824(a)(5), and alternatively, that the balance of the other factors in this case weighs heavily in favor of a finding that Respondent's registration would be inconsistent with the public interest under § 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 (DC 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 FR 72,311 (DEA 1980).

Additionally, where a potential registrant has committed acts inconsistent with the public interest, she must accept responsibility for her actions and demonstrate that she will not engage in future misconduct. *See Patrick W. Stodola,* 74 FR 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 FR 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 (DC 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. I find the evidence as a whole demonstrates that Respondent has not accepted responsibility. To the contrary, Respondent maintains without credibility that she is being unfairly persecuted because of her pain management practice. Respondent's past performance, including a felony conviction for health care fraud, past and recent history of non-compliance with applicable laws and regulations, and overall lack of candor while testifying at hearing is fully consistent with a denial of Respondent's application for a DEA COR.

Dated: December 30, 2010.

Timothy D. Wing,

Administrative Law Judge

[FR Doc. 2011–28002 Filed 10–27–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–73]

Shawn M. Gallegos, D.D.S., Decision and Order

On May 19, 2011, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact, conclusions of law and recommended order in its entirety except as explained below.[1] Accordingly, I will order that the Respondent's application be denied.

Order

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

Dated: October 7, 2011.

Michele M. Leonhart,

Administrator.

Theresa Krause, Esq. & Brian Bayly, Esq., for the Government

Shawn M. Gallegos, D.D.S., pro se, Respondent

Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

Introduction

Administrative Law Judge Timothy D. Wing. 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 dentist's application for a DEA Certificate of Registration (COR) as a practitioner. Without this registration the dentist, Shawn M. Gallegos, D.D.S. (Respondent or Dr. Gallegos), of Martinez, California, will be unable to lawfully prescribe, dispense or otherwise handle controlled substances in the course of his practice.

On August 3, 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 why the DEA should not deny Respondent's application for a DEA COR, filed on or around January 27, 2010, pursuant to 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), on the grounds that Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

In part and in substance, the OSC alleges that Respondent voluntarily surrendered his DEA registration number BG6936491 for cause on December 2, 2009, alleging that during the course of a DEA investigation concerning suspicious orders of hydrocodone and phentermine, Respondent stated the controlled substances were not used in the normal course of his dental practice. The OSC further alleges that on multiple occasions, Respondent failed in his responsibility as a practitioner to ensure that the controlled substances ordered and dispensed by him were for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, in violation of 21 CFR 1306.04(a). Additional alleged violations include the inability to account for the dispensing of the controlled substances in violation of 21 CFR 1304.04(a); the failure to keep a dispensing log for controlled substances, in violation of 21 CFR 1304.03(b); the failure to keep accurate, complete and mandatory records of controlled substances in violation of 21 CFR 1304.21(a); the failure to properly report the theft of hydrocodone and the unauthorized use of Respondent's registration, in violation of 21 CFR 1301.76(b); the failure to establish a valid doctor-patient relationship before issuing and dispensing controlled substances (diet pills), which were for other than a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04; and the commission of ''such acts that would render Respondent's registration inconsistent

[1] At page 19 of the slip opinion, the ALJ explained that ''Respondent's statement during the December 2, 2009 audit that the dispensing records were located within his patient records was found to be inaccurate. Even if true, the patient records would not substitute for required copies of DEA Form 222 relating to the Schedule II controlled substance oxycodone, among other recordkeeping requirements.'' To make clear, a DEA Form 222, which is otherwise known as an ''order form,'' must be executed for each distribution of a schedule II controlled substance with the exception of those distributions which are exempt under 21 CFR 1305.03. This form is not required, however, to document a practitioner's dispensing of controlled substances, which must be recorded in a dispensing log. *See* 21 CFR 1304.03(b), 1304.22(c). While the record establishes that Respondent ordered oxycodone only a single time (for which he did not have a copy of the requisite Form 222), Respondent was also required to maintain, for a period of two years, records documenting the receipt of all controlled substances he acquired, as well as an initial inventory when he first engaged in controlled substances activities and biennial inventories thereafter for each controlled substance he acquired. *Id.* 1304.04(a), 1304.11, 1304.21(a). Respondent, however, had no such records.

