

DEPARTMENT OF JUSTICE**Drug Enforcement Administration****[Docket No. 10–59]****Daniel B. Brubaker, D.O.; Decision and Order**

On April 29, 2011, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the record as a whole, I have decided to adopt the ALJ's recommended rulings, findings of fact, and conclusions of law in their entirety. Accordingly, I also adopt the ALJ's recommended order.

Order

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

Dated: March 16, 2012.

Michele M. Leonhart,
Administrator.

Frank Mann, Esq., for the Government
Ronald Kaldor, Esq., for the Respondent

Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge**I. Introduction****A. The Order To Show Cause**

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 551 et seq., to determine whether the Drug Enforcement Administration (DEA) should deny a physician's application for a DEA Certificate of Registration (COR) as a practitioner pursuant to 21 U.S.C. § 823(f). Without this registration Respondent, Daniel B. Brubaker, D.O. (Respondent), of Fresno, California, will be unable to lawfully prescribe, dispense or otherwise handle controlled substances in the course of his practice.

On May 27, 2010, the DEA Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause (OSC) to Respondent, giving Respondent notice of an opportunity to show cause as to why the DEA should not deny Respondent's application for registration on grounds that his registration would be inconsistent with the public interest as that term is used in 21 U.S.C. § 823(f).

In substance, the OSC alleges that Respondent prescribed controlled substances to patients for no legitimate medical purpose and with "extreme deviations from the standard of care." The OSC further alleges that Respondent was arrested for driving under the influence of controlled substances on June 13, 2008, and that toxicology results revealed the presence of the controlled substances marijuana, modafinil, oxazepam and temazepam, for which Respondent lacked a prescription.

B. Prehearing Proceedings

Because conduct by Respondent's counsel prior to hearing played a prominent role in the constriction of evidence that Respondent was permitted to present at hearing, I address the prehearing proceedings in some detail.

Respondent, through his counsel Ronald Kaldor, Esq., requested a hearing on June 25, 2010. On July 6, 2010, I issued an Order for Prehearing Statements directing the Government to file a prehearing statement by July 13, 2010, and Respondent to file a prehearing statement by July 20, 2010. The Order for Prehearing Statements itemized numerous instructions designed to give the parties notice, *inter alia*, of the grounds upon which claims and defenses would be based, the identity and location of witnesses and the contents of their testimony, and the exhibits each party intended to introduce into evidence. The overriding purpose of prehearing statements in registration proceedings pursuant to section 304 of the Controlled Substances Act (CSA) is to provide parties with an opportunity to fairly and adequately prepare for hearing. *See generally CBS Wholesale Distribs., Inc.*, 74 Fed. Reg. 36,746 (DEA 2009).

The Government timely filed its prehearing statement on July 13, 2010. Respondent filed a document entitled "Respondent's Prehearing Statements" on July 20, 2010. Although filed within the deadline for exchanging prehearing statements, this filing was deficient in numerous regards: Respondent failed to identify a single witness, summarize witness testimony, or describe any documents to be potentially offered as exhibits. Arguing that Respondent had impliedly withdrawn his request for a hearing by failing to file a compliant prehearing statement, the Government moved to terminate proceedings on July 22, 2010. After providing Respondent an opportunity to respond to the Government's motion, I found that although Respondent's initial prehearing statement of July 20, 2010,

was "substantially deficient and does not comply with the directions set forth in the Order for Prehearing Statements or 21 C.F.R. § 1316.57, I do not find at this time that Respondent's actions constitute a waiver of hearing." (Mem. to Counsel and Order, July 30, 2010.) I ordered Respondent to file a compliant supplemental prehearing statement no later than August 3, 2010.

On August 3, 2010, Respondent filed a supplemental prehearing statement. This document, too, was deficient in numerous respects. For instance, Respondent vaguely outlined the testimony of his witnesses instead of "stat[ing] what the testimony will be rather than merely listing the areas to be covered," as required by the Order for Prehearing Statements. Respondent also failed to provide addresses for three witnesses. In addition, although the Order for Prehearing Statements directed that "[i]f Respondent intends to testify, Respondent must be identified as a witness, and a summary of the testimony * * * must be provided," Respondent's August 3, 2010 supplemental prehearing statement did not list Respondent as a witness.

I issued a Prehearing Ruling on August 6, 2010. The Prehearing Ruling noted that any testimony not summarized in prehearing statements, and any documents not listed therein, could be excluded at hearing. The Prehearing Ruling also set a deadline of October 4, 2010, for the filing of supplemental prehearing statements; set November 8, 2010, as the deadline for filing any anticipated motions and exchanging documents intended to be offered as exhibits at hearing; and set November 15, 2010, as the deadline for providing the Administrative Law Judge (ALJ) with copies of all such documents.¹

On October 28, 2010, the Government filed a Motion of Government to File Supplemental Prehearing Statement Out of Time, seeking to eliminate several Government exhibits and add the curriculum vitae (CV) of the Government's expert witness. The Government represented that Respondent did not object, and I granted the Government's motion on October 29, 2010.

On November 12, 2010, a telephonic Supplemental Prehearing Conference

¹ On November 15, 2010, the Government timely filed its exhibits in compliance with the August 6, 2010 Prehearing Ruling. Prior to hearing, Respondent did not file any exhibits with the ALJ, and the Government represents, and Respondent does not challenge, that Respondent did not serve on the Government any of the seven documents listed in his August 3, 2010, supplemental prehearing statement.

was held with Government counsel and Respondent's counsel. At the Supplemental Prehearing Conference, counsel for Respondent withdrew Respondent's expert witness, Thomas O'Laughlin, M.D., and indicated Respondent's desire to obtain a replacement expert. Respondent also indicated his desire to call Respondent to testify as a witness, despite the fact that Respondent's prehearing statement and supplemental prehearing statement did not list Respondent as a witness.² Counsel for the Government indicated, however, that from previous conversations with counsel, the Government was on notice of Respondent's intention to call Respondent as a witness.³

In addition, counsel for Respondent stated that Respondent no longer intended to call Karen Fu, LMFT, as a witness.⁴ Finally, counsel for Respondent stated that he intended to provide addresses for Respondent's witnesses Stephen Duvall, Anita Peralda and "Jerry McDonadl" [sic] (Resp't Supp. PHS at 2), and that he intended to indicate with specificity, albeit belatedly by approximately forty days,⁵ their proposed testimony.

Counsel for Respondent further indicated his intention to file a (second) supplemental prehearing statement on Monday, November 15, 2010, embracing the changes and updates to witness information discussed *supra*. Counsel for Respondent acknowledged that the August 6, 2010 Prehearing Ruling set the deadline for supplemental prehearing statements at October 4, 2010, and set the deadline for filing motions at November 8, 2010. Counsel for Respondent accepted responsibility for missing these deadlines, but attributed this failure to a lack of familiarity with the "federal rules."

I issued a Supplemental Prehearing Ruling on November 12, 2010, summarizing the Supplemental Prehearing Conference and ordering Respondent to file a proposed second supplemental prehearing statement, accompanied by a separate motion to

accept late filing supported by a statement of good cause, no later than November 15, 2010.

On Wednesday, November 17, 2010, Respondent filed, two days out of time, a document entitled "Second Supplemental Respondent's Prehearing Statement," along with a Motion to Accept Late Filing, also filed two days out of time. On November 19, 2010, the Government filed its Opposition to Respondent's Motion to Accept Late Filing, Motion to Terminate Proceedings or, in the alternative, Motion *In Limine*. Pursuant to the August 6, 2010 Prehearing Ruling, Respondent had three business days after service of the Government's motions to file a response. Respondent did not respond.⁶

Ruling on Respondent's Motion to Accept Late Filing of his proposed supplemental prehearing statement on November 30, 2010, I found that

Viewed as a whole, Respondent's failures are serious and present the specter of real prejudice to the Government. Because Respondent's motion to accept late filing was itself filed late without good cause, because the motion was not supported by good cause, and because the proposed second supplemental prehearing [statement] is noncompliant with the Order for Prehearing Statements, I reject the filing of Respondent's second supplemental prehearing statement.

(Mem. and Order, Nov. 30, 2010, at 9.)

Turning to the Government's Motion to Terminate, I found that "although the deficiencies in Respondent's counsel's handling of Respondent's case are indeed serious, they cannot support a finding that Respondent has actually withdrawn or waived his request for a hearing." (*Id.* at 11.)

Addressing the Government's Motion *in limine*, I found that fairness and Agency precedent required the constriction of the evidence that Respondent could permissibly present at hearing, in light of Respondent's numerous, repeated and prejudicial failures to comply with the Order for Prehearing Statements and subsequent Orders, as detailed above and analyzed in my November 30, 2010 ruling. I

therefore ordered that with the exception of Respondent himself, no witness would be permitted to testify who was not named either by the Government in its prehearing statement, as duly supplemented on October 28, 2010, or by Respondent in Respondent's supplemental prehearing statement filed August 3, 2010; that Respondent would not be permitted to introduce documentary evidence regarding the prescribing, dispensing or administering of controlled substances to any of the patients named in the Government's prehearing statement, as supplemented; that Respondent would not be permitted to introduce documentary evidence that he legally consumed, or had legal authority to possess and consume, the controlled substances found in his system following his arrest on June 13, 2008; and that Respondent would not be permitted to introduce any documentary evidence of any kind or manner, absent a specific showing of good cause at hearing. Respondent was not precluded from seeking admission of documents related to issues such as witness credibility or rebuttal of evidence.⁷

On December 3, 2010, Respondent filed Respondent's Motion *In Limine*, seeking to prevent the Government's expert witness, Dr. James L. Gagné, from testifying at the hearing. In support of his motion, Respondent stated he interpreted my November 30, 2010 ruling on the Government's motion *in limine* to "limit the testimony of Respondent in his defense," arguing that the Government's expert should not be permitted to testify because otherwise "Respondent will be precluded from a fair opportunity to defend himself and from receiving his due process rights . . ." (Resp't Mot. in *Limine*, Dec. 3, 2010, at 1.) Inasmuch as Respondent filed his motion two business days before the hearing, Respondent's motion was resolved on the record at the beginning of the hearing. After giving each party an opportunity to be heard, I denied Respondent's motion as meritless.⁸ (Transcript (Tr.) 21.)

Following prehearing procedures, a hearing was held in Fresno, California, between December 7, 2010, and December 8, 2010, with the Government represented by counsel and Respondent

² The July 6, 2010 Order for Prehearing Statements states: "If Respondent intends to testify, Respondent must be listed as a witness, and a summary of the testimony * * * must be provided."

³ Counsel also suggested that James Hambuechen, previous Government counsel, requested a subpoena for Respondent's testimony. The record, however, reveals no such subpoena or request.

⁴ Ms. Fu's name appears as a potential witness in Respondent's August 3, 2010 "Supplemental Respondent's Prehearing Statements."

⁵ The July 6, 2010 Order for Prehearing Statements set forth a deadline of July 20, 2010, for the filing of Respondent's prehearing statement. Per the August 6, 2010 Prehearing Ruling, supplemental prehearing statements were due on October 4, 2010.

⁶ Counsel for Respondent had indicated that "I will be out of my office on vacation . . . from November 22 to November 29 and will not be able to access any communications." (Resp't Mot. Late Filing, Nov. 17, 2010, at 2.) Under the

circumstances, I declined to construe this unsworn statement as a motion to extend the three-day deadline for responding to motions, established by the August 6, 2010 Prehearing Ruling. Even so construed, I found there was no good cause for extending the filing deadline. First, counsel for Respondent's duty of diligence requires that he designate alternate counsel during his anticipated absence. Second, "if one can find time to take vacation, he can also find time to file a . . . pleading . . ." *Kamir Garces-Mejias*, 72 Fed. Reg. 54,931-02, 54,933 (DEA 2007).

⁷ See Mem. Order, Nov. 30, 2010, at 14 n.10. At hearing Respondent only offered, and subsequently withdrew, Respondent's CV. I indicated the document would in any case be excluded in accordance with an earlier ruling. (Tr. 299-300.) Respondent did not provide a copy of the CV to this tribunal, and consequently no copy is included in the record.

⁸ Respondent's testimony at hearing spans approximately 181 transcript pages. (See Tr. 300-481.)

represented by counsel. Both parties called witnesses to testify and both had the opportunity to introduce documentary evidence, although the evidence Respondent was ultimately permitted to introduce was limited by my November 30, 2010 ruling as noted above. After the hearing, both parties filed proposed findings of fact, conclusions of law, and argument.⁹ All of the evidence and post-hearing submissions have been considered, and to the extent the parties' proposed findings of fact have been adopted, they are substantively incorporated into those set forth below.

II. Issue

Whether the record establishes by substantial evidence that Respondent's application for a DEA COR, assigned control number W09177610C, should be denied because Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. § 823(f).

III. Evidence and Incorporated Findings of Fact¹⁰

I find, by a preponderance of the evidence, the following facts:

A. Stipulated Facts

Respondent applied for a DEA registration as a practitioner in Schedules II through V on or around August 26, 2009. (ALJ Ex. 4.) Respondent surrendered his previous DEA registration on August 21, 2008. (*Id.*)

B. The Government's Evidence

DEA Diversion Investigator Jack L. Lewis (DI Lewis) has been a DEA Diversion Investigator for five years. (Tr. 271.) DI Lewis received training as a diversion investigator at a DEA training facility in Quantico, Virginia. (Tr. 272.)

Dr. James Laurent Gagné (Dr. Gagné) is a physician. (Tr. 27.) He resides in Valley Village, California and received a bachelor's degree from Columbia University and a medical degree from Albert Einstein College of Medicine of Yeshiva University in Bronx, New York. (Gov't Ex. 4.) He is board certified in

internal medicine, addiction medicine and pain medicine and presently sees several hundred patients. (Tr. 28.) Approximately one third of them are pain management patients. (Tr. 197.) He estimates that he prescribes opiates to approximately half of his pain patients. (Tr. 203.)

