ing] him for his failure to immediately confess wrongdoing in response to naked allegations.” *Id.* at 4–5 n.11. Alternatively, he argues that:

[i]f the applicable precedent really provides that the gateway to presentation of mitigation evidence requires [him to] demonstrate penitence in the form of “accepting responsibility for” conduct in which he did not engage . . . and/or to admit to counterfactual matters, e.g., that some of the prescriptions at issue were written outside of a legitimate[] physician patient relationship, then that precedent is inconsistent with procedural due process.

Id. at 4; see also *id.* at 5 n.11 (“to the extent that the Agency concludes the [ALJ's] application was proper, however, the precedent is inconsistent with procedural due process”). Respondent thus seeks “a functional remand to allow the parties to fully develop [his] remediation evidence and to allow” for the consideration of “that evidence in assessing the appropriate sanction.” *Id.* at 9.

While I find some of Respondent's arguments well taken, I reject his exception. As for the ALJ's pre-hearing ruling barring Respondent from eliciting the testimony of Ms. Richards, (who would have testified regarding a risk assessment audit and the training she provided to Respondent's staff), in his Recommended Decision, the ALJ asserted that he would have allowed Ms. Richards to testify if Respondent had “informed the Government in its prehearing statements that he acknowledged the noncompliance of his prescription practice.” R.D. at 60. However, while not mentioned in the Recommended Decision, the ALJ granted the Government's motion based also on Respondent's failure to describe Ms. Richard's testimony “with sufficient particularity.” Tr. 39 (Nov. 3, 2014). This was an independent and adequate ground to bar her testimony, and yet, Respondent does not challenge the ALJ's ruling on this basis.

Had the ALJ's ruling barring Ms. Richard's testimony been based solely on Respondent's failure to state in his pre-hearing statements that he was acknowledging his misconduct, I would agree with Respondent. Contrary to the ALJ's understanding, although the Agency has held that proof of remedial measures is rendered irrelevant where a respondent fails to accept responsibility

Respondent was barred from introducing testimony by a third party on the issue.

for his knowing or intentional misconduct, none of the cases cited by the Government or the ALJ have held that a respondent, as a condition of being able to offer evidence of his remedial measures, is required to admit to the allegations before he even has the opportunity to challenge the Government's evidence and the Agency has never held as much. Indeed, while the Agency frequently places dispositive weight on a respondent's failure to fully acknowledge his misconduct, in each of the cases cited by the ALJ, the Agency discussed the respondent's failure to acknowledge his/her/its misconduct only after discussing the evidence put forward by the Government and determining which allegations had been proved. See, e.g., *Joe Morgan*, 78 FR 61961, 61963 (2013) ("where the Government has proved that a respondent has knowingly or intentionally diverted controlled substances, a registrant's acceptance of responsibility is an essential showing for rebutting the Government's *prima facie* case") (emphasis added); *Medicine Shoppe-Jonesborough*, 73 FR at 387.

Notwithstanding that the Government provided, in its prehearing statements, notice of the evidence it intended to rely on in supporting the allegations of the Show Cause Order, Respondent was entitled to challenge the reliability of that evidence at the hearing and to show that the allegations were untrue. However, I decline to decide the question of whether it was consistent with principles of due process to require Respondent, as a condition of being able to subsequently present evidence of his remedial measures, to admit to his misconduct before it had even been proven on the record.⁵² Notably, while Respondent suggests that if the ALJ's reading of the Agency's precedent was correct—as explained above, it was not—"the precedent is inconsistent with procedural due process," and the ALJ reasoned that Respondent's "concern regarding due process is not wholly unfounded," R.D. at 56, neither Respondent nor the ALJ offered anything more than these conclusory assertions. Moreover, as explained previously, the ALJ's original ruling barring Respondent from putting on Ms. Richard's testimony was also supported

⁵² The constitutional question presented by this scenario can be avoided by waiting until the hearing itself and moving to bar or strike the testimony and evidence of remedial measures when the Respondent fails to acknowledge the misconduct proven by the Government. However, where, as here, a respondent fails to provide an adequate disclosure of its proposed evidence of its remedial measures, the Government can still move to bar the admission of the evidence prior to the hearing.

by the independent basis that Respondent failed to adequately disclose the nature of her proposed testimony with sufficient particularity.⁵³