with the public interest, particularly in light of [the] failure to comply with State and Federal laws relating to controlled substances,'' citing 21 U.S.C. 823(f)(4) and 824(a)(4).[2]

In addition to the OSC, the Government also noticed and alleged in its September 24, 2010 prehearing statement that on January 16, 2010, Respondent used his previously surrendered DEA registration to call in a prescription for the controlled substance lorazepam, which was filled and dispensed to patient [GS]. (Gov't PHS at 7.) The Government further alleged that ''DI Windsor will testify that this [lorazepam] controlled substance is not used in the normal course of the Respondent's dental practice.'' [3] (Gov't PHS at 7–8.) The Government further alleged that ''Respondent will testify that he told DI Windsor and DI Myers that his suspicious orders of hydrocodone and phentermine were not used in the normal course of his dental practice.'' [4] (Gov't PHS at 3.) Finally, the Government alleged various instances of unprofessional conduct contained within a document entitled: ''In the Matter of the Accusation Against [Respondent],'' brought on behalf of the Dental Board of California, and dated January 31, 2011. (Gov't Ex. 10.)

On September 13, 2010, Respondent, acting *pro se,* requested a hearing on the allegations in the OSC. Following prehearing procedures, a hearing was held on April 5, 2011, in San Francisco, California, with the Government represented by counsel and Respondent appearing *pro se.*[5] Both parties called witnesses to testify and introduced documentary evidence. Respondent elected not to testify. After the hearing, both parties filed proposed findings of fact, conclusions of law and argument. 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.

Issue

Whether the record establishes by substantial evidence that Respondent's application for a DEA COR, W10004582C, as a practitioner, should be denied pursuant to 21 U.S.C. 823(f) and 824(a)(4), because Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).

Evidence and Incorporated Findings of Fact

I. Background

Respondent was assigned DEA registration BG6936491 on September 7, 2000, as a practitioner in Schedules II–V. (Gov't Ex. 1.) The last renewal of this registration was on October 1, 2009, at the address of 220 E. Alamo Plaza, Alamo, California. On December 2, 2009, Respondent voluntarily surrendered this registration, ''after which date no controlled substances could be obtained, stored, administered, prescribed, or dispensed under DEA registration BG6936491.'' (Gov't Exs. 1 & 2.) On January 27, 2010, Respondent submitted an application for registration W10004582C as a practitioner in Schedules II–V, at the address of 220 E. Alamo Plaza, Alamo, California. (Gov't Exs. 1 & 3.)

II. The Government's Evidence

At hearing, the Government presented the testimony of three witnesses: Respondent's former patient [GS];[6] Respondent's ex-wife and former employee Maria Muratalla (Ms. Muratalla), and DEA Diversion Investigator Jamee Windsor (DI Windsor). DI Windsor testified in substance to having over ten years of experience in law enforcement, and to having been a diversion investigator with DEA since July 2009. (Tr. 107–109.) DI Windsor first became involved in an investigation of Respondent following receipt of a June 11, 2009 ''Suspicious Order'' report by The Harvard Drug Group (Harvard),[7] noting Respondent's order of four controlled substances that were inconsistent with his dental practice.[8] The report noted in bold print, with asterisks: ''*This dentist ordered the above items for their personal use.*'' [9] (Tr. 113; Gov't Ex. 5 at 1.) DI Windsor testified that the four controlled substances in question [10] are Schedule IV controlled substances used as diet aids to treat moderate to extreme obesity. (Tr. 113–14.)