Among other certifications, Dr. Gagné holds Diplomas from the National Board of Medical Examiners and the American Board of Internal Medicine. (Gov't Ex. 4; see Tr. 29.) He is certified in addiction medicine by the American Society of Addiction Medicine, and holds a Diplomate from the American Board of Pain Medicine. (Gov't Ex. 4; see Tr. 31.) Dr. Gagné is a member of nineteen professional associations, including the International Association for the Study of Pain, the American Pain Society, the Western Pain Society, the American Association for Pain Medicine, the American Society for Addiction Medicine and the California Society for Addiction Medicine. (Gov't Ex. 4.)

Dr. Gagné completed an internship and his first medical residency at Lincoln Hospital, Albert Einstein College of Medicine between 1973 and 1975. (Gov't Ex. 4; Tr. 32.) He completed a second residency at Kaiser-Permanente Medical Center in Santa Clara, California in 1976. (Gov't Ex. 4.) Between 1976 and the present, Dr. Gagné has served in a variety of positions ranging from Clinical Medical Director, UCLA Pain Control Unit in Los Angeles, to Chairman of the Department of Medicine at the Verdugo Hills Hospital in Glendale, California. (Gov't Ex. 4; see Tr. 32–34.)

Presently, Dr. Gagné is an associate physician at a Glendale, California primary care internal medicine group and a consulting physician at a Malibu, California recovery home. (Gov't Ex. 4.) He previously taught as an Assistant Professor of Family Medicine at USC Keck School of Medicine from 2000 to 2008. (Gov't Ex. 4; Tr. 30.) Dr. Gagné has also given numerous lectures, authored various publications and participated in continuing medical education programs. (Gov't Ex. 4; Tr. 35–36.) He has served as an expert reviewer for the California Medical Board and has served as an expert witness on two cases for the United States Department of Justice. (Tr. 36–39.)

Dr. Gagné was qualified and I have accepted him as an expert witness, without objection, in the profession of internal medicine, addiction medicine and pain management medicine in the State of California. (Tr. 39–40; Gov't Ex. 4.)

DEA Investigation of Respondent's Prescribing Practices

Dr. Gagné testified to being familiar with California and federal law regarding the prescribing of controlled substances. (Tr. 40.) To issue a prescription for controlled substances within the usual course of a physician's professional practice, there must be a genuine and valid physician-patient relationship. (Tr. 40–41.) The physician must keep a medical record, determine the patient's history and symptoms, conduct a physical examination and document laboratory findings. (Tr. 41.) When prescribing drugs with side-effects, the physician must make a risk-benefit assessment. (Tr. 41.) Standards can differ depending on whether a patient is seeking treatment on an emergency basis, but Dr. Gagné testified that none of the nine patients of Respondent whose files Dr. Gagné reviewed sought treatment on an emergency basis. (Tr. 41–42.)

Dr. Gagné defined "chronic pain" as a painful condition lasting more than three months after the acute illness giving rise to the pain has been resolved. (Tr. 42, 209.) In determining whether a patient is truly suffering from chronic pain, a physician must trust the patient but also must compare objective evidence with a patient's subjective complaints because some patients exaggerate symptoms. (Tr. 43.) A physician must listen both to what the patient says and to what the patient does not say, to "learn[] some of the implications and context and things that people are not saying but are kind of present in the room." (Tr. 207.) In treating a pain patient, a physician must obtain several aspects of a patient's history, to include the patient's present illness, past medical history, social history, psychiatric history, family history, review of symptoms and addiction history.¹¹ (Tr. 43–44.) In obtaining this information,¹² Dr. Gagné called the following components essential: How the pain began, the course of the illness, the course of treatment and diagnostic procedures and the patient's current symptoms, including neurological symptoms. (Tr. 45–46.) When prescribing controlled

¹¹ In the case of a patient using marijuana or other illicit drugs, Dr. Gagné "would take 100 percent full-fledged addiction history." (Tr. 56–57.)

¹² As for the amount of time it takes to gather this information from the patient, Dr. Gagné testified that "I am very much of an outlier, so I take longer than most of my colleagues. And it takes me one or two hours [which is] not the standard of practice, that's how I do it." (Tr. 206.) Moreover, it is not necessarily required or advisable to obtain all this patient information at once or in a single visit. (Tr. 206.)

⁹ In a December 27, 2010 letter to counsel, the Office of Administrative Law Judges advised that briefs would be due by 4 p.m. Eastern Daylight Time on January 25, 2011. The Government timely filed its brief. Respondent filed his brief on January 26, 2011, and on January 27, 2011, filed a motion to accept the late filing. In the absence of an objection from the Government, and inasmuch as it appeared no prejudice would result, I granted Respondent's motion. (See Ruling on Resp't Mot. to Accept Late Filing, Apr. 28, 2011.)

¹⁰ In addition to the evidence discussed in this Section, additional evidence and findings of fact are discussed in later Sections of this Recommended Decision.

substances, it is critical to obtain a list of the patient's prior medications. (Tr. 47.) Among other reasons, a patient's history of medication gives a physician a "sense of the appropriateness of the patient's use of the controlled substances and whether they're likely to be a problem." (Tr. 48.)

It is also important to collaborate with a patient's previous physicians to verify that a patient has truthfully represented the amount of medication she has taken in the past. (Tr. 48.) The importance of obtaining a patient's prior medical records, and ordering X-rays or MRIs, varies with the patient based on the complexity of the illness and the previous course of treatment. (Tr. 48–49, 54.) The importance of obtaining such documentation increases when prescribing controlled substances because among therapies, controlled substances are unique in that some patients "will engage in substantial misdirection, lying, and manipulation to obtain them." (See Tr. 51.)

Conducting a physical examination is also critical prior to prescribing controlled substances. (Tr. 52.) In addition to at least one comprehensive "head to toe" exam, a physician should conduct a "relatively-detailed orthopedic-style examination or rheumatologic-style evaluation." (Tr. 52.) In a patient with lower back pain, for instance, such an examination might include watching the patient walk and observing range of motion, checking for tenderness or deformity of the spine, checking the neurologic function for weakness or lack of sensation and checking muscles and joints for spasm or tenderness. (Tr. 52.) Prescribing controlled substances without an office visit by the patient is something

that mostly you don't do, but there are circumstances in which you have a long-term patient who's stable, where the drug doses aren't changing, and there's absolutely no problem at all, and you know very well that they're doing well, and they're not going to come in and telling you they're crashing or they need more or this or that.

(Tr. 222.)

The upshot, Dr. Gagné explained, is that before prescribing controlled substances, "there has to be enough information in the record to be meaningful, it has to add up to something. Or if you don't, you refer somebody out for * * * evaluation and then you base your treatment on a specialist's evaluation." (Tr. 213.)

Documenting the various steps described above in a patient's medical record is important. Although it is not practical to document every word spoken or action taken at a patient consultation, the medical community

nevertheless presumes that "if it's not in the medical records, it's assumed not to have happened."¹³ (Tr. 54.) Dr. Gagné elaborated that the burden of proof is on the physician: "[T]he standard is that a competent physician can pick up the medical record and understand without too much trouble what happened." (Tr. 214.) Physicians who treat a patient based on an analysis not documented in the patient's medical chart are "subjecting themselves to high risk of problems down the road." (Tr. 216.)

Dr. Gagné also clarified that there is a difference between a diagnosis and a symptom. Low back pain, for instance, is not a diagnosis of an illness but is instead a symptom that can be due to at least a dozen causes. (Tr. 56.) When patients seek controlled substances, it is important to perform an independent diagnosis regarding any possible addiction. (Tr. 56.)

Dr. Gagné recognizes the validity of opiates in the treatment of chronic pain and relies on opiates to treat some of his patients. (Tr. 57–58.) But even when a patient is in pain and the pain is confirmed by a doctor, it is not necessarily appropriate to prescribe opiates in all instances; other treatments may be more effective.¹⁴ (Tr. 57–58.) When prescribing controlled substances, the physician should give the lowest dose consistent with a beneficial clinical outcome and periodically review the treatment's efficacy. (Tr. 59–60.) Although there is a legitimate "role for dose finding," it is inappropriate to blindly increase a dosage when a given dosage isn't working. (Tr. 60.) Increasing a dosage on the sole grounds that a patient requests an increase is inappropriate without an assessment of the patient's symptoms, function, sleep, mood and other factors. (Tr. 61.)

As signals indicating the potential addiction to or diversion of controlled substances, Dr. Gagné identified a number of "red flags." When a red flag occurs, "one needs to sort out what's going on before continuing to prescribe the medications * * * there are kinds of red flags where you simply have to stop, you can't continue to prescribe controlled drugs." (Tr. 64–65.) Red flags include a patient asking for larger doses; a claim that "my dog ate my prescription," that the patient dumped the prescription down the toilet, that the prescription was stolen or other

"dramatic stories of how my drugs suddenly disappeared and I need more"; a patient requesting an advance supply due to anticipated travel when the patient later tries to refill the prescription before the extra dosage should have been consumed; evidence that the patient has obtained controlled substances from more than one physician or is using more than one or two pharmacies; increasingly bizarre statements about the need for opiates; and missing appointments frequently. (Tr. 62–64.) Moreover, a patient who exaggerates the type of medication she has previously taken under the care of a prior doctor poses the sort of red flag that requires a physician to "stop prescribing controlled substances until you sort out what's going on." (Tr. 63.) A patient who uses illicit drugs is a "huge red flag" and "it would be very inappropriate to prescribe controlled prescription medications to such a patient absent other extremes." (Tr. 63.) A patient's reluctance to provide medical records or claims of frequent injuries are also red flags. (Tr. 64.)

As "yellow flags" that could signal addiction or diversion, Dr. Gagné identified instances of patients requesting brand-name drugs instead of settling for generic alternatives; patients who pay by cash; patients who use marijuana for medicinal purposes¹⁵ (Tr. 62–64); and a prescribing physician writing "DAW" or "dispense as written" on a prescription.¹⁶ (Tr. 93.)

Dr. Gagné also identified various controlled substances.¹⁷ Oxycodone is a powerful opiate with a high abuse potential. (Tr. 49.) Oxydose and Oxyfast are varieties of oxycodone.¹⁸ (Tr. 49, 113.) Hydrocodone is another powerful opiate with a lower strength but high abuse potential. (Tr. 49.) Norco is a brand name of hydrocodone mixed with Tylenol or acetaminophen. (Tr. 49.)

¹⁵ Dr. Gagné elaborated that in California, where marijuana may legally be prescribed for medical purposes, a doctor must first establish a medical diagnosis and also conduct an addiction history, given the drug's high addiction potential. (Tr. 77–78.)

¹⁶ This practice can indicate a potential for diversion, as follows. (Tr. 94.) With respect to OxyContin and Vicodin ES, for example, there is no difference therapeutically between the brand name and the generic version. (Tr. 94.) Although some patients believe the brand name is more effective, requesting a brand name "can be a way of showing customers who are buying the drugs secondarily that this is the real thing, because generics are pretty nondescript tablets, and you don't know what you're getting." (Tr. 94.)

¹⁷ See generally 21 U.S.C. § 812 (establishing five schedules of controlled substances); 21 C.F.R. § 1308.11–15 (2010) (listing the controlled substances in Schedules I–V).

¹⁸ Dr. Gagné's also testified that OxyContin is a brand of oxycodone, an opiate and a controlled substance. (Tr. 39, 114, 126.)

¹³ For instance, a doctor should have a serious discussion with a chronic pain patient about the possibility of physical therapy, and document the conversation in the record. (Tr. 59.)

¹⁴ Dr. Gagné also cautioned that "there is not one single medical or scientific study that shows that opiates are safe or effective in the treatment of chronic pain." (Tr. 57.)

Kadian is a time-release form of morphine and Actiq is a brand name of fentanyl. (Tr. 49.) Xanax is a highly-addicting and frequently abused opiate. (Tr. 39, 78.) Valium is diazepam, a benzodiazepine and sedative with moderate addiction potential. (Tr. 50.) Dilaudid is “the most powerful opiate that I’m aware of with an incredibly high addiction potential.” (Tr. 50.) Phenergan is a powerful sedative with anti-nausea properties, and codeine is an opiate with moderate abuse potential. (Tr. 50.)

Based upon a review of nine of Respondent’s patient files offered at hearing,¹⁹ Dr. Gagné opined that “there were some patients where there was nothing that really approached what I consider anything like medical care, and others where it was more like medical care.” (Tr. 215–16.) As detailed in a later Section of this Recommended Decision, Dr. Gagné opined that Respondent’s prescribing of controlled substances to his patients was characterized by

grossly inadequate medical records and virtually a complete absence of clinical information. No meaningful history, no meaningful physical examination, no past medical history, no family history, no review of systems, et cetera, nothing. No physical exam worthy of the name * * *. there were structures in the chart that had those titles, but the data was absent. Another reason is patients who it became clear were grossly misusing their medications or getting them from multiple sources. At that point there can no longer be a legitimate medical purpose of continuing controlled drugs. Or when a patient is being admitted [or referred] to rehabilitation facility for drugs * * * you don’t keep just prescribing the same old controlled drugs you always were.

(Tr. 223–24.)

C. Respondent’s Evidence

Daniel B. Brubaker, D.O. (Respondent) is an osteopathic physician. (E.g., Tr. 204.) Respondent was previously registered with DEA as a practitioner and surrendered his registration on August 21, 2008. (ALJ Ex. 4.) Respondent subsequently applied for a new COR following the execution of a search warrant at his office. (E.g., Tr. at 273–74.) The number associated with Respondent’s application is W09177610C. (Gov’t Ex. 1.)

¹⁹ The record reflects some variance on the number of files reviewed. The OSC indicated that Dr. Gagné reviewed ten of Respondent’s files. (ALJ Ex. 1.) Dr. Gagné’s written report states that “eight” patient files were reviewed, but substantively addresses nine patients. (Gov’t Ex. 3 at 1.) Testimony at hearing also indicated there was “yet another file that Dr. Gagné reviewed” (Tr. 288) but that was not included in this particular case, reflecting a total of ten files reviewed by Dr. Gagné.