⁵³ In his Exceptions, Respondent "incorporates as if fully set out herein the [ALJ's] additional observations as to recent Agency precedent's misapplication of *Hoxie v. DEA*, 419 F.3d 477 (6th Cir. 2005)." Resp. Exceptions, at 4 n.11 (citing R.D. at 58). According to the ALJ, the Agency has been misreading the Sixth Circuit's *Hoxie* decision because "while admitting fault is an important factor, it is not the *sole* factor." R.D. 58. The ALJ criticized the Agency's decisions in two cases, which he viewed as being "representative of the coercive pressure to either fully accept responsibility or contest all possible allegations." R.D. 56 (discussing *Jeri Hassman, M.D.*, 75 FR 8194 (2010), and *George Mathew, M.D.*, 75 FR 66138 (2010)). According to the ALJ, his discussion was "intended to present the argument that the DEA is holding registrants to an unfair standard. Although accepting responsibility for one's actions is an important factor to consider once the Government proves its *prima facie* case, there is much more to determining what constitutes the public interest than this one criterion." R.D. at 58. However, the ALJ then noted that in Respondent's case, "the outcome would arguably not be different if [he] had been allowed to present additional rehabilitation witnesses. His admitted misconduct while treating patients and his lackluster efforts of rehabilitation require that result." R.D. 58–59.

I respectfully disagree with the ALJ's assertion that the Agency "is holding registrants to an unfair standard." On the contrary, given the harm to public safety caused by the diversion of controlled substances, the Agency's policy of requiring those respondents, who have been shown to have engaged in knowing or intentional misconduct to acknowledge their misconduct, is fully within the Agency's discretion. *Hoxie* is not to the contrary. As the Tenth Circuit explained in *MacKay*, a case which received barely a mention by the ALJ:

When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether [his] continued registration is in the public interest. Without Dr. MacKay's testimony, the . . . Administrator had no evidence that Dr. MacKay recognized the extent of his misconduct and was prepared to remedy his prescribing practices.

664 F.3d at 820. Absent evidence that a registrant acknowledges his misconduct in intentionally or knowingly diverting controlled substances, there is no basis to conclude that the registrant is prepared to remedy his prescribing practices and allowing the registrant to maintain his registration "is inconsistent with the public interest." 21 U.S.C. 824(a)(4). As for the ALJ's further contention that there is "more to determining what constitute the public interest than this one criterion," R.D. 58, the Agency considers other factors including the egregiousness of the proven misconduct. Thus, in cases of less egregious misconduct, the Agency has frequently imposed sanctions less than a denial or revocation notwithstanding that a respondent failed to fully acknowledge his misconduct. However, the intentional or knowing diversion of controlled substances strikes at the CSA's core purpose of preventing drug abuse and diversion.

As for the ALJ's reliance on *Hassman* and *Mathew*, neither of these cases supports his assertion that the Agency is imposing an unfair standard on registrants. As for *Hassman*, the ALJ's characterization of the Agency's decision as having "found that the respondent had issued several prescriptions not for a legitimate medical purpose for several of her patients," R.D. at 56, is a gross

Nor was Respondent the only party displeased with the ALJ's ruling on the issue of the adequacy of his acceptance of responsibility. Indeed, the Government argues that the ALJ obstructed its cross-examination of Respondent on this very issue. Gov. Exceptions, at 9–18. The Government sets forth various instances in which the ALJ precluded it from conducting a meaningful inquiry into the sincerity of Respondent's acceptance of responsibility and the scope of his present understanding of lawfully appropriate prescribing practices. See *id.* at 10–11; 17–18.

The Government further points to various incongruities in the ALJ's decision, including his conclusion that Respondent "failed to take the full and unconditional acceptance of responsibility," while later in the same paragraph, finding that Respondent "unequivocally stated that he did not dispute the evidence brought against him." Gov. Exceptions, at 12 (quoting R.D. 55). To similar effect, the Government argues that notwithstanding the various instances in which the ALJ cut off its cross-examination of Respondent, the ALJ later explained that he could not evaluate Respondent's contention that he should be able to continue to prescribe controlled substances subject to various restrictions, "without first providing the Government a full and fair opportunity to first thoroughly test the depth of [Respondent's] acknowledgment of noncompliance." Gov. Exceptions, at 12 (quoting R.D. 63).

The Government also argues that "[t]he ALJ's decisions make it difficult for the Administrator to know if Respondent would have 'acknowledg[ed] that his conduct violated the law' at hearing." Gov.

understatement of the Agency's findings in the case, which established that the respondent had issued hundreds of unlawful prescriptions to some 15 patients, and continued to deny material facts even when there was conclusive proof to the contrary. See, e.g., 75 FR at 8200–237. And his reliance on *Mathew* is especially remarkable given that Dr. Mathew was implicated in prescribing controlled substances for two separate internet prescribing rings and did not testify in the proceeding.