The evidence also included a transaction history report from DEA's Automation of Reports and Consolidated Orders System (ARCOS),[11] reflecting six controlled substance transactions between Harvard and Respondent between October 2, 2007, and March 27, 2009. (Gov't Ex. 5 at 2–5; Tr. 121–22.) Five of the orders were for Schedule III controlled substances, and one transaction, dated July 30, 2008, was for the Schedule II controlled substance oxycodone. (Tr. 141; Gov't Ex. 5 at 2.)

DI Windsor next testified to visiting Respondent's registered practice location on the morning of December 2, 2009, accompanied by another DEA diversion investigator. (Tr. 129.) Respondent was present in the office along with a receptionist, and possibly a third employee. When the diversion investigators arrived they presented Respondent with a DEA form entitled Notice of Inspection of Controlled Premises, which was subsequently

[2] ALJ Ex. 1.

[3] At hearing, DI Windsor offered no testimony specifically addressing this issue. The Government did offer testimony from Ms. Muratalla which was mixed in terms of the use of lorazepam in Respondent's dental practice. Ms. Muratalla testified in substance that lorazepam was ''used for other people'' and also for dental patients. (Tr. 63–64.)

[4] Notably, the only testimony offered at hearing by DI Windsor regarding Respondent's December 2, 2009 statements arguably relevant to controlled substances not being used in the normal course of his dental practice, consisted of the following: ''Dr. Gallegos had said that he ordered diet pills for his wife and he had also said that she had ordered them for herself.'' (Tr. 146.) DI Windsor further testified based on her knowledge and experience as a diversion investigator that diet pills were inconsistent with a dental practice. (Tr. 119–20.) There was no testimony supporting the allegation that Respondent made similar reference to hydrocodone. DI Myers was not called to testify at hearing and Respondent did not testify. No written reports were offered memorializing any statements made to DEA diversion investigators by Respondent.

[5] Throughout the course of prehearing procedures Respondent was afforded various opportunities to obtain counsel, to include a letter to Respondent from the Office of Administrative Law Judges identifying Respondent's right to counsel pursuant to 21 CFR 1316.50 (2010) (ALJ Ex. 3), a similar notation in a November 12, 2010 prehearing ruling (ALJ Ex. 5 at 1–2) and the granting of a continuance at Respondent's request so that Respondent might obtain counsel. (ALJ Ex. 8 at 1–2.) At hearing, Respondent affirmed that he wished to proceed with the hearing without the assistance of counsel. (Tr. 4.)

[6] The patient's initials are used to protect patient privacy.

[7] Harvard was described by DI Windsor as a re-distributor of controlled substances to DEA registrants. (Tr. 116.)

[8] The report by Harvard contains a note at the bottom of the page which was determined by DI Windsor to be an error by Harvard. The notation ''[p]lease note that these are 3 separate 222 forms * * * all three signed by the same person'' was acknowledged by Harvard to be a mistake (''a typo'') on Harvard's part, but the remaining information in the report was believed to be accurate. (Tr. 127.)

[9] No testimony or evidence was offered regarding what knowledge or information formed the basis for this statement.

[10] Adipex (100 count bottle), Fastin (1000 count bottle), phentermine (1000 count bottle) and Tenuate (100 count bottle). (*See* Gov't Ex. 5 at 1.)

[11] DI Windsor offered testimony regarding the system. I also note that ''Registrants are also required to report records of sales or acquisitions of controlled substances in Schedules I and II, of narcotic controlled substances listed in Schedules III, IV and V, and of psychotropic controlled substances listed in Schedules III and IV with the DEA's Automation of Reports and Consolidated Orders System (ARCOS). 21 CFR 1304.33(c); 21 U.S.C. 827(d). These reports must be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted. 21 CFR 1304.33(b).'' *Easy Returns Worldwide, Inc.* v. *United States,* 266 F. Supp. 2d 1014, 1016 (E.D. Mo. 2003).