Respondent attended Elizabethtown College in Pennsylvania and graduated from Philadelphia College of Osteopathic Medicine in 1974. (Tr. 300.) He undertook clinical and pathological training and completed a residency at the University of Pittsburgh. (Tr. 300.) Respondent is board certified in anatomic pathology, clinical pathology and immunohematology and holds certifications for various procedures. (Tr. 301.) He possesses seventeen years of experience in transfusion and transplantation medicine, has served as medical director of three different blood centers and has completed continuing medical education units since beginning his medical career. (See Tr. 301–02.) Respondent has also taught medical students, residents and interns at the University of Oklahoma and UCLA and has published in twenty-five peer-reviewed journals, including articles on innovative approaches to making blood transfusions safer. (Tr. 301–02, 310.)

Respondent also testified to his medical history. He developed cancer of the colon in late November 2000, which was resolved by chemotherapy and surgery in 2004. (Tr. 307.) Because the cancer had metastasized to his liver, Respondent underwent surgery to remove the right lobe of his liver in February 2002. (Tr. 307.) In 2004, Respondent underwent surgery for sleep apnea. (Tr. 311.) In 2005, Respondent underwent an invasive inpatient operation to perform three ablations to address atrial fibrillation. (Tr. 312.)

Respondent further testified to marital and family issues, and his own related mental health issues. In 2004, Respondent was divorced. (Tr. 313.) In 2006, Respondent and his ex-wife disputed the custody of their son. (Tr. 313–14.) At that time, Respondent was experiencing depression. (Tr. 314.) As a result of the custody dispute, Respondent was permitted to see his son for three hours. (Tr. 314.) Thereafter, Respondent was not permitted to see his son. (See Tr. 314.)

Turning to Respondent’s medical practice, Respondent testified that in or around 1997, Respondent went into private practice as an internist. (Tr. 304–05.) For approximately ten years he performed workers’ compensation assessments. (Tr. 305.) During this time Respondent worked under a grant from the National Institutes of Health to develop an *in vitro* bleeding time test. (Tr. 306.)

From 2000 to the present, Respondent has taken pain management courses with the American Academy of Pain Management. (Tr. 308.) In 2004 or 2005, Respondent purchased a medical practice in Fresno, California and began

treating pain management patients at a time when approximately five or six area physicians practiced pain management. (Tr. 307, 315; 310.) The practice slowly evolved to the point where most of his patients were pain management patients. (Tr. 309.) Respondent testified to experiencing managerial difficulties and theft during the early years of this practice. (Tr. 316–20.)

Paul J. Markowitz (Dr. Markowitz), a board-certified psychiatrist, testified on behalf of Respondent. (Tr. 258.) Dr. Markowitz received a bachelor’s degree and subsequently completed the M.D.-Ph.D. program at Case Western Reserve University in Cleveland, Ohio. (Tr. 256.) Following an internship at the University Hospitals of Cleveland, Dr. Markowitz completed a post-doctoral fellowship in neuropsychopharmacology at Oxford through the National Science Foundation. (Tr. 257.) Following two years working at the Cleveland Clinic and a residency at the University Hospitals of Cleveland, Dr. Markowitz worked as a professor. (Tr. 257.) In approximately 2000 Dr. Markowitz moved to California, where he has practiced for the past ten years. (Tr. 257.) His practice consists of a sixty-hour week, with twenty or twenty-five hours devoted to seeing patients and the balance of his time spent on research trials. (Tr. 258.) Respondent became a patient of Dr. Markowitz in 2005. (Tr. 259.)

David Smiley Purvis (Mr. Purvis), who testified on behalf of Respondent, is a licensed clinical social worker. (Tr. 292.) He holds a bachelor’s degree from Fresno State University and in 1985 received a master’s degree in social work. (Tr. 292.) Mr. Purvis testified to having counseled Respondent on a weekly basis on anger and frustration management since approximately May 2008. (Tr. 292, 294.) He explained that Respondent’s divorce and lack of contact with his son, for whom Respondent cares deeply, were a very difficult and emotional experience for Respondent. (Tr. 293.) Mr. Purvis also testified to having visited Respondent’s practice location to observe how Respondent treated pain management patients, based on Mr. Purvis’s own professional and personal²⁰ interest in how doctors treat pain management. (Tr. 294–95.) Respondent expressed interest in how his own therapy with Mr. Purvis

²⁰ Mr. Purvis explained that his wife was on “very, very serious medications” to treat pain arising out of a 2005 airplane crash. (Tr. 295, 297.)

could help Respondent's patients. (Tr. 297.)

IV. The Parties' Contentions

A. The Government

The Government urges that Respondent's registration would be inconsistent with the public interest and states as follows. (Tr. 8.) First, Respondent repeatedly issued large quantities of highly-addictive controlled substances to patients without a legitimate medical purpose and outside the usual course of professional practice. (Tr. 8–9.) Some of these patients were suspected drug abusers, addicts and dealers, and yet Respondent continued to supply them with narcotics. (Tr. 9.) Second, Respondent has misused controlled substances, having been arrested while driving under the influence of controlled substances, and having tested positive for several controlled substances, including marijuana. (Tr. 8.)

The Government argues in its post hearing brief that “factors two, four and five are relevant in determining whether Respondent's application * * * should be denied.” (Gov't Br. at 25.) The Government argues in substance that Respondent has been responsible for the diversion of large quantities of controlled substances by prescribing “controlled substances to patients without a legitimate medical purpose and/or outside the course of professional practice.” (*Id.*) The Government further argues that Respondent “arguably violated Federal and state law prohibiting the unauthorized use of marijuana and prescription drugs.” (*Id.* at 28 (citing 21 U.S.C. § 844).) The Government argues that “Respondent's complete failure to admit fault or accept responsibility weighs heavily in the public interest determination.” (*Id.* at 28.) Finally, the Government argues that Respondent has provided no facts demonstrating mitigating circumstances and due to Respondent's lack of credibility, his testimony should be given no weight. (*Id.* 29–31.)

B. Respondent

Respondent argues that he is a competent, capable, able physician who is nothing like the image that the Government has portrayed. (Tr. 11.) Respondent denies having prescribed large amounts of controlled substances without a legitimate medical purpose. (Tr. 12.) Moreover, Respondent contends that the Government's expert witness, Dr. Gagné, has a different approach to pain management than does Respondent. (Tr. 12.)

Respondent also argues that evidence of medical and domestic issues affecting Respondent during the time period in question should inform an interpretation of Respondent's conduct. (Tr. 12.) In his post hearing brief, Respondent further argues that the voluntary surrender of his registration on August 21, 2008, is not a ground to support denial. (Resp't Br. at 8.) Similarly, Respondent argues that the “sole conviction for a ‘wet and reckless’ misdemeanor,” in light of Respondent's medical and personal history, does not support a denial of his application for registration. (*Id.* at 8–9.)

Respondent argues that Factors One and Three are inapplicable. Respondent maintains the major issue is his clinical treatment of nine patients, and notes there “were specific mistakes which Respondent made in treating those patients.” (*Id.* at 9.) Respondent argues in substance that there is “little conclusive evidence” of Respondent acting with disregard to the health of his patients or public, and that the record contains substantial evidence that Respondent “was improving his pain and medical practice protocols.” (*Id.*) Respondent “acknowledges that his record-keeping can improve” but argues that he “had significant difficulties with office staff, burglaries and has taken a remedial records course.” (*Id.*)

V. Discussion

A. The Applicable Statutory and Regulatory Provisions

The CSA provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.²¹ “A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner” with a corresponding responsibility on the pharmacist who fills the prescription.²² It is unlawful for any person to possess a controlled substance unless that substance was obtained pursuant to a valid prescription from a practitioner acting in the course of his professional practice.²³ In addition, I conclude that the reference in 21 U.S.C. § 823(f)(5) to “other conduct which may threaten the public health and safety” would as a

matter of statutory interpretation logically encompass the factors listed in § 824(a).²⁴

B. The Public Interest Standard

Pursuant to 21 U.S.C. § 823(f), the Deputy Administrator may deny an application for a DEA COR if she determines that such registration would be inconsistent with the public interest. In determining the public interest, the Deputy Administrator is required to consider the following factors:

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

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: the Deputy Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.*, 58 Fed. Reg. 37,507, 37,508 (DEA 1993); *see also D & S Sales*, 71 Fed. Reg. 37,607, 37,610 (DEA 2006); *Joy's Ideas*, 70 Fed. Reg. 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.*, 54 Fed. Reg. 16,422, 16,424 (DEA 1989). Application of the public interest factors requires an individualized determination and assessment of prescribing and record-keeping practices that are “tethered securely to state law . . . and federal regulations.” *Volkman v. DEA*, 567 F.3d 215, 223 (6th Cir. 2009). Additionally, in an action to deny a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.²⁵ The burden of proof shifts to the respondent once the Government has made its *prima facie* case.²⁶

²⁴ *See Kuen H. Chen, M.D.*, 58 Fed. Reg. 65,401, 65,402 (DEA 1993).

²⁵ *See* 21 C.F.R. § 1301.44(e) (2010).

²⁶ *See Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 380 (DEA 2008); *see also Thomas E. Johnston*, 45 Fed. Reg. 72,311, 72,311 (DEA 1980).

²¹ 21 U.S.C. § 822(a)(2); 21 U.S.C. § 802(10).

²² 21 C.F.R. § 1306.04(a).

²³ 21 U.S.C. § 844(a).

C. The Factors To Be Considered

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

In this case, regarding Factor One, it is undisputed that Respondent currently holds a valid unrestricted osteopathic medical license in California, but Respondent's license has been the subject of a "review [by] the California Medical Board with regard to the appropriateness of [Respondent's] care" (Tr. 71), the results of which are unknown.²⁷ While not dispositive, Respondent's possession of a valid unrestricted osteopathic medical license in California does weigh in favor of a finding that Respondent's registration would not be inconsistent with the public interest. *See Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (DEA 2003) (state license is a necessary, but not a sufficient condition for registration, and therefore, this factor is not dispositive).

Regarding Factor Three, there is no evidence that Respondent has ever been convicted under any federal or state law relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, *see Leslie*, 68 Fed. Reg. at 15,230, weighs against a finding that Respondent's registration would be inconsistent with the public interest.

Factors 2 and 4: Respondent's Experience in Handling Controlled Substances; and Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances

In this case, there is indeed evidence that Respondent has failed to remain in compliance with applicable federal and state law relating to controlled substances, and that his past experience in dispensing controlled substances with regard to nine patients was inconsistent with the public interest. The evidence at hearing centered in substantial part on nine patient files previously seized from Respondent's office on August 21, 2008.²⁸ (ALJ Ex. 1;

Tr. 336–38.) In addition to the patient files, the Government presented the testimony and written report of a medical expert witness, Dr. Gagné, with regard to his review of the nine patient files along with his opinion as to whether Respondent issued prescriptions in each instance for a legitimate medical purpose and in the usual course of professional practice. The patient files related to office visits with Respondent occurring at various dates between 2006 and 2008.²⁹ Respondent testified as to his standard of care and treatment for each of the nine patients, along with his past experience, among other testimony.

Evaluation of Respondent's prescribing conduct in this case is governed by applicable federal and state law. The applicable standard under federal law is whether a prescription for a controlled substance is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The standard of care refers to that generally recognized and accepted in the medical community rather than a standard unique to the practitioner. *Robert L. Dougherty, M.D.*, 76 Fed. Reg. 16,823, 16,832 (DEA 2011) (citing *Brown v. Colm*, 11 Cal.3d 639, 642–43 (1974)). Although it is recognized that state law is a relevant factor in determining whether a practitioner is acting in the "usual course of professional practice," it is also appropriate in the context of an inquiry under federal law to also consider "generally recognized and accepted medical practices" in the United States. *Bienvenido Tan, M.D.*, 76 Fed. Reg. 17,673, 17,681 (DEA 2011).

The applicable standards under California law may be found in various provisions of the California Business and Professional Code as well as the California Health and Safety Code. Mirroring federal law in substantial part, California law provides that:

[a] prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

Cal. Health & Safety Code § 11153(a). Except as authorized by Cal. Bus. & Prof.

fact that the "files appeared to be incomplete." (Tr. 287.)

²⁹ As discussed below, however, not every prescription for controlled substance that Respondent issued is associated with an office visit.

Code § 2241,³⁰ "no person shall prescribe for, or administer, or dispense a controlled substance to, an addict, or to any person representing himself or herself as such. * * *" Cal. Health & Safety code § 11156(a).

Additionally, state law "governing licentiates of the Osteopathic Medical Board of California is found in the Osteopathic Act and in Chapter 5 of Division 2, relating to medicine." Cal. Bus. & Prof. Code § 3600. Relevant provisions of Chapter 5 include:

"Prescribing, dispensing, or furnishing dangerous drugs³¹ * * * without an appropriate prior examination and a medical indication, constitutes unprofessional conduct." *Id.* § 2242(a). "A physician * * * may prescribe * * * prescription drugs * * * to an addict for purposes of maintenance [or] detoxification. * * *" only as set forth pursuant to specified provisions of law limiting continuing treatment to programs licensed by California. *Id.* § 2441(b); Cal. Health & Safety Code § 11217. This requirement does not apply "during emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age." Cal. Health & Safety Code § 11217(h).

Turning to the evidence in the instant case, the testimony and written report of the Government's medical expert, Dr. Gagné, centered on a file review for patients [D.A.], [L.G.], [R.G.H.], [A.L.], [L.M.], [K.P.], [D.S.], [A.W.] and [T.W.].³² With regard to patient [D.A.], Dr. Gagné noted in his report that the medical file consisting of five pages arguably "establishes the minimal documentation necessary to treat a medical problem," but also noted the "record omits the detail necessary to form a medical diagnosis, and there is no basis for the diagnosis stated." (Gov't Ex. 3 at 2.) Dr. Gagné further noted that the "standard of practice for patient records is to document all important aspects of the patient encounter, including: History, current medications, physical examination, tests, assessment, and plan." (*Id.*) Based on a review of [D.A.]'s medical record, Dr. Gagné found

³⁰ § 2241 authorizes a practitioner to "prescribe, dispense, or administer" controlled substances to an addict "for a purpose other than maintenance on, or detoxification from" controlled substances. Moreover, "a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict. * * *" Cal. Health & Safety Code § 11156(b)(2).