Of further note, while both physicians sought judicial review of the respective agency decision, in each case, the Court of Appeals denied their petitions in an unpublished decision. See *Hassman v. DEA*, 515 Fed. App'x. 667 (9th Cir. 2013) (Holding that "[n]one of her proffered statements amount to an admission of wrongdoing; they are nothing more than further denials and claims that she was the unwitting victim of cunning patients. While Hassman offered some evidence of corrective measures, the DEA was entitled to give greater weight to the evidence indicating that Hassman has not learned from or improved upon her past misconduct."); *Mathew v. DEA*, 472 Fed Appx. 453 (9th Cir. 2012).

Exceptions, at 13 (citing *Morgan*, 78 FR 61961, 61980 (2013)). I agree, and while Respondent bore the burden of production on the issue, given the ALJ's on-the-record statement that "right now I have fairly compelling evidence that [Respondent] has accepted responsibility, even though he didn't tell me he did so or he was going to do so in his prehearing statement," Tr. 491, it was not unreasonable for Respondent's counsel to conclude that it was not necessary to further develop the record on this issue.⁵⁴

I conclude, however, that a remand is unwarranted for multiple reasons. As explained above, *see supra* n.53, while a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, the Agency has repeatedly held that it is entitled to consider the egregiousness and extent of a registrant's misconduct in determining the appropriate sanction. *See Dreszer*, 76 FR at 19387–88; *Volkman*, 73 FR at 30644. Indeed, while proceedings under 21 U.S.C. 823 and 824 are remedial in nature, there are cases in which, notwithstanding a finding that a registrant has credibly accepted responsibility, the misconduct is so egregious and extensive that the protection of the public interest nonetheless warrants the revocation of a registration or the denial of an application. *See Fred Samimi*, 79 FR 18698, 18714 (2014) (denying recommendation to grant restricted registration, explaining that "even assuming . . . that Respondent has credibly accepted responsibility for his misconduct, this is a case where actions speak louder than words").

Here, the evidence shows that Respondent is an egregious violator of the CSA in that he ignored countless red flags presented by the patients that they were either abusing or diverting (or both) the controlled substances he prescribed for them. And with respect to Patients J.H. and R.E.H., the evidence shows that this went on for several years. Given the egregiousness of his misconduct, the Agency's interest in protecting the public by both preventing him from being able to dispense controlled substances as well as by deterring misconduct by others is substantial. I thus conclude that

continuing Respondent's existing registrations and granting his applications for the additional registrations would be "inconsistent with the public interest." 21 U.S.C. 823(f), 824(a)(4).

There is further reason to conclude that a remand is unwarranted. As found above, the State of Michigan has now revoked Respondent's medical license, thus rendering him without authority to dispense controlled substances in the State in which he holds his registrations and seeks the additional registrations. Thus, Respondent no longer meets the CSA's prerequisite for obtaining and maintaining a registration. *See* 21 U.S.C. 802(21) (defining "the term 'practitioner' [to] mean[] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice"); *see also* id. § 823(f) ("The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.").

Thus, pursuant to 21 U.S.C. 824(a)(3), the Attorney General is also authorized to suspend or revoke a registration issued under section 823, "upon a finding that the registrant . . . has had his State license or registration suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the Act, DEA has long held that the revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices medicine. *See James L. Hooper*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *see also Maynard v. DEA*, 117 Fed. Appx. 941, 945 (5th Cir. 2004); *Sheran Arden Yeates, M.D.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988).

The Government nonetheless argues that because this issue was "never raised in the Order to Show Cause," a decision on this ground "could arguably upend basic protections afforded to DEA registrants and would surely diminish the perceived fairness of the . . . administrative process." Govt's Resp. to Admin. Order, at 11. The Government

acknowledges that it "is certainly empowered to issue an Order to Show Cause (or an Amended Order to Show Cause) alleging this factual basis and legal ground for revocation or denial" and to submit evidence. *Id.* However, it then contends that to impose a sanction "based on events that occurred outside of the administrative litigation process . . . runs up against 'one of the fundamental tenets of Due Process,'" this being that the "'Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking . . . revocation . . . so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action.'" *Id.* at 11–12. (quoting *Farmacía Yani*, 80 FR 29053, 29059 (2015)).