signed by Respondent.[12] (Tr. 131–34.) DI Windsor further testified that the inspection included ''an inventory of [Respondent's] dispensing of his controlled substances * * *.'' (Tr. 134–35.) The results of the inventory reflected 89.5 tablets of 5mg/500mg hydrocodone present in the office. (Gov't Ex. 8; Tr. 138.) In addition to the inventory, the inspection also sought to review required records, to include biennial inventories, dispensing logs, copies of DEA Form 222 for Schedule II controlled substances and other invoices for Schedule III–V controlled substances. (Tr. 139–41.) DI Windsor testified that none of the required records could be located and Respondent was unable to produce any. (*E.g.,* Tr. 141–42.) The diversion investigators reviewed a random sampling of Respondent's patient files, none of which included dispensing records for hydrocodone or oxycodone. (Tr. 142–43.)

DI Windsor also testified regarding statements made by Respondent during the inspection relating to controlled substances. With regard to diet pills, DI Windsor testified that Respondent first raised the issue, stating that ''he had ordered diet pills for his wife [referring to Ms. Muratalla] and he had also said that she ordered them for herself.'' (Tr. 146.) DI Windsor did not recall specifically discussing the diet pills Adipex, Fastin, phentermine or Tenuate with Respondent, or the specific time frames for the orders. (Tr. 147.) The inspection revealed no invoices, inventory or dispensing records of any type for any of the diet pills referenced in shipment records to Respondent. (Tr. 147–48.) DI Windsor further testified that Respondent stated he purchased the diet pills with a company credit card, and informed DI Windsor that he would work on getting a copy of the bill, but as recently as the date of hearing Respondent had not produced a copy. (Tr. 153.)

DI Windsor next testified that Respondent stated during the inspection that there had been two occasions within the preceding one or two years in which controlled substances believed to be hydrocodone that had been placed on his desk ''had come up missing.'' (Tr. 148, 150.) Respondent further stated that ''on one occasion he did not contact law enforcement [and] on the second occasion he thought law enforcement had been contacted by one of his staff, but he wasn't certain of that.'' (Tr. 149.) Respondent was certain that neither incident had been reported to DEA. (*Id.*) The lack of available records at Respondent's registered location precluded DI Windsor from determining the amount of the loss.

The evidence also included a form entitled Voluntary Surrender of Controlled Substances Privileges, dated December 2, 2009, and signed by Respondent. (Gov't Ex. 2.) DI Windsor testified that after the completion of the closing inventory and request for documentation, Respondent was presented the form, including an explanation of its terms and Respondent's right to re-apply at a later date. (Tr. 155–56.) Respondent signed the form but was unable to produce a copy of his DEA COR. (Tr. 159; Gov't Ex. 9.)

On cross- and redirect examination, DI Windsor testified to being at Respondent's office on December 2, 2009 for approximately two hours. (Tr. 168.) DI Windsor testified that between December 2, 2009, and August 3, 2010, she spoke with Respondent by telephone approximately six times regarding Respondent's application and the California Dental Board, but DI Windsor ceased communication with Respondent after becoming aware that Respondent ''had a patient call [DI Windsor] pretending to be [Respondent's] attorney.'' (Tr. 169, 173.) DI Windsor further testified that upon Respondent's request that she contact Harvard to inquire about the ordering of diet pills, DI Windsor called Harvard and was informed that the person who ordered the diet pills in June 2009 was not Ms. Muratalla.[13] (Tr. 170; 182–83.) DI Windsor's testimony was fully credible. Her testimony was internally consistent, corroborated by documentary evidence of record and the witness was able to recall factual events with a reasonable level of certainty.

The Government presented the testimony of Respondent's former patient [GS], who credibly testified in substance to being Respondent's patient from December 2009 until approximately March 2010. (Tr. 38–40.) [GS] testified that Respondent treated her initially in December 2009 for an infected tooth, and later in or about January 2010 Respondent performed a root canal. (Tr. 38.) [GS] further testified that Respondent prescribed ''two rounds of antibiotics * * * initially [and] on the third visit * * * he gave me a prescription for lorazepam.'' (Tr. 39.) [GS] specifically recalls being prescribed the lorazepam in the latter part of January or February of 2010. (*Id.*) On cross-examination, [GS] admitted to filing a complaint against Respondent with the California Dental Board ''for not finishing the work that I paid for.'' [14] (Tr. 41.)