³¹ "Dangerous drugs" are broadly defined to include any "drug * * * that by federal or state law can be lawfully dispensed only on prescription. * * *" Cal. Bus. & Prof. Code § 4022.

³² To protect patient privacy, patient initials are used in this Recommended Decision.

²⁷ No further evidence or testimony was offered with regard to the status or outcome of the state review.

²⁸ Testimony at hearing revealed that the process for selecting nine of Respondent's patient files began with the seizure of approximately seventy patient files pursuant to a search warrant, all of which were "individuals that were known to have been either drug dealers or drug abusers and their associates." (Tr. 287.) A California Medical Board Investigator then selected the files to be reviewed by Dr. Gagné based on the "file structure" and the

the “record contains many of these elements in skeletal form,” and further noted as a “glaring omission” with regard to Respondent’s authorization of medicinal cannabis “the absence of a psychiatric or addiction history or any notation as to the patient’s response to cannabis to date.” (*Id.* at 3.) Dr. Gagné also noted the prescription for a large quantity of OxyContin to be “an extreme deviation from the standard of practice, as is the absence of an adequate evaluation to support such a prescription on a medical basis.” (Gov’t Ex. 3 at 2–3; Gov’t Ex. 8 at 5.)

Consistent with his written report, Dr. Gagné testified at hearing that in his opinion Respondent prescribed controlled substances to patient [D.A.] without a legitimate medical purpose and outside of the usual course of professional practice because there was an inadequate medical evaluation. (Tr. 79–80.) Dr. Gagné explained that it is outside of the usual course of professional practice to prescribe OxyContin without an appointment and without a treatment plan or some basis for issuing the prescription, which were lacking here. (Tr. 74–75.) Respondent’s prescription for 180 OxyContin 40 mg was dated January 7, 2007, but the patient file contains no record of an office visit on that day, which occurred approximately four weeks after the previous appointment. (Tr. 74; Gov’t Ex. 3 at 2.) Dr. Gagné indicated that “[t]here may be a medical purpose for prescribing OxyContin (chronic pain), but the record is completely inadequate as to why this is needed rather than a less dangerous alternative.” (Gov’t Ex. 3 at 2.) Dr. Gagné further opined that there is no documented basis, such as an MRI or CT scan report, to support Respondent’s diagnosis of annular tears in lumbar disks; without a basis for diagnosis there can be no basis for treatment. (Tr. 72–73.)

On cross-examination, Dr. Gagné elaborated on the level of detail required for a medical history and physical examination, noting that “best practice is different from the standard practice, and it’s different from the minimal standard one must meet in order to prescribe any treatment appropriately.” (Tr. 212.)

Respondent testified in substance that he initially saw patient [D.A.] on the evening of December 6, 2006, for a cannabis recommendation, and on January 3, 2007, for a pain management visit. (Tr. 345, 351.) Respondent indicated his practice was to see four or five cannabis recommendation patients two evenings per week, and if the patient requested to establish treatment with Respondent on an ongoing basis,

the patient would be required to make another appointment during the day. (Tr. 345.) Respondent explained that he was able to determine that patient [D.A.] had “annular tears” by experience rather than with imaging such as an MRI. (Tr. 346–47.) In sharp contrast, Dr. Gagné testified that an “annular tear is a finding that one would obtain on imaging, probably an MRI or a CT scan, and no imaging was present in this file.” (Tr. 73.) Respondent further explained his ability to diagnose “annular tears” from a variety of physical examination tests he performed, stating that the reason none of the tests were documented in the file was due to “bouts of epicondylitis in my right elbow” that limited his writing ability, among other reasons. (Tr. 348.) Somewhat inconsistently, Respondent also testified that he has “had five of my charts reviewed by the University of California Davis, and they had no problems with what I was doing.” (Tr. 349.) Respondent agreed with Dr. Gagné insofar as the prescription dated January 3, 2007, did not have a corresponding chart entry associated with it. (Tr. 352.) Respondent testified that he prepared a chart “every single time,” but testified to the possibility the file was incomplete because of a staff error. (*Id.*)

With regard to patient [D.A.], I do not find Respondent’s testimony fully credible, particularly given Dr. Gagné’s credible testimony that diagnosis of an annular tear would require imaging. Respondent’s attempt to justify his findings based on “experience” and “testing” finds no objective support in the medical file or other record evidence. To the contrary, other patient files in this record contradict Respondent’s assertion that he prepares a patient chart “every single time.” I accept Dr. Gagné’s findings and opinions regarding Respondent’s deviations from the standard of care for [D.A.], as described above, which are well supported and consistent with the evidence of record.

In the case of patient [L.G.], Dr. Gagné noted in his report a medical file consisting of approximately 126 pages, commenting that “this is an average sort of workup for a primary care physician treating a pain problem,” but noted a number of blank pain management forms and concluded that the “physical examination is completely inadequate.” (Gov’t Ex. 3 at 4.) Dr. Gagné noted that “immediately starting the patient on a high-dose OxyContin is extremely inappropriate without more information.” (*Id.*) Dr. Gagné concluded that the medical records for patient [L.G.] are a “substantial departure from the standard of practice,” further

characterizing the departure as a difficult choice between “simple and extreme departures” but ultimately characterizing it as a simple departure.³³ Finally, Dr. Gagné opined that Respondent’s “[p]rescribing controlled drugs (including opiates) to an addict [and] [p]rescribing sedating drugs to someone having recurrent falls and automobile accidents and altered mental status, presumably due to the drugs being prescribed” was an extreme departure from the standard of care. (Gov’t Ex. 3 at 9.)

Dr. Gagné testified consistent with his report, stating that in his opinion prescribing controlled substances to patient [L.G.] “was inappropriate, it was without a medical basis, it was somebody having recurring problems as a result of the substances, falls and automobile accidents, and there was no medical basis.” (Tr. 108.) Dr. Gagné further testified that “[i]t was clear from the medical record” that [L.G.] was a drug addict. (Tr. 82.) [L.G.]’s urine toxicology screen showed drugs of abuse. (Tr. 83.) In particular, the patient file indicates that [L.G.] tested positive for methamphetamine, opiates, oxycodone and amphetamines even though a review of the patient file reveals the patient was not being prescribed amphetamine or methamphetamine. (Tr. 98; *See* Gov’t Ex. 9 at 4–5.)³⁴ Despite the evidence of drug addiction or drug abuse, Respondent did not take an addiction history for [L.G.] (Tr. 82.) And on February 20, 2008, the same day [L.G.] tested positive for methamphetamine and amphetamines, for which the patient lacked a prescription, Respondent issued a prescription for OxyContin, Roxicodone and an anti-inflammatory drug at the same levels the patient had previously been receiving. (Tr. 98–99.) Dr. Gagné testified that Respondent therefore acted inappropriately, because the patient’s positive test results for methamphetamine and amphetamines should have been “the type of red flag that is a full stop, meaning that one

³³ While not relevant to Respondent’s prescribing practices, Dr. Gagné characterized Respondent’s failure to evaluate, treat or refer patient [L.G.] to a psychiatrist regarding [L.G.]’s depression as a simple departure. (Gov’t Ex. 3 at 9.)

³⁴ Although the transcript reflects that Dr. Gagné referred to Government Exhibit 8, that file does not relate to patient [L.G.] and the pages referenced are inconsistent with a toxicology report. (*See* Gov’t Ex. 8 at 4–5 (patient file for [D.A.]).) Under the circumstances it seems more likely that Dr. Gagné intended to identify Government Exhibit 9. *See* Gov’t Br. at 6 n.4 (acknowledging that Government failed to correct misstatement at hearing).

must stop providing controlled drugs and reevaluate the situation.” (Tr. 99.)

Respondent testified that the pages of the medical chart for [L.G.] were not in the usual order but recalls first treating [L.G.] in December 2006. (Tr. 357.) Respondent acknowledged that he began a practice of urine drug testing toward the end of [L.G.]’s treatment, and that was when he first discovered improper drug use based on a positive test for methamphetamine, opiates, oxycodone and amphetamines. (Tr. 368; Gov’t Ex. 9 at 4.) Respondent stated his intent was to refer [L.G.] to counseling and treat the patient’s pain (Tr. 370) but that stopping the opioids immediately would have caused withdrawal. (Tr. 371.) A February 20, 2008 follow-up consult report states: “Patient took methamphetamine in her coffee a few days ago. She hasn’t injected. She does it once to twice a week.” (Gov’t Ex. 9 at 32.) Notwithstanding this information, Respondent continued to prescribe controlled substances to [L.G.] until August 14, 2008. (Tr. 371.) Respondent further explained that between 2005 and 2008 he was on “a learning curve” and by 2008 “I was getting much better at it. * * *” (Tr. 373.) Respondent also testified that he did not treat [L.G.]’s depression with antidepressants, stating that “I’m not sure why I didn’t do that at the time.” (Tr. 374.)

I find Respondent’s testimony with regard to patient [L.G.] not entirely credible insofar as he maintains his practice was getting much better by 2008. There is simply no credible evidence of record reflecting substantial improvement in Respondent’s prescribing practices and compliance with applicable law. Additionally, Respondent’s explanations that he intended to both refer [L.G.] to counseling and treat her pain is not credible. There is no evidence that a referral was made or any meaningful follow-up in that regard by Respondent. The testimony of Dr. Gagné, supported by [L.G.]’s patient file, reflects a prescribing pattern that is a substantial departure from the standard of care under federal and state law. Dr. Gagné’s opinion that Respondent’s conduct with regard to “[p]rescribing controlled drugs (including opiates) to an addict [and] [p]rescribing sedating drugs to someone having recurrent fall * * *,” among other issues, constituted an extreme departure from the standard of care, is fully supported by the objective evidence of record.

The medical chart pertaining to patient [R.G.H.] consisted of approximately seventy-seven pages. Dr. Gagné commented that the documentation on the first visit of

February 22, 2007, “fills in all the blanks” but “is skeletal and grossly inadequate.” (Gov’t Ex. 3 at 9.) Dr. Gagné documented his review of a series of ongoing office visits by patient [R.G.H.] with Respondent from March 2007 to August 2008, concluding that Respondent had engaged in a number of extreme departures from the standard of care, to include inadequate medical records, prescribing controlled drugs (opiates) to an addict and using opiates with an inadequate evaluation or consideration of therapeutic alternatives. (*Id.* at 12.)

Dr. Gagné testified that [R.G.H.]’s patient file reflected a number of prescriptions for controlled substances for which there was no corresponding appointment with Respondent. (Tr. 112–117.) Dr. Gagné was of the opinion that Respondent’s issuance of prescriptions without a corresponding appointment “was highly inappropriate and without a medical purpose.” (Tr. 118.) Additionally, the patient file for [R.G.H.] included an undated notation indicating positive for “Ecstasy”, “Amph”, Methamph”, “Benzo” and “Methadone.” (Gov’t Ex. 10 at 1.) There is no other record evidence in the patient file further explaining the note, other than a July 9, 2008 follow-up treatment report noting: “Diversion: States [R.G.H.] is not diverting?” (*Id.* at 14) and a July 22, 2008 report noting: “Diversion: Possibly.” (*Id.* at 13.) Dr. Gagné also testified in substance that [R.G.H.] clearly became addicted to powerful controlled substances and Respondent continued to prescribe controlled substances for [R.G.H.] after the addiction became apparent. (Tr. 110.) Dr. Gagné testified to a number of “red flags” in the patient file suggestive of diversion or addiction. (*See* Tr. 110.)

Respondent testified that he initially saw [R.G.H.] on an unscheduled visit while [R.G.H.] was with [R.G.H.]’s mother, for a non-pain management matter, and Respondent referred [R.G.H.] to a specialist for treatment. (Tr. 376–77.) Respondent testified he next saw [R.G.H.] for a pain management appointment on February 22, 2007, when he diagnosed [R.G.H.] with “lumbar disc problems from a motor vehicle accident.” (Tr. 378.) Respondent testified to prescribing various controlled substances to [R.G.H.] at the initial appointment, as well as follow-up appointments, but was uncertain at various points in his testimony as to actions taken because of a lack of information in the chart. For example, when asked why he did not continue to prescribe Soma on a follow-up visit, Respondent indicated “I’m not sure,” further testifying that he would not

ordinarily put information in a patient’s chart if medication was reduced, and “sometimes” put a note in the chart for an increase. (Tr. 380.) When asked why he added Actiq during an April 24, 2007 follow-up appointment, Respondent testified that it was “probably for breakthrough pain,” and further explained that the only time he would prescribe Actiq was for “breakthrough pain or migraine headaches.” (Tr. 381–82.)

Respondent’s testimony with regard to prescribing Actiq is inconsistent with his follow-up chart for the April 24, 2007 appointment. (Gov’t Ex. 10 at 26–27.) There is no reference to “migraine headaches” other than a note in the history section indicating [R.G.H.] went to the emergency room after “feeling really tired, sick, headache, etc.” (*Id.* at 26.) Similarly, there is no reference in the chart to the addition of Actiq, nor any reference to problems with breakthrough pain. To the contrary, the pain scale is circled in the “moderate” pain category. (*Id.*) In fact the “Interval History” form bearing a signature consistent with [R.G.H.]’s name for the date of the appointment describes how [R.G.H.] has been doing since the last appointment which [R.G.H.] marks as “same.” (*Id.* at 27.) Respondent’s explanation for prescribing Actiq to [R.G.H.] is simply not credible.

Respondent next testified to believing that [R.G.H.] was “using * * * and diverting” controlled substances, stating “I was prescribing OxyContin to her, and she was obviously not taking it since it wasn’t in her urine.” (Tr. 384.) Respondent initially testified he did not know when [R.G.H.] was tested because a lot of things “are missing from this chart possibly because they were friends,” further explaining that [R.G.H.] was friends with members of Respondent’s staff. Respondent’s testimony suggested that his medical assistant had taken documents out of the chart, but in the same sentence Respondent said he “was not sure” and had “no way of knowing it.” (Tr. 385.) Moreover, somewhat inconsistent with his initial statement that he did not know when [R.G.H.] was tested, Respondent next testified based on his chart notes of July 22, 2008, that he was aware of the urine test results on that date and refilled [R.G.H.]’s medications, elaborating that “I only refilled it one time” which would be within the thirty-day discharge period for a patient. (Tr. 386.)