For his part, Respondent does not dispute that the Michigan Board has revoked his medical license and that he "no longer has any legal authority to dispense controlled substances." Respondent's Resp. to Admin. Order, at 1. However, he then states that as a procedural matter, he agrees with the Government that "simply skipping ahead to a 21 U.S.C. 824(a)(3) revocation that the parties never litigated would likely be inconsistent with due process." *Id.* at 4. Respondent acknowledges that "it might well be within the Administrator's purview . . . to invite the Government to issue an Amended Order to Show Cause seeking revocation [under section] 824(a)(3) grounds because of [his] loss of his license." *Id.* at 4–5.

I reject both parties' contention that I cannot rely on Respondent's loss of his state authority absent the Government's submission of an amended show cause order. Because the possession of state authority is a prerequisite for obtaining a registration and for maintaining a registration, the issue can be raised *sua sponte* even at this stage of the proceeding.⁵⁵ Indeed, under the Government's position, had I rejected the Government's case, I would be required to grant Respondent's applications even though he does not meet a statutory requirement for obtaining a registration.

Notably, the Government's position is fundamentally inconsistent with the position it has taken in numerous cases where it has issued an Order to Show Cause based on public interest grounds only to subsequently move for summary disposition upon learning that the

⁵⁴ While Respondent's counsel raised numerous objections to the Government's attempts to cross-examine him as to the sincerity of his acceptance of responsibility, Respondent's counsel was obliged to zealously defend his client. Thus, the state of the record is primarily attributable to the ALJ's undue limitation of the Government's cross-examination.

⁵⁵ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979).

applicable state board had taken action which rendered the practitioner without state authority. *See, e.g., Morgan*, 78 FR at 61973–74 (upholding ALJ’s granting of government motion for summary disposition based on physician’s loss of state authority which occurred post-hearing and holding that due process did not require amending the show cause order; motion for summary disposition provided adequate notice); *Roy E. Berkowitz*, 74 FR 36758, 36759–60 (2009) (rejecting argument that revocation based on loss of state authority was improper based on board action not alleged in the Show Cause Order; “The rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence. The Government’s failure to file an amended Show Cause Order alleging that Respondent’s state CDS license had expired does not render the proceeding fundamentally unfair.”). *See also Kamal Tiwari, et al.*, 76 FR 71604 (2011); *Silviu Ziscovici*, 76 FR 71370 (2011); *Deanwood Pharmacy*, 68 FR 41662 (2003); *Michael D. Jackson*, 68 FR 24760; *Robert P. Doughton*, 65 FR 30614 (2000); *Michael G. Dolin*, 65 FR 5661 (2000).

Here, by virtue of my order directing the parties to address the issues of: (1) Whether Respondent currently possesses authority to dispense controlled substances, and (2) if Respondent does not possess such authority, what consequence attaches for this proceeding, Respondent was provided with a meaningful opportunity to show that he retains his state authority. Of consequence, Respondent does not dispute that he no longer holds authority to dispense controlled substances under Michigan law, this being the only material fact that must be adjudicated in determining whether Respondent’s registrations can be revoked and his applications denied under 21 U.S.C. 823(f) and 824(a)(3) as well as the Agency’s precedent. That there are no dispositive legal arguments to preclude my reliance on this basis as an additional ground to revoke Respondent’s registrations and to deny his applications is not the result of constitutionally inadequate notice. Rather, it is the result of the statute itself, which makes the possession of state authority mandatory for obtaining and maintaining a registration and renders irrelevant the issues of acceptance of responsibility and the adequacy of remedial measures. Accordingly, I will order that Respondent’s registrations be revoked and that his pending applications be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 28 CFR 0.100(b), I order that DEA Certificates of Registration BA7776353 and FA2278201 issued to Hatem M. Ataya, M.D., be, and they hereby are, revoked. Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that all pending applications submitted by Hatem M. Ataya, M.D. be, and they hereby are, denied. This Order is effective immediately.⁵⁶

Dated: February 10, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–03359 Filed 2–17–16; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Mallinckrodt, LLC

ACTION: Notice of registration.

SUMMARY: Mallinckrodt, LLC applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Mallinckrodt, LLC registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated September 16, 2015, and published in the **Federal Register** on September 23, 2015, 80 FR 57388, Mallinckrodt, LLC, 3600 North Second Street, Saint Louis, Missouri 63147 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Mallinckrodt, LLC to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the

⁵⁶ Based on the extensive findings of egregious misconduct by Respondent, I conclude that the public interest necessitates that this Order be effective immediately.

company’s compliance with state and local laws, and reviewing the company’s background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) (9821).	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Nabilone (7379)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333).	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254) ...	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacture bulk active pharmaceutical ingredients (API) for distribution to its customers.

Dated: February 10, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

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