The evidence also included a pharmacy prescription record dated January 16, 2010, detailing a prescription for ''Amox'' and ''Lorazepam'' to patient [GS], and listing Respondent as the prescriber. (Gov't Ex. 6.) DI Windsor credibly testified in relevant part that the prescription was ''phoned in'' and lorazepam was the only controlled substance prescribed and dispensed.[15] (Tr. 162–63.)

The Government next offered the testimony of Ms. Muratalla, who testified in substance to having married Respondent in 1999, separated in May 2008, and divorced in June 2010. (Tr. 47–48.) Ms. Muratalla explained that she also had a working relationship with Respondent, initially working as colleagues and eventually opening their own practice in September 2002. (Tr. 48.) Ms. Muratalla testified that her primary duty was working as a dental hygienist, but also had responsibilities such as ''management, payroll * * * accounts receivable and accounts payable, as well as * * * cleaning crew on weekends.'' (Tr. 49.) Ms. Muratalla explained that she performed all of the above duties until July 22, 2008, when Respondent removed her access to his financial accounts. (Tr. 53–54.) From July 22, 2008, until September 11, 2008, Ms. Muratalla testified that she was not involved in any ordering of drugs and only worked in Respondent's office as a hygienist.[16] (Tr. 51 & 53.)

Ms. Muratalla outlined the drug ordering system in Respondent's office between 2002 and July 2008, noting that ''I'm not sure how we came across Harvard drugstore'' but opened an account and eventually began placing all orders through Harvard for financial reasons. (Tr. 49.) In terms of Respondent's role in ordering drugs, Ms. Muratalla testified that Respondent did not make requests verbally, but was ''very specific as far as writing down a list for me. He did every time.'' (Tr. 50.) Ms. Muratalla did not recall amounts ordered but did not believe the amounts

[12] The notice includes in pertinent part a statement of rights, to include the right to ''not have administrative inspection without an administrative inspection warrant,'' and an acknowledgment and consent section, requiring signature by the registrant to consent to the inspection. (Gov't Ex. 4.)

[13] No testimony or other evidence was offered regarding the identity of the person Harvard said ordered the diet pills.

[14] [GS] had also testified on direct examination to being awarded a court judgment for $6649. (Tr. 40.)

[15] Lorazepam is a Schedule IV controlled substance. (Tr. 163.)

[16] Ms. Muratalla testified that she stopped working in Respondent's office altogether on September 11, 2008, because ''I had an official restraining order that was placed by [Respondent] on me.'' (Tr. 51.)

were excessive. (Tr. 51.) Ms. Muratalla further explained that she was the contact person in the office for drug orders which were sent to Respondent's office address using only Respondent's DEA number, because ''[h]e was the sole proprietor * * * [and] only dentist working at the practice.'' (Tr. 55.) Ms. Muratalla testified that Respondent had ''specific instructions to all staff members including myself, no one to open the box from [Harvard], it had to be placed on his desk without opening.'' (*Id.*) Respondent maintained the drugs in his office in a locked drawer and maintained possession of the key as well as the key to his office. (Tr. 60.)

Ms. Muratalla further testified about a series of drug orders placed between October 2007 and March 2009. (Tr. 59; *see* Gov't Ex. 5 at 2.) Ms. Muratalla indicated that the October 2, 2007 and February 5, 2008 orders for hydrocodone and acetaminophen were common orders that she placed for the office, but would not have placed the remaining four orders.[17] (Tr. 59.) Ms. Muratalla explained that she did not place the July 30, 2008 order for oxycodone and never recalled the office previously ordering or dispensing oxycodone. (Tr. 61.) Ms. Muratalla next testified to ordering controlled substances at the request of Respondent that she knew were used within and outside Respondent's dental practice, to include phentermine, Valium and Ambien, as well as ''over-the-counter drugs.'' (Tr. 63–64.) With regard to diet pills, Ms. Muratalla is positive she did not order any after July 2008 but did make diet pill orders before that at the written direction of Respondent, stating that none were for her use. (Tr. 64.) Ms. Muratalla testified that she had suspicions as to who was using the diet pills but had ''never seen anyone take those pills.'' (Tr. 65.)