I find Respondent’s testimony that he only refilled [R.G.H.]’s prescription for controlled substances one time on July 22, 2008, and subsequently discharged [R.G.H.], palpably not credible. The

unequivocal evidence of record reflects that rather than discharge [R.G.H.], Respondent continued to treat and refill [R.G.H.]’s prescriptions for controlled substances on August 6 and August 20, 2008, even though he knew [R.G.H.] was “using and diverting.” (Gov’t Ex. 10 at 12, 34.) Dr. Gagné found the August 6 and August 20, 2008 prescriptions concerning and opined that they were issued outside the scope of usual professional practice in light of the patient’s acknowledged addiction. (Tr. 123.) He observed:

Having someone self-identify as an addict and be referred to addiction treatment produces an absolute contraindication to provision of any controlled drug whatsoever unless one is working with the diversion—or the addiction treatment program and does so under their direction. So you would need to have close coordination of care. And there’s no evidence that any discussion was had with anybody else about her addiction.

(Tr. 122.) Dr. Gagné opined that Respondent’s controlled substances prescriptions were without medical foundation or basis and constituted prescribing to an addict. (Tr. 123.) I accept the findings and opinions of Dr. Gagné as noted above, which are well supported and consistent with other credible evidence of record.

Turning next to the medical chart of patient [A.L.], Dr. Gagné noted in his report that it consisted of approximately fifty-four pages covering the time period from June to December 2006. (Gov’t Ex. 3 at 12.) Dr. Gagné noted that the initial visit resulted in a prescription dated June 22, 2006, for “180 OxyContin 80mg, 120 Actiq 1600 mcg, and 60 10-mg Valium” along with another prescription with the same date for “another 120 Actiq 1600 mcg and sixty Valium.” (*Id.*) Dr. Gagné further commented that “[t]his is an enormous amount of medication and constitutes overprescribing on its face.” (*Id.* at 13.) A comparative review of the two June 22, 2006 prescriptions from the patient file reveals that one bears in capital letters the word “VOID,” as well as a line through it, indicating that only one prescription was actually issued. (Gov’t Ex. 11 at 23–24.) Accordingly, I give no weight to Dr. Gagné’s specific finding of overprescribing on its face.

In his report, Dr. Gagné also commented that the “initial two visits are an extreme example of form without content,” noting “no good-faith attempt to obtain an adequate history, evaluate for possible addiction, detail precise symptoms, determine neurologic status, or perform an adequate physical evaluation.” (*Id.*) After reviewing chart information for patient [A.L.] surrounding a September 20, 2006

follow-up visit, Dr. Gagné commented that this “has now become bizarre,” noting in part that the file contained a Controlled Substance Utilization Review & Evaluation System (CURES) report dated September 5, 2006, showing another doctor was prescribing to [A.L.] 90 OxyContin 80 mg once a month from March 22 to July 21, 2006. Dr. Gagné referenced a final office visit dated December 14, 2006, in which the patient chart for [A.L.] contains a notation from Respondent regarding the patient’s abuse of drugs and medications, stating

I am upset and really let him know it. He kept making excuses. And I stopped the excuses. I will fill his meds, have him come back in a month. He has to come back with a drug treatment facility—phone number, etc., then I may discharge. I will make that decision next time.

(*Id.* at 14; *see* Gov’t Ex. 11 at 25.)³⁵

Consistent with his written report, Dr. Gagné’s testimony emphasized that Respondent’s prescribing of controlled substances to [A.L.] was not in the context of a good-faith physician-patient relationship, there was no medical purpose served and the prescriptions were not issued in the usual course of professional practice. (Tr. 137.) In support of this conclusion, Dr. Gagné explained that [A.L.] tested positive for metabolites of methadone, Soma, marijuana and benzodiazepines, based on a specimen given November 16, 2006, and a report printed November 21, 2006. (Gov’t Ex. 11 at 48–53; Tr. 130–33.) The patient file contains a printed toxicology report containing a handwritten notation indicating that “Benzo prescribed—last time was August,” which Dr. Gagné interpreted as referring to three months before [A.L.] underwent the drug test. (Gov’t Ex. 11 at 53; *see* Tr. 130–31.) Dr. Gagné further testified that although this handwritten comment did not raise any concerns because it can be appropriate for patients to take medication intermittently, three other handwritten comments are concerning. (Tr. 131.) The toxicology report reflects a handwritten notation next to “methadone” stating “Not Prescribed by me—stated a Family Member Gave to Him;” next to Carisoprodol, a note appears stating “not Prescribed;” next to Cannabinoids, a note states “not Prescribed or Made Legal.” (Gov’t Ex. 11 at 53; *see* Tr. 131.)

Dr. Gagné further testified that these notes “confirm[] that we have a problem here” with respect to Respondent’s prescribing practices. (Tr.

131.) Respondent received [A.L.]’s toxicology report at least as early as December 14, 2006 (Gov’t Ex. 11 at 48; Tr. 132), confronted the patient about [A.L.]’s abusive drug habits (Gov’t Ex. 11 at 25; Tr. 133), but nevertheless prescribed to [A.L.] 240 OxyContin 80 mg and 90 Roxicodone 30 mg on that day (Gov’t Ex. 11 at 46; Tr. 132). Dr. Gagné testified that Respondent issued the December 14, 2006 prescriptions outside the usual course of professional practice in light of “evidence that the patient is not only abusing drugs but has additional sources of opiates.” (Tr. 134.)

Respondent testified with varying levels of certainty and specificity with regard to his prescribing practices for patient [A.L.] (Tr. 387–395.) For example, when asked why there was a discrepancy in the chart as to an initial visit date of June 22, 2006, but a medication agreement was dated June 26, Respondent replied “I don’t know.” (Tr. 394.) In terms of specifics of what he might do differently in the future, Respondent testified “I think I’d be better educated in abuse * * *” (Tr. 395.) As to the issue of diversion, Respondent testified that “I noticed that he was either using or diverting. And we got a CURES Report that showed that * * * [A.L.] was discharged within six or so visits as well, but there’s no discharge letter in this chart. And I know for a fact he was discharged. I know he was discharged.” (Tr. 393.) But the evidence contradicts Respondent’s testimony. The evidence reflects that after the September 5, 2006 CURES report which Respondent acknowledges as confirmation of “using or diverting,” Respondent continued to prescribe controlled substances on four additional occasions.³⁶ Additionally, contrary to Respondent’s testimony that [A.L.] was discharged, a phone message note in [A.L.]’s chart dated January 17, 2007, states: “[A.L.] need his oxy. All the paperwork you asked for. Per Dr. B 1/17/07 just bring in paperwork will speak to rehab place 1st before meds are given.” (Gov’t Ex. 11 at 22.) This note directly contradicts Respondent’s assertion that [A.L.] had been discharged.

For the foregoing reasons, I find Respondent’s testimony with regard to patient [A.L.] not credible. Dr. Gagné’s conclusions and opinion of extreme deviations in Respondent’s compliance with the standard of care as to patient [A.L.] pertaining to the absence of a good-faith medical evaluation prior to prescribing controlled drugs, prescribing controlled drugs to someone

³⁵ I give no weight to Dr. Gagné’s reference in his written report to Respondent’s credibility. (Gov’t Ex. 3 at 14.)

³⁶ September 20, October 20, November 16 and December 14, 2006. (Gov’t Ex. 11 at 32, 28 & 25.)

Respondent knew or should have known was an addict and prescribing controlled drugs without a legitimate medical purpose, are fully consistent with the objective evidence of record. I also accept Dr. Gagné's opinion as to a "simple deviation for the standard of practice" as it pertains to [A.L.]'s medical records. (Gov't Ex. 3 at 14.)

With regard to patient [L.M.], the patient chart consisted of sixty-three pages covering the period from July 2006 to April 2007. Dr. Gagné testified that based on his review of the chart, "medications were not given in a good-faith manner or for a legitimate medical purpose." (Tr. 139.) Dr. Gagné noted in his report that the initial July 12, 2006 consultation note indicated: "diagnosis is 'chronic pain from fractured ankle,' and the treatment two OxyContin 80 mg every 12 hours and two Norco 10/325 three times a day." (Gov't Ex. 3 at 15.) Dr. Gagné commented that the chart did not "qualify as a good-faith medical evaluation" and there was no basis for prescribing large quantities of opiates." (*Id.*) Of note, Dr. Gagné stated "[c]ertainly the dose of opiates provided would be fatal in an opiate-naïve patient." (*Id.*) In summary, Dr. Gagné found the overall chart contained "elements of the history and physical exam" but there was "no meaningful content," and therefore "the records themselves reflect a simple deviation from the standard of practice." (*Id.* at 17.) Additionally, Dr. Gagné found extreme deviations from the standard of practice given the absence of a good-faith medical evaluation prior to prescribing controlled drugs, prescribing controlled drugs without legitimate medical purpose and overprescribing much larger doses of opiates than was indicated clinically. (*Id.*)

Respondent testified that he could not explain the absence from the chart of items such as past medical history, review of alcohol or drug abuse, and work history. (Tr. 395–96.) Respondent stated he would ordinarily gather that information. Respondent explained that he was deceived by patients, but doing better now, "although I'm not seeing any pain management patients * * * ." (Tr. 397.) Respondent further testified that if given a DEA registration, he would never again prescribe OxyContin but was unsure if he would engage in pain management. (Tr. 398.) Respondent testified that he believes he first discovered [L.M.] was engaging in duplicitous conduct "when we got the CURES Report." (Tr. 398.) Respondent next stated the "patient was discharged as well" but "believed [L.M.] was discharged soon after * * * ." the urine

test and CURES report. (Tr. 399.) In contrast, Respondent testified on cross-examination that he did not know when he received the CURES report, claiming he did not see the report or "it wasn't in the chart until later." (Tr. 460.)

The patient file for [L.M.] contains a CURES report dated September 22, 2006, bearing a handwritten notation consistent with the word "file." (Gov't Ex. 12 at 56.)³⁷ A review of [L.M.]'s chart reveals no other reference to receipt of the CURES report.³⁸ Contrary to Respondent's testimony, [L.M.] was not discharged. Rather, Respondent continued to prescribe controlled substances on successive follow-up visits dated: October 20, 2006; November 17, 2006; December 15, 2006; January 11, 2007; January 30, 2007; and February 28, 2007. (Gov't Ex. 12 at 23–33.) In fact, the chart contains a "communication log" dated April 24 to 27, 2007, confirming conversations consistent with notations by a staff member in Respondent's office, indicating [L.M.] was "asking for refill of Oxyfast was told had to ask Dr., come back tomorrow." (*Id.* at 15.) A subsequent entry reflects [L.M.] "came back in late p.m. advised per doctor needs to have drug screen 1st before new RX," to which [L.M.] questioned the need, stated [L.M.] was unable to provide a urine sample and indicated an intention to return the next day. (Gov't Ex. 12 at 15.) The entry the next day indicated [L.M.] "never returned." (Gov't Ex. 12 at 15.) [L.M.]'s return to Respondent's office in April of 2007 for a "refill" is inconsistent with Respondent's assertion that [L.M.] had been discharged, at any time. Clearly, [L.M.] did not believe [L.M.] had been discharged and the chart notations suggest that Respondent had not discharged [L.M.], which if true would have precluded the necessity of a urine screen.

Accordingly, I find Respondent's testimony with regard to [L.M.] not credible based in part on various factual inconsistencies, as well as his numerous non-responsive and evasive answers to questions posed on both direct and cross-examination. (*See* Tr. 396–99; 457–60.) I accept Dr. Gagné's findings and opinions regarding Respondent's deviations from the standard of care for [L.M.], as described above, which are well supported and consistent with the evidence of record.

³⁷ The CURES Report is dated September 22, 2006 and reflects various prescriptions for [L.M.] between March 30, 2006 and August 10, 2006, listing four other prescribers in addition to Respondent.

³⁸ A urine drug screen report for [L.M.] is dated November 22, 2006. (Gov't Ex. 11 at 54.)

The evidence and testimony pertaining to patient [K.P.] included a patient chart consisting of forty-one pages covering the time period January to July 2007. The patient chart includes prescriptions for various controlled substances dated: January 11, 2007; February 8, 2007; February 15, 2007; February 16, 2007; March 6, 2007 ("to pick up on March 14"); March 6, 2007; March 30, 2007; April 20, 2007; April 30, 2007; May 16, 2007; June 8, 2007; June 18, 2007; July 3, 2007; July 12, 2007; and July 12, 2007. (Gov't Ex. 13 at 24–38.) The patient chart reflects an initial consultation report dated January 11, 2007, with follow-up reports dated: February 8, 2007; March 6, 2007; March 30, 2007; May 16, 2007; June 8, 2007; June 19, 2007; and July 5, 2007. (*Id.* at 5–15.)

Dr. Gagné commented in his written report that based on chart documentation relating to the initial January 11, 2007 consultation,

the information in this visit constitutes an inadequate basis for treating any disease or condition and does not in my view reflect a good-faith medical evaluation. There is no real diagnosis and no basis for a diagnosis of "annular tears." ³⁹ The amount of medication prescribed is egregious: 750 mg/day of oxycodone. Finally, there is no information in the chart from any other physician, including the doctor who presumably referred the patient.

(Gov't Ex. 3 at 18.) The chart information for the February 8, 2007 follow-up visit reflects an increase in medication at the request of [K.P.], noting "pt would like to ↑ oxy to #240" (Gov't Ex. 13 at 13.) A corresponding prescription "dated 2/8/07 is for 240 OxyContin 80 mg (taken as four every 12 hours) and 240 Roxicodone 30 mg, for a total of 1,200 mg daily." (*Id.*) The evidence also reflects two additional prescriptions issued to [K.P.] on February 15 and 16, 2007, with no associated clinic note present in the chart. (*Id.* at 35–36.) Dr. Gagné noted the prescription dated "2/15/07 is for 150 Actiq 1600 mcg * * * and ten 100-mcg/hour fentanyl patches [and] yet another prescription on 2/16/07 is for another sixty OxyContin." (Gov't Ex. 3 at 18.) Dr. Gagné commented in his report that there "is no legitimate medical purpose for this medication. Anyone who actually took this much would be at risk

³⁹ The January 11, 2007 consult chart reflects "current medications Dose/Freq" as "OxyContin 80 x 180;" "Roxicodone 30 x 540." (Gov't Ex. 13 at 15.) This quantity reflected [K.P.]'s self-reported current medications which Respondent recorded. (Tr. 460.) Dr. Gagné noted in his report that this would reflect a daily dose of 1020 mg of oxycodone, which would be a "staggering dose" if accurate. (Gov't Ex. 3 at 17.)

for extreme opiate side effects, including seizure and death.” (*Id.*)

Consistent with his report, Dr. Gagné testified that the indication in [K.P.]’s patient file that the patient was receiving 540 Roxicodone 30 mg from another doctor constitutes a “huge red flag full stop * * * when you see something like that, you can’t prescribe controlled drugs until you sort out what’s going on.” (Tr. 162.) Dr. Gagné also noted that the patient file contains the notation “Patient of Dr. [W.]’s,” with no corresponding evidence that Respondent consulted with or obtained records from

Dr. [W.] (Tr. 162–63.) The patient file also indicates that [K.P.] rated [K.P.]’s level of aerobic exercise as moderate, which raises a red flag because “[i]t’s inconsistent with somebody who has extreme pain requiring stupendous doses of opiates.” (Tr. 163.) The patient file further reflects a notation by Respondent “Need to do drug screen,” but the record contains no evidence that a drug screen was performed and further reflects that Respondent later prescribed Roxicodone, fentanyl, Dilaudid and two prescriptions for OxyContin in July of 2007. (Tr. 163, 164.) To Dr. Gagné, this “reinforces the impression that there’s no legitimate medical purpose underway here.” (Tr. 163–64.) Dr. Gagné further testified that Respondent’s prescribing behavior with respect to [K.P.] was “completely inconsistent” with someone who is concerned that a person is diverting drugs. (Tr. 163.) Dr. Gagné opined that in prescribing to [K.P.] Respondent overlooked the high probability of diversion, lacked a good-faith medical evaluation and issued prescriptions outside the usual course of professional practice. (Tr. 165.)

Respondent testified in substance that [K.P.] came to him from Dr. [W.] who Respondent described as “doing pain management in town, who I got a lot of patients from and who I discovered were abusing their medications. In fact, there’s at least a handful of patients I reduced their medications significantly.” (Tr. 401.) Respondent further testified regarding the current level of medication [K.P.] self-reported, stating this “is what Dr. [W.] had a lot of patients on. And it is absurd.” (Tr. 461.) Respondent could not explain the absence of records from Dr. [W.] in the patient chart, stating that “most all my charts have records from Dr. [W.]” (Tr. 401.) Respondent suggested that the absence of records were not due to a lack of request on his part, but due to staff problems in his office at the time. “It was—it was a problem in the office that I had so much turnover between 2003 and 2007. You know how costly it

is and how difficult it is to keep training new help. * * *” (Tr. 403–04.) Respondent’s knowledge that “a lot” of patients from Dr. [W.] were abusing their medications, and that Dr. [W.] was prescribing absurd amounts of medications, at a minimum should have caused Respondent to have a heightened level of scrutiny in the case of [K.P.] Instead, the patient chart is effectively devoid of any evidence that Respondent took any reasonable action to meet his “responsibility for the proper prescribing * * * of controlled substances.”⁴⁰

Respondent also testified with regard to dosage levels, stating that he first prescribes the medication and then over a three or four month period evaluates the patient’s medical problems and determines if an increase or decrease is warranted. (Tr. 402.) That testimony is inconsistent with Respondent’s treatment of [K.P.], because the objective chart information indicates Respondent increased [K.P.]’s medication less than thirty days from the initial consult visit, notably at the patient’s request, rather than for a stated medical reason. In fact, on the “Interval History” form bearing [K.P.]’s signature for the February 8, 2007 appointment, which asks the patient to assess how the patient has been doing since the last visit with regard to back pain, [K.P.] notes “same.” (Gov’t Ex. 13 at 14.)

Respondent also testified that he had gone through “these records about a half dozen times” and noticed “yesterday” that several signatures relating to prescriptions for [K.P.] were not his, apparently suggesting that people other than Respondent wrote the prescriptions. (Tr. 404–05.) Referring to page numbers of prescriptions contained in Government Exhibit 13, Respondent elaborated further on direct examination: “The prescription on 38 is not my signature”; “Page 34 is not my signature”; “The one on page 31 is not my signature. I’m not sure about 29 * * * I can’t really tell.” (Tr. 405–06.) On cross-examination, Respondent presented conflicting testimony. Respondent acknowledged his signature with regard to most prescriptions,⁴¹ but testified initially that “34 looks like it’s mine” but later testified “Looks like it’s not mine.” (Tr. 465, 466.) Directly contradicting his earlier testimony with

regard to page twenty-nine, Respondent testified “That appears to be mine.” (Tr. 465.) Similarly, Respondent directly contradicted his earlier testimony with regard to page 38, testifying “It’s mine.” (Tr. 467.) Respondent’s testimony with regard to the questionable signatures for three other prescriptions was vague: “This one I can’t tell * * * I do not know” (Tr. 466 (Page 31).); “I’m not sure” (*Id.* (Page 35).); “I can’t tell on that.” (Tr. 467 (Page 37).)

I do not find credible Respondent’s testimony suggesting that several signatures on prescriptions issued to [K.P.] may be forged. There is no objective evidence of record to support the suggestion that someone else forged Respondent’s signature, and Respondent’s conflicting testimony on something as fundamental as recognition of his own signature, particularly with regard to the prescriptions reproduced in Government Exhibit 13 at pages twenty-nine, thirty-four and thirty-eight, is plainly incredible. I also do not find credible Respondent’s testimony suggesting his staff may have been at fault for the lack of follow-up or documentation in the patient chart. There is simply no evidence to support the assertion and Respondent’s demonstrated lack of credibility in numerous specific portions of his testimony casts significant doubt on his entire testimony.

I accept Dr. Gagné’s conclusions and opinion of extreme deviations in the standard of care for patient [K.P.] pertaining to Respondent’s: Grossly inadequate medical records, including no visit at all for several prescriptions; prescribing of controlled drugs without a legitimate medical purpose; lack of a good-faith medical evaluation prior to prescribing controlled drugs; and overlooking of the high probability of diversion. (Gov’t Ex. 3 at 19.) As to the last point, Respondent not only overlooked but in fact knowingly accepted a high probability of diversion by admittedly accepting what he agreed was an “absurd” level of dosing for [K.P.] (Tr. 461.)

I do not, however, accept Dr. Gagné’s conclusion and opinion with regard to Respondent’s “prescribing controlled drugs to an addict or to someone he should have known was an addict.” There is no reference in [K.P.]’s patient chart to drug use or addiction. Any opinion or conclusion in that regard by Dr. Gagné is mere speculation.⁴²

⁴⁰ 21 C.F.R. § 1306.04(a).

⁴¹ Page numbers referenced herein refer to page numbers on bottom center of Government Exhibit 13, consistent with the presentation of evidence at hearing. Respondent acknowledged his signature on pages twenty-four to thirty, thirty-three, thirty-six and thirty-eight. (Tr. 465–67.) No testimony was offered with regard to the March 30, 2007 prescription. (Gov’t Ex. 13, at 32.)

⁴² Dr. Gagné also speculates that the “only reason I can fathom for someone requesting all this medication is so [K.P.] can sell it,” which notably

The evidence as to patient [D.S.] included a patient chart numbering thirty-one pages covering the time period from October 2007 to January 2008. The chart includes a "Consultation" note dated October 29, 2007, stating "Pt was seen during cannibus nite [sic]," with no other entries for history of present illness, current medications, physical exam or diagnosis, among other fields. (Gov't Ex. 14 at 31.) The patient chart also contains a copy of a prescription dated October 24, 2007⁴³ for "180 Norco 10/325 with two refills, 180 soma with two refills, and a pint of Phenergan with Codeine" although there is no corresponding entry in the chart documenting a clinical visit consistent with the prescribed medication. (Gov't Ex. 3 at 20.) A follow-up report dated December 15, 2007, under "History of Present Illness" stated "med refill" and included a diagnosis of "Lumbar disc degeneration, chronic pain, depression." (*Id.*; Gov't Ex. 14 at 30.) A copy of a prescription⁴⁴ dated December 15, 2007 is for 180 OxyContin 80 mg, 180 Norco 10/325, 180 soma, a pint of Phenergan with codeine, and 60 Zolof 100 mg. (Gov't Ex. 3 at 20; *see* Gov't Ex. 14 at 2 & 25.)

The testimony and report by Dr. Gagné include findings and opinions as to extreme deviations from the standard of practice: Grossly inadequate medical records, including no visit at all when Respondent wrote one prescription; prescribing large quantities of dangerous, potentially lethal sedating medications to a depressed patient for whom no assessment was made for suicidal ideation or intent; absence of good-faith medical evaluation prior to prescribing controlled drugs; prescribing controlled drugs without a legitimate medical purpose; prescribing

conflicts with his opinion as to addiction. (Gov't Ex. 3 at 18.) I give no weight to these comments as to [K.P.]'s specific intent. Intent aside, the evidence is fully consistent with a high probability of diversion.

⁴³ The date could arguably read October 29, 2007, coinciding with chart information of an office visit for "cannabis night." (Gov't Ex. 14 at 24.) Further confusing the issue, Respondent's counsel asked Respondent to describe this patient "when she presented in your office apparently October 27th, '07," to which Respondent replied in context stating that he first saw [D.S.] on December 15, 2007. (Tr. 408.) In any event, there is no supporting chart information for prescribing controlled substances on October 29, 2007. (*See* Gov't Ex. 14 at 31.)

⁴⁴ Notes related to the prescription reflect that Respondent prescribed a three-month supply because the patient stated "she was going to Texas to see family & would not be back for 3 mo." (Gov't Ex. 14 at 30.) Dr. Gagné commented in his report that "[g]iving someone who is depressed and possibly suicidal enough controlled and sedating medication to kill themselves and then planning not to see them for three months is extraordinarily poor care to say the least." (Gov't Ex. 3 at 20.)

controlled drugs to an addict or to someone Respondent should have known was an addict; and overlooking a high probability of diversion. (Gov't Ex. 3 at 21.) Dr. Gagné testified in substance that Respondent prescribed "large quantities of controlled drugs with multiple refills with no legitimate medical purpose." (Tr. 148, 154.) He also testified that Respondent's diagnosis of lumbar disc disease and chronic pain lacks a medical basis. (Tr. 148–49.)

Respondent testified in substance to first seeing [D.S.] on December 15, 2007, and said the patient "was in for pain medications and cough and colds." (Tr. 408.) Respondent testified that he noted on [D.S.]'s chart "that she doesn't have her pain managed" but did not "understand why" he stated that. (*Id.*) Respondent then explained that he was "really putting the history of present illness down" noting that [D.S.] had injured [D.S.]'s back while lifting. (*Id.*) Respondent further explained that he diagnosed lumbar disc degeneration, chronic pain and depression, and "I ordered an X-ray be done on her." (*Id.*) Inconsistent with Respondent's testimony, the corresponding chart does not reflect a contemporaneous order of an X-ray but rather includes a January 15, 2008 order for a "Lumbar spine X-ray Multiview." (Gov't Ex. 14 at 26.)

By way of explanation for prescribing a three-month supply, Respondent testified: "And then I gave her a three-month supply where she stated she was going to Texas to visit family. And I trusted that was the truth, and so I wrote it out for three months or enough for three months." (Tr. 409.) Respondent testified in substance that, other than [D.S.], he has not had a patient on an initial visit ask for a three-month supply, and even for longstanding patients it is "not usually something that I normally do." (Tr. 411–12.) Respondent explained that in retrospect he would have questioned [D.S.] differently and "I wouldn't prescribe it." (Tr. 412.) Respondent further acknowledged that with regard to his initial evaluation of [D.S.] "there is room for improvement" but never suspected at the time of [D.S.]'s first visit that [D.S.] was an addict or was diverting the medication. (*Id.*)

The evidence of record is consistent with Respondent's testimony that he normally does not prescribe a three-month supply. Respondent also testified that in January 2008 when [D.S.] came in on an unscheduled walk-in visit, [D.S.] was discharged. (Tr. 410.) A follow-up patient chart report is consistent with Respondent's testimony, reflecting in part a notation: "No longer

Seeing Patient. I think this patient has scammed me" and another notation: "Patient threatened me to have my license revoked." (Gov't Ex. 14 at 29.)

Although I find Respondent's testimony partially credible as noted above, there is no testimony or other evidence of record addressing in any way the October 24, 2007 prescription signed by Respondent, nor does any credible testimony or evidence rebut the findings of the only expert witness in the case, Dr. Gagné, concerning his findings and opinions of extreme deviations from the standard of practice for patient [D.S.] Accordingly, I accept the findings and opinions of Dr. Gagné pertaining to extreme deviations from the standard of practice as noted above, with the exception of Dr. Gagné's opinion that Respondent prescribed "controlled drugs to an addict or to someone he should have known was an addict." (Gov't Ex. 3 at 21.) There is insufficient evidence of record to support such a finding as to patient [D.S.]