On cross- and redirect examination, Ms. Muratalla testified that prior to 2007 when the dental practice was very busy approximately 4500 hydrocodone pills could reasonably have been distributed to patients, who were given ten to twenty pills at a time. (Tr. 76.) After 2007, Ms. Muratalla testified that that level of distribution was not possible because ''there was absolutely no patients coming through the doors.'' (Tr. 75–76.) Ms. Muratalla testified that she was familiar with a person named Jennifer Savarese, a dental distributor who visited Respondent's office, but she never reviewed a Harvard drug catalogue with Ms. Savarese regarding diet pills and never handed diet pills to Ms. Savarese. (Tr. 77–78; 81–82.) Ms. Muratalla further testified that her relationship with Ms. Savarese was strictly professional, and she did not socialize with Ms. Savarese or consider her a friend. (Tr. 80.)

In addition to the foregoing, the Government also introduced a document entitled: ''In the Matter of the Accusation Against'' [Respondent], brought on behalf of the Dental Board of California, and dated January 31, 2011.[18] (Gov't Ex. 10 at 1, 14.) The Accusation includes various allegations against Respondent to include, among others, unprofessional conduct by: prescribing controlled substances after voluntary surrender of privileges, citing California Health and Safety Code 11155; procuring a prescription for controlled substances by misrepresentation, concealment of material fact and making a false statement, citing California Health and Safety Code 11173; obtaining, possessing or administering to oneself cocaine between May and October 2008, and marijuana between March and April 2010, citing California Health and Safety Code 11054 and 11055; and using alcohol in a dangerous manner in or about January 8, 2010, citing California Business and Professions Code 1681(b).

III. Respondent's Evidence

Respondent did not testify and presented only one witness, Jennifer Yuen (*née* Savarese) (Ms. Savarese),[19] a dental products representative. Ms. Savarese testified in substance that she worked as a dental products representative and was professionally introduced to Respondent through a mutual acquaintance. Initially, Ms. Savarese had only a business relationship with Respondent and Ms. Muratalla but over time became friends, describing her relationship with Respondent as ''my dentist and friend.'' (Tr. 90.) Ms. Savarese described Ms. Muratalla as ''a very good friend of mine'' to include going out to lunch with Ms. Savarese and attending her wedding. (*Id.*)

With regard to the issue of diet pills, Ms. Savarese recalled going through a catalogue with Ms. Muratalla to order diet pills, and testified that ''she said she would order them through her rep for me.'' (*Id.*) When the pills came back to the office ''Maria gave them to me [and] I gave her cash.'' (Tr. 91.) Ms. Savarese specifically recalled that the only brand of diet pills ordered were phentermine, recalling placing two separate orders prior to 2007. (Tr. 94; 99–100.) She believed the total quantity ordered in 2006 and 2007 was at most 600 dosage units based on two separate orders of 300. (Tr. 101.) Ms. Savarese also admitted that at the time she placed the order for phentermine she did not ''think that it was illegal'' but now realizes that it was illegal. (Tr. 105.)

Respondent's evidence also included a May 11, 2000 Certificate of Recognition for high achievement in the Undergraduate Curriculum in Dental Care for Persons with Disabilities, a daily schedule calendar covering the period October 2007 to March 2009 and contact information for a probation office in Utah.[20] (Resp't Exs. 2–4.)