The patient record for [A.W.] included a patient chart numbering 205 pages covering the time period from November 2005 to August 2008. Dr. Gagné's initial findings and opinion regarding the prescribing practices for [A.W.] differed in some respects from his testimony at hearing. Dr. Gagné stated in his written report that he is "of two minds about this case," noting at one point that Respondent "treats the patient's symptoms without establishing a medical diagnosis," but also stating shortly thereafter "I did feel the diagnoses at the initial visit of plantar fasciitis and possible facet arthropathy had some basis." (Gov't Ex. 3 at 24.) Dr. Gagné further stated in his report: "I do not see overprescribing or sense the patient is abusing or diverting the medications." (*Id.*) Dr. Gagné's report also included a notation consistent with the foregoing, to include a review of records pertaining to [A.W.]'s January 2007 hospital admission, where Dr. Gagné noted: "Chemistries are unremarkable, as is the urinalysis." (*Id.* at 22 (interpreting Gov't Ex. 15 at 189–205).)

On direct examination, Dr. Gagné testified in substance that although "I had not spotted this in my initial review," there was a urine drug screen dated January 2007 that was positive for cocaine. (Tr. 181–82.) Dr. Gagné further testified in substance that this report was in the patient chart but Respondent "had not ordered it * * * [so] we have no idea [if] it was something that he saw [but] I think there's plenty of evidence of doctor shopping and other aberrant medication behaviors." (Tr. 182.) Dr.

Gagné's reference to "plenty of evidence" was a reference to other aspects of his testimony on direct examination that highlighted chart information inconsistent with prescribing for a legitimate medical purpose. For example, Dr. Gagné was of the opinion that Respondent issued various prescriptions for controlled substances for other than a legitimate medical purpose or outside the usual course of professional practice. (Tr. 170–78.) The patient record for [A.W.] reflects additional warning signs. Dr. Gagné testified that [A.W.]'s medical record in multiple instances contains evidence of phone calls from other clinics to the extent that [A.W.] "has been getting pain medications referred by multiple physicians and three different pharmacies." (Tr. 179.) Upon specific questioning about an April 2006 chart note and a July 2008 letter, Dr. Gagné testified that "this is clear-cut evidence of * * * doctor shopping." (Tr. 179; see Gov't Ex. 15 at 7 & 72.) Moreover, Dr. Gagné stated that a note by Respondent that "History of Present Illness: She gives me very little information to obtain those records" would "absolutely" give a practitioner cause for concern before prescribing opiates. (Tr. 180.) Additionally, [A.W.]'s patient file indicates that the patient requested—and Respondent denied—early refills. (Tr. 180.) Another yellow flag is an indication that the patient requested a brand name medication. (Tr. 180–81.) And significantly, a drug screen report also showed that [A.W.] tested positive for cocaine, and there is no evidence that Respondent discharged the patient for using illegal substances.⁴⁵ (Tr. 181–82.)

Respondent testified in substance with regard to [A.W.] that [A.W.] "came to me from the other practice in central Fresno" where Respondent believed a full history and physical had been conducted. (Tr. 414.) Respondent testified that he did not "recall if I had [A.W.] on OxyContin from the other office or whether I just started treating [A.W.] then with OxyContin." (*Id.*) Respondent also testified that staff should have obtained prior records but

did not, and acknowledged in retrospect that he should have done another history and physical examination. (*Id.*) Respondent testified that he never believed [A.W.] was drug seeking when he began treatment and never determined that [A.W.] was diverting. (Tr. 416; 421.) Respondent further testified that he does not consider therapeutic alternatives with every patient but does have a mission statement to "use as many different modalities as possible to help the patient with pain." (Tr. 422.)

Respondent's testimony with regard to his knowledge of possible diversion by [A.W.] is not consistent with the objective evidence of record, as early as April 2006. Dr. Gagné testified that the January 2007 lab report finding [A.W.] positive for cocaine, and related chart information, does not indicate whether Respondent was aware of such a finding, particularly because it was not ordered by Respondent. Standing alone, the possibility of overlooking such a finding is not unreasonable, and in fact Dr. Gagné overlooked it in his initial file review. The same cannot be said for the April 2006 chart notation and the July 19, 2008 letter addressed to Respondent. The chart contains a prescription log bearing an entry dated April 10, 2006:

Margie from central Valley Clinic called to inform us that patient is getting Valium, Lortab & Soma from their office. Also she says that patient uses Valium, Lortab & Soma from their office. Also she says that patient uses various pharmacies using different insurances to refill [A.W.]'s meds.

(Gov't Ex. 15 at 7.) A second entry dated April 19, 2006, states:

Patient given a RX for [O]xy[C]ontin since we had to reschedule appt. [A.W.] was advise[d] to keep [A.W.]'s appt. This is the last Rx because [A.W.] will be discharged *per Dr. Brubaker*.

(*Id.* (emphasis added).)

Clearly Respondent was aware of diversion issues related to [A.W.] no later than April 19, 2006, because he had instructed his staff that [A.W.] was to be discharged. Notably, patient chart notes on and after April 10, 2006, make no reference to the known issue of diversion, or to discharge. To the contrary, a follow-up report dated July 11, 2006, notes in part "No evidence of abuse * * *." (*Id.* at 139.) A letter addressed to Respondent from the pharmacy benefit manager Wellpoint Next Rx dated July 19, 2008, is further to the point, stating in relevant part: "Our pharmacy claim records indicate that your patient listed above has had pain medications prescribed by you and at least 2 other physicians and have filled prescriptions in at least 3 different

pharmacies in a 3-month period." (*Id.* at 72.) This evidence unequivocally contradicts Respondent's testimony suggesting he had no knowledge of diversion by [A.W.] Rather, the July 19, 2008 letter confirms [A.W.]'s ongoing diversion of controlled substances consistent with information known to Respondent in April 2006. As with other material portions of Respondent's testimony, I find Respondent's relatively brief testimony on this issue not credible.

Dr. Gagné concluded in his written report for patient [A.W.] that Respondent's medical records are "a substantial departure from the standard of practice," further characterizing it as a simple rather than extreme departure. (Gov't Ex. 3 at 25.) Dr. Gagné also concluded that "the final simple departure from the standard of practice is using opiates without consideration of therapeutic alternatives." (*Id.*) I accept the findings and opinions of Dr. Gagné with the exception of his opinion that there is no evidence of "overprescribing" or evidence that "the patient is abusing or diverting the medications," as reflected in his written report. That finding is inconsistent with the objective chart information, as early as April 2006, and Dr. Gagné credibly testified that he had overlooked the information for purposes of his written report.

The evidence as to patient [T.W.] included a patient chart numbering forty-six pages covering the time period from September 2006 to January 2007. Dr. Gagné noted that the initial visit resulted in a diagnosis of chronic hip, back and leg pain from stress fracture and that Respondent's "recommended treatment is 'herbal meds.'" (*Id.* (citing Gov't Ex. 16 at 42).) The chart contains a corresponding prescription dated September 20, 2006, "for 180 OxyContin 20 mg, three every 12 hours, 120 Norco 10/325, 1–2 every 4 hours as needed, and 90 Xanax 2 mg, one 3 times a day." (Gov't Ex. 16 at 39.) Dr. Gagné commented in his report that "[t]here is no basis in this record for any but the most minimal treatment; there is certainly no legitimate medical purpose to prescribe such enormous quantities of opiates, which would be fatal in an opiate-naïve person." (Gov't Ex. 3 at 25; see Gov't Ex. 16 at 39.) The patient chart contains a November 1, 2006 prescription for "120 Dilaudid 8 mg, 120 Norco 10/325, and 90 Xanax 2 mg," with no evidence of a corresponding clinic visit. (See Gov't Ex. 3 at 25.)

Dr. Gagné's report outlines additional visits by [T.W.] with corresponding controlled substances prescriptions, noting finally that a

⁴⁵ Moreover, Dr. Gagné testified that Respondent did not order the drug screen that there is no indication whether Respondent saw the drug screen report. (Tr. 182.) But because the drug screen report was in Respondent's patient file for [A.W.], I find that Respondent was on inquiry notice of the contents of the report, even if he did not possess actual knowledge of it. There is no indication that the drug screen report was added to the patient file after the file left Respondent's custody and control following the execution of a warrant at Respondent's registered location (*e.g.*, Tr. 324), and counsel for Respondent did not object to the report's admission at hearing. (Tr. 183.)

“Consultation” note dated 1/31/07 is clearly not a patient visit: “Discovered in the Fresno Bee [newspaper] that this patient has been selling drugs of abuse and [T.W.]’s pain meds and cannabis. This type of behavior ruins treatment for other patients. I hope [T.W.]’s put away for 10+ years. [T.W.] sure had me fooled. This patient has note in the computer now to never be seen again, ever.”

(*Id.* at 26 (citing Gov’t Ex. 16 at 8).) Dr. Gagné’s findings and opinion with regard to Respondent’s standard of practice for [T.W.] included extreme departures in the following areas: grossly inadequate medical records, including no visit at all when Respondent wrote one prescription; absence of a good faith medical evaluation prior to prescribing controlled drugs; prescribing controlled drugs without a legitimate medical purpose; prescribing controlled drugs to an addict;⁴⁶ and overlooking a high probability of diversion. (*Id.* at 27; see Tr. 189.) Elaborating on his report, Dr. Gagné testified that [T.W.]’s patient file reflects that Respondent prescribed Dilaudid to [T.W.] on November 1, 2006, without an associated patient consultation, and without mention in the medical notes that Respondent wrote such a prescription. (Tr. 184–85.) Nor is there any mention of Dilaudid in contemporaneous patient notes. (Tr. 185.) Dr. Gagné opined that there is no record that would justify the prescription. (Tr. 185.) The record further reflects a significant increase in an OxyContin prescription from 20 mg, 180 count on September 20, 2006, to 80 mg, 300 count on November 21, 2006. (Tr. 186.) The record associated with [T.W.]’s November 21, 2006 doctor’s appointment does not justify increasing the patient’s OxyContin by that amount. (Tr. 186.) Dr. Gagné testified that the entire situation “has a trolling-for-drugs quality.” (Tr. 186.) Dr. Gagné further found it unusual that on the day Respondent increased the dose to 300 pills a month, Respondent wrote “Stable on 5 OC two 12 H,” because the patient was not yet taking that many pills. (Tr. 187.) Patient [T.W.]’s medical file also contains references to MRI and X-ray reports that are not contained in the patient’s medical file. (Tr. 187.)

Respondent testified he initially saw [T.W.] on September 20, 2006, for a “cannabis recommendation.” (Tr. 424; Gov’t Ex. 16 at 41.) Respondent further testified that he did not learn who was prescribing [T.W.]’s current medications, stating “I don’t really do

that for cannabis recommendations.”⁴⁷ Respondent testified in substance that he normally handled cannabis recommendations at night, but after review of [T.W.]’s chart information testified that [T.W.] must have come in during the afternoon for a cannabis recommendation and pain management visit. (Tr. 426 & 435–36.) Respondent testified that during the initial consult with [T.W.] he prescribed the same medications [T.W.] had stated [T.W.] was already prescribed. (Tr. 427.) Respondent provided no credible explanation for the November 1, 2006 prescription that is not associated with a corresponding clinical visit, other than to refer to the November 21, 2006 note.⁴⁸ (Tr. 428.) Respondent testified consistent with the November 21, 2006 chart note that his plan was to have [T.W.] obtain an X-ray, adding: “[T.W.] never did it, so I discharged [T.W.]” (Tr. 428.) On the issue of suspecting [T.W.] may be diverting, Respondent testified: “Intuitively I felt there was something wrong with this patient, and I couldn’t in just a few visits really tell what—what [T.W.] was up to. But in retrospect, he was one of the patients that sold, along with one other patient that sold * * *.” (Tr. 429.)

I do not find Respondent’s testimony credible. Contrary to his assertion that he “discharged” [T.W.] because of lack of an X-ray following the November 21, 2006 appointment, the patient chart reflects a follow-up note dated January 15, 2007, stating in part “Refill med Patient stable * * * Need to repeat CT scan * * *.” (Gov’t Ex. 16 at 9.) There is no credible evidence of record to support the suggestion that [T.W.] was discharged by Respondent at any point prior to the January 31, 2007 chart note indicating [T.W.] had been arrested for “selling.”⁴⁹ Accordingly, I accept the

findings and opinions of Dr. Gagné pertaining to extreme deviations from the standard of practice as noted above, which are well supported and consistent with other credible evidence of record.

In addition to the foregoing, Respondent also testified at various points that the nine patient files admitted as evidence may be incomplete, or may otherwise have been altered, but offered no credible evidence to support this suggestion.⁵⁰ Respondent suggested staff problems may have been the cause, but testified that “overall I’m responsible because I’m the physician, owner of the practice; but when you have difficulties with staff, they can burn you, they can burn you bad.” (Tr. 353.) I do not find credible Respondent’s testimony suggesting that his files would have been complete but for staff neglect or tampering. As an initial matter, there is no objective evidence of record to support Respondent’s claim. To the contrary, as discussed above, the objective record in numerous instances calls into question the accuracy of Respondent’s chart entries, Respondent’s testimony, or both.⁵¹ Additionally, the overall credibility of Respondent’s testimony was significantly undermined in numerous other material areas, making it less likely that Respondent’s unsupported claims of tampering are true. In any event, Respondent is ultimately responsible for the proper prescribing and dispensing of controlled substances. 21 CFR § 1306.04.

Respondent also testified that he never received copies of the fifty to seventy files seized by the police in August 2008, and maintained that he was unaware the files had been returned to his attorney. (Tr. 325–26.) On the issue of seized files, DI Lewis testified that after the patient files were seized from Respondent pursuant to a search warrant, two copies were made and one “copy of these records w[as] returned through [Respondent’s] attorney at the time, and a second copy was provided to the Medical Board of California.” (Tr.

⁴⁷ Respondent qualified his testimony, stating that he currently determines who is prescribing medications for a new patient, but was not doing so at the time of [T.W.]’s initial visit. (Tr. 424.)

⁴⁸ Reference to the November 21, 2006 chart note is irrelevant to the November 1, 2006 prescriptions, which precede the November 21, 2006 visit. In any event, there is another prescription for controlled substances associated with the November 21, 2006 visit. (See Gov’t Ex. 16 at 36.)

⁴⁹ There is evidence of Respondent’s lack of truthfulness with regard patient [T.W.] after January 31, 2007. Apparently following a telephone conversation with staff members of the facility detaining [T.W.], Respondent wrote a letter to “Physician’s at the Prison & His attorney” stating in relevant part, “I saw [T.W.] a few visits in my office where I prescribed [T.W.] [X]anax * * * for anxiety * * * wellbutrin * * * for ADHD * * * Norco 10/325 * * *.” (Gov’t Ex. 16 at 16; see Tr. 432.) On cross-examination Respondent stated he was confused and did not “understand what was transpiring between the prison doctor and myself at this time.” (Tr. 433.) Respondent admitted he wrote the letter and the statement as to prescribed medications was “not a true statement.” (*Id.*)

⁵⁰ For example, Respondent testified at one point that “a lot of things, I think are missing from this chart possibly because they were friends. And the MA took it out and excluded it. I’m not sure. I have no way of knowing it.” (Tr. 385.) Respondent also testified to a March 2007 theft of a computer containing prescription information. (Tr. 316–19.)

⁵¹ See, e.g., Tr. 73 (finding annular tears absent medical imaging); Tr. 394 (unexplained discrepancy in patient file as to initial visit date and medication agreement); Tr. 424 (recording “current medications” on patient representations alone, absent corroboration from other prescriber); Gov’t Ex. 15 at 7, 139 (notations in chart of “no evidence of abuse * * *” when Respondent in fact did have such evidence).

⁴⁶ In support of this opinion, Dr. Gagné notes in his report [T.W.]’s self-reported “huge marijuana habit” which is “telegraphing that he’s an addict.” (Gov’t Ex. 3 at 26.)

289.) The issue of whether Respondent ever received copies of his patient files from his then-attorney is not directly relevant to the instant case, because it is undisputed that Respondent received copies of the patient files discussed herein well in advance of hearing.⁵²

For the foregoing reasons, I find by substantial evidence that Respondent issued a substantial number of controlled substance prescriptions for other than a legitimate medical purpose and outside the usual course of professional practice, in violation of federal and state law.⁵³ This finding weighs heavily in favor of a finding under Factors Two and Four of 21 U.S.C. § 823(f) that Respondent's registration would be inconsistent with the public interest.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

Under Factor Five, the Deputy Administrator is authorized to consider "other conduct which may threaten the public health and safety." 5 U.S.C. § 823(f)(5). The Agency has accordingly held that "where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct. *Patrick W. Stodola*, 74 Fed. Reg. 20,727, 20,734 (DEA 2009).⁵⁴ A "[r]espondent's lack of candor and inconsistent explanations" may serve as a basis for denial of a registration. *John Stanford Noell, M.D.*, 59 Fed. Reg. 47,359, 47,361 (DEA 1994). Additionally, "[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest." *Joseph Gaudio, M.D.*, 74 Fed. Reg. 10,083, 10,094 (DEA 2009).

There was evidence presented at hearing pertaining to "other conduct which may threaten the public health and safety." 5 U.S.C. § 823(f)(5). The

OSC alleges that Respondent was arrested for driving under the influence of controlled substances on June 13, 2008, and that toxicology results revealed the presence of the controlled substances marijuana, modafinil, oxazepam and temazepam, for which Respondent lacked a prescription. The Government's evidence at hearing included the testimony of DI Lewis, along with related alcohol and toxicology reports and California Highway Patrol arrest reports. (Gov't Exs. 6 & 7.) DI Lewis testified in substance that based on his investigation, including a review of a CURES Report, there were corresponding prescriptions for identified controlled substances in Respondent's system with the exception of temazepam and marijuana. (Tr. 278–79.)

Respondent argues in substance that the "sole conviction for a 'wet and reckless' misdemeanor, to which Respondent pleaded guilty, and which there is little evidence of any drugs for which he did not have a valid prescription," as a single error, "is not any indication of impairment or abuse, nor is there any other evidence of impairment or abuse." (Resp't Br. at 8–9.) Respondent presented testimony from Dr. Markowitz, who testified in substance that he is board-certified and currently practicing psychiatry. (Tr. 257–58.) Dr. Markowitz testified that he began treating Respondent in 2005, noting that Respondent was "pretty severely depressed at the time," for which Dr. Markowitz prescribed medications and Respondent "improved markedly pretty quickly." (Tr. 259.) Dr. Markowitz diagnosed Respondent with major depression along with generalized anxiety disorder, noting past stressors of divorce, health, child visitation and financial issues. (Tr. 260.) Dr. Markowitz further testified that upon review of the toxicology document (Gov't Ex. 6) he prescribed two of the listed medications, namely clorazepate, sold under the trade name Tranxene, and Provigil, referred to on the toxicology report as "modafinil." (Tr. 263–64.) Dr. Markowitz also opined that Respondent is not "depressed at this time" and "from a psychiatric perspective, I don't have any issues with his ability to practice." (Tr. 265.)

David Smiley Purvis also credibly testified to counseling Respondent on a weekly basis since May 2008 for anger and frustration management issues related to family matters. (Tr. 292–93.)

Respondent presented testimony in response to the June 2008 arrest, along with testimony explaining his health and other personal issues leading up to

his August 2008 surrender of registration. Respondent testified in substance to having serious health issues and surgery between 2000 and 2002, as well as surgery again in 2004, and a heart condition in 2005 that involved inpatient treatment. (Tr. 307.) Additionally, Respondent testified to personal problems impacting his life including a 2004 divorce with custody issues involving his child. (Tr. 313–14.) Respondent further testified to ongoing issues with depression, staff problems in his office, and two break-ins and thefts from his office in 2007.

Turning to the June 2008 arrest, Respondent testified to pleading to a "wet reckless" charge,⁵⁵ and then took six months of classes which "were about alcohol addiction." ⁵⁶ (Tr. 330.) Respondent testified that he was taking three medications at the time: "Provigil," "Tranxene," and an antidepressant which Respondent thinks was "Pristiq." (Tr. 328.) Respondent testified that all three were prescribed by Dr. Markowitz. Respondent's counsel then reminded Respondent that Dr. Markowitz only identified two prescriptions, "but you mentioned you were on three medications," to which Respondent stated "[w]ell the third one was the metabolite of benzodiazepine." ⁵⁷

I find by a preponderance of the evidence that Respondent used controlled substances, namely temazepam and marijuana, without a valid prescription and contrary to state and federal law in or about June 2008.⁵⁸

⁵⁵ No further evidence or explanation at hearing of term "wet reckless" was offered, although as a matter of California practice the term refers to violations of Cal. Veh. Code § 23103.5 (West 2009). See, e.g., *People v. Claire*, 280 Cal. Rptr. 269, 271 n.2 (Cal. Ct. App. 1991) ("For the sake of convenience, we adopt this sodden terminology.").

⁵⁶ Respondent presented testimony regarding events surrounding his arrest for driving under the influence, including testimony of consumption of "one" glass of "ale." I note that Respondent's testimony differs in various respects from the California Highway Patrol report, including notations in the police reports that Respondent admitted to drinking two beers. (See Gov't Ex. 7 at 2, 10.) In any event, given the absence of other evidence or explanation for the discrepancies, I generally accept the testimony of Respondent that this was an isolated incident involving consumption of a relatively small quantity of alcohol. I also accept Respondent's testimony that he completed a class on alcohol addiction.

⁵⁷ Respondent's answer regarding the "third" prescription is at best non-responsive. Whether or not the third one was a metabolite of benzodiazepine does not respond to the substantive issue of whether Respondent had a prescription for the controlled substance, nor does it explain Respondent's earlier testimony that he thinks it was "Pristiq." No other testimony or evidence was offered.

⁵⁸ Gov't Ex. 6 at 3; 21 U.S.C. § 844(a); 21 CFR § 1306.04(a); Cal. Bus. & Prof. Code. § 4060.

⁵² At no time during pre-hearing proceedings did Respondent raise by motion or otherwise this issue of unavailable files despite numerous opportunities to do so, as more fully explained in the procedural portion of this Recommended Decision. Respondent's suggestion in testimony that the missing files impeded his ability to take care of his patients is not a relevant issue in the instant proceeding, even if true, because Respondent's misconduct at issue in this proceeding predated the seizure of the nine patient files discussed above. (Tr. 325.)

⁵³ See 21 CFR § 1306.04(a); 21 U.S.C. § 841(a)(1); and Cal. Health & Safety code §§ 11217; 11153(a) and 11156(a); Cal. Bus. & Prof. Code §§ 2241; 2442(a) and 3600.

⁵⁴ See also *Hoxie v. DEA*, 419 F.3d 477, 484 (6th Cir. 2005) (decision to revoke registration "consistent with the DEA's view of the importance of physician candor and cooperation.")

Respondent's argument that he was prescribed all of the controlled substances in his system is directly contradicted by the credible testimony of Dr. Markowitz and Dr. Lewis. I find no evidence of any alcohol or other non-prescribed controlled substance use by Respondent after June 2008, which is consistent with Dr. Markowitz's testimony and opinion that Respondent is not currently suffering from depression.

Agency precedent has "long held that a practitioner's self-abuse of a controlled substance is a relevant consideration under factor five and has done so even when there is no evidence that the registrant abused his prescription writing authority." *Tony T. Bui, M.D.*, 75 Fed. Reg. 49,979, 49,989 (DEA 2010). Respondent's unlawful conduct in June 2008, which was associated with his use of alcohol and non-prescribed controlled substances, is clearly an "indication of impairment or abuse" at least in June 2008, and Respondent's argument to the contrary is without merit. That said, Respondent's conduct appears to be a relatively isolated event. Respondent testified to completing a class on alcohol addiction and there is no evidence to support a finding of alcohol or controlled substance abuse after June of 2008. *See Azen v. DEA*, 1996 WL 56114 at *2 (9th Cir. Feb. 9, 1996) (impressive evidence of rehabilitation and continued abstinence important consideration). Accordingly, I find Respondent's conduct in June 2008 to be inconsistent with the public interest and a relevant consideration weighing somewhat against registration.⁵⁹ *See David E. Trawick, D.D.S.*, 53 Fed. Reg. 5326, 5326 (DEA 1988) (holding that "offences or wrongful acts committed by a registrant outside of his professional practice, but which relate to controlled substances may constitute sufficient grounds" for denying relief favorable to Respondent, where Respondent had history of alcohol and controlled substances abuse).

Because the Government has made out a prima facie case against Respondent, a remaining issue in this case is whether Respondent has adequately accepted responsibility for his past misconduct such that his registration might nevertheless be consistent with the public interest. *See Patrick W. Stodola*, 74 Fed. Reg. 20,727, 20,734 (DEA 2009). Respondent argues generally that the Government has failed

to demonstrate that granting Respondent a new registration would be inconsistent with the public interest. But across various dimensions, the record reveals that Respondent has not sustained his burden in this regard. In fact, as discussed above, Respondent's testimony in numerous material instances was not credible and reflected an overall lack of admission of past misconduct, let alone acceptance of responsibility. The passage of time since Respondent's misconduct is of no consequence with regard to the issue of acceptance of responsibility. "DEA has long held that '[t]he paramount issue is not how much time has elapsed since [his] unlawful conduct, but rather, whether during that time * * * Respondent has learned from past mistakes and has demonstrated that he would handle controlled substances properly if entrusted with a new registration.'" *Robert L. Dougherty, M.D.*, 76 Fed. Reg. 16,823, 16,835 (DEA 2011) (citing *Leonardo V. Lopez, M.D.*, 54 Fed. Reg. 36,915, 36,915 (DEA 1989) and *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,227 (DEA 2003)). Respondent's testimony with regard to his June 2008 misconduct, and his misconduct pertaining to Factors Two and Four, clearly indicate a complete lack of acceptance of responsibility.

I find that Respondent's lack of credibility during numerous material portions of his testimony weighs heavily in favor of denying Respondent's application. *See Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005) (DEA properly considers physician's candor, forthrightness in assisting investigation and admitting of fault as important factors in determining whether registration is consistent with public interest). In light of the foregoing, Respondent's evidence as a whole fails to sustain his burden to accept responsibility for his misconduct and demonstrate that he will not engage in future misconduct. I find that Factor Five weighs heavily in favor of a finding that Respondent's registration would be inconsistent with the public interest.

VI. Conclusion and Recommendation

After balancing the foregoing public interest factors, I find that the Government has established by substantial evidence a prima facie case in support of denying Respondent's application for registration, based on Factors Two, Four and Five of 21 U.S.C. § 823(f). Once DEA has made its prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be

appropriate. *See Morall v. DEA*, 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys v. DEA*, 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. United States Dep't of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston*, 45 Fed. Reg. 72, 311 (DEA 1980).

Additionally, where a registrant has committed acts inconsistent with the public interest, he must accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *See Patrick W. Stodola*, 74 Fed. Reg. 20,727, 20,735 (DEA 2009). Also, "[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest." *Joseph Gaudio, M.D.*, 74 Fed. Reg. 10,083, 10,094 (DEA 2009). An agency's choice of sanction will be upheld unless unwarranted in law or without justification in fact. A sanction must be rationally related to the evidence of record and proportionate to the error committed. *See Morall v. DEA*, 412 F.3d 165, 181 (D.C. Cir. 2005). Finally, an "agency rationally may conclude that past performance is the best predictor of future performance." *Alra Laboratories, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995).

I recommend denial of Respondent's application for a COR. I find the evidence as a whole demonstrates that Respondent has not accepted responsibility and his registration would be inconsistent with the public interest. Respondent's overall lack of candor while testifying at hearing is fully consistent with a denial of Respondent's application for a DEA COR.

Dated: April 29, 2011.

Timothy D. Wing,

Administrative Law Judge.

[FR Doc. 2012-7619 Filed 3-29-12; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Application No. D-11679]

Notice of Amendment to Proposed Exemption Sammons Enterprises, Inc. Employee Stock Ownership Plan (the ESOP); Located in Dallas, TX

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Notice of amendment to proposed exemption.

⁵⁹ In light of the absence of other evidence of controlled substance and alcohol abuse, the passage of time, and Respondent's attendance at alcohol addiction classes, I give this issue little overall weight for purposes of my recommended decision.