I find the testimony of Ms. Savarese fully credible. Her testimony was internally consistent, and the witness was able to recall factual events with a reasonable level of certainty. There is no documentary evidence of record that contradicts the testimony of Ms. Savarese, nor was there any evidence to suggest that she had a bias or other personal interest in the outcome of the case. Ms. Savarese's past relationship to Respondent was both professional and social, but no evidence was offered to suggest that the witness's relationship with Respondent or Ms. Muratalla would influence her testimony. Ms. Savarese's demeanor was serious and forthright throughout her testimony. The credibility of Ms. Savarese's testimony was further enhanced by her statement against interest, admitting that at the time she placed the order for phentermine she did not ''think that it was illegal'' but now realizes that it was illegal. (Tr. 105.)

I find the testimony of Ms. Muratalla only partially credible. I do not find credible Ms. Muratalla's testimony that she never reviewed a Harvard drug

[17] July 30, 2008 (oxycodone); October 16, 2008 (hydrocodone and acetaminophen); November 19, 2008 (hydrocodone); and March 27, 2009 (hydrocodone and acetaminophen). (Gov't Ex. 5 at 2.)

[18] When the document was tendered, DI Windsor testified in response to a question of when it is dated: ''This one. August 2nd, 2000 (sic), is when they got the complaint, and it expires on March 6th, 2011.'' (Tr. 188.) A review of the document reflects at paragraph two that the August 2, 2000 date refers to the issue date for Respondent's dental license with an expiration date of March 6, 2011, unless renewed. (Gov't Ex. 10 at 1.) The document is dated January 31, 2011. (*Id.* at 14.)

[19] The witness testified that she married in June 2008, but previously went by the last name Savarese. For purposes of this Recommended Decision, the witness will be referred to as Ms. Savarese.

[20] Respondent stated that he had prior employment as a probation officer with the State of Utah from 1992 to 1996. (Tr. 205.) Respondent also stated that the calendar was offered to show how many patients he had seen over a seventeen month period and ''the work that I did, that [patients] would require pain medication, and to where the 4500 pills would have went to, over 17 months.'' (Tr. 210.)

catalogue with Ms. Savarese regarding diet pills and never handed the pills to Ms. Muratalla. Nor do I find credible Ms. Muratalla's testimony that she did not socialize with Ms. Savarese. Evidence of Ms. Muratalla's past history with Respondent, including a severance of their professional and personal relationship in 2008, suggests the witness had a bias or interest in the outcome of the case. The witness's demeanor while testifying was fully consistent with that bias or interest, to include at various times nonresponsive answers or unsolicited comments adverse to Respondent.

The Parties' Contentions

I. The Government

The Government argues in its post-hearing brief that ''the ALJ and Deputy Administrator may consider the Dental Board's complaint as a recommendation * * * 'of the appropriate State licensing board.' '' [21] (Gov't Br. at 21.) The Government further argues in substance that Respondent issued a prescription for lorazepam without authorization using his surrendered DEA registration, failed to keep records such as invoices, dispensing logs and inventories related to his purchases of hydrocodone and oxycodone and failed to keep required records related to his purchases of controlled substance diet pills. (*Id.* 22–24.) The Government further argues that Respondent failed to report thefts of controlled substances on two occasions to DEA, as required by regulation. Finally, the Government argues that ''Respondent has not demonstrated to DEA that the problems that have been on-going in his practice since at least 2007 will not continue * * * [and] Respondent has forfeited his opportunity to show remorse.'' (*Id.* at 27.)

II. Respondent

Respondent argues in his post-hearing brief that the Government has not met its burden to identify who ordered the diet pills from Harvard, and further argues that the testimony of Ms. Muratalla should be given no weight. (Resp't Br. at 8–9.) Respondent maintains that the DEA made insufficient investigation regarding mistaken information contained within Government Exhibit 5, noting that this ''page could definitely have altered the whole scope of this investigation if proper investigation was done.'' (*Id.* at 3.)

[21] I have specifically declined to consider the California Dental Board complaint as a ''recommendation,'' because at most it contains accusations that are unresolved.

Respondent argues at various points that the Government has not met its burden of proof,[22] noting in part that Respondent has been an ''outstanding citizen who served the country as a probation officer * * * [and] was awarded an exclusive award from 'The Academy of Dentistry' for working with people with Disabilities when no one else would.'' (*Id.* at 9–10.) Respondent further argues that forms such as biennial inventories and invoice records were in the possession of Ms. Muratalla and the Government. (*Id.* at 6, 10.) Finally, Respondent argues in substance that due to reliance on hearsay and ''perjuries'' the Government has failed to establish by a preponderance of the evidence that Respondent's registration would be inconsistent with the public interest, and his application for registration should be granted. (*Id.* at 10.)

Discussion

I. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act (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.[23] ''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.[24] 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.[25] 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).[26]

A. The Public Interest Standard

The CSA, at 21 U.S.C. 824(a)(4), provides, insofar as pertinent to this proceeding, that the Deputy Administrator may revoke a COR if she finds that the registrant's continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). 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 deemed appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 FR. 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 FR. 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 FR. 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR. 16,422, 16,424 (DEA 1989). Additionally, in an action to deny a registrant's COR application, the DEA has the burden of proving that the requirements for revocation are satisfied.[27] The burden of proof shifts to the respondent once the Government has made its prima facie case.[28]

B. Other Factors

In addition to the public interest factors discussed above, 21 U.S.C. 824(a) provides four other factors that

[22] Respondent appears to assert that the applicable standard of proof is the ''beyond a reasonable doubt'' standard. (*See, e.g.,* Resp't Br. at 4.) Contrary to Respondent's argument, however, the applicable standard of proof in this administrative proceeding is ''preponderance of the evidence.'' *Arthur Sklar, R.Ph., d/b/a King Pharmacy,* 54 FR. 34,623, 34,627 (DEA 1989). ''A sanction may not be imposed* * *except on consideration of the whole record* * *and supported by and in accordance with the reliable, probative, and substantial evidence.'' *See* 5 U.S.C. 556(d). Respondent appears to acknowledge as much, arguing that the ''issue before the court is whether the government has established by a *preponderance of the evidence* that Respondent's continued registration would be inconsistent with the public interest.'' (Resp't Br. at 8 (emphasis supplied).)

[23] 21 U.S.C. 822(a)(2); 21 U.S.C. 802(10).

[24] 21 CFR 1306.04(a).

[25] 21 U.S.C. 844(a).

[26] *See Kuen H. Chen, M.D.,* 58 FR. 65,401, 65,402 (DEA 1993).

[27] *See* 21 CFR 1301.44(e) (2010).

[28] *See Medicine Shoppe—Jonesborough,* 73 FR. 364, 380 (DEA 2008); *see also Thomas E. Johnston,* 45 FR. 72,311, 72,311 (DEA 1980).

the Deputy Administrator may consider in a proceeding to suspend or revoke a DEA COR.[29] Despite the lack of an explicit provision applying these factors to a denial of an application

[t]he agency has consistently held that the Administrator may also apply these bases to the denial of a registration, since the law would not require an agency to indulge in the useless act of granting a license on one day only to withdraw it on the next.[30]

In addition, I conclude that the reference in 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).[31]

II. 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 dental license in California, but Respondent's dental license is presently the subject of state disciplinary action pursuant to a pending state Accusation against Respondent, the results of which are unknown.[32] (Gov't Ex. 10.) While not dispositive, Respondent's possession of a valid unrestricted dental 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 FR. 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 FR. 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

The Government alleges that Respondent failed to effectively monitor the receipt and distribution of controlled substances because Respondent did not maintain an effective recordkeeping system in accordance with 21 CFR 1304.03, 1304.04 and 1304.21, among others. The evidence and testimony in this case centered in significant part on Respondent's failure to properly handle controlled substances, as well as his failure to comply with applicable laws regarding mandatory record keeping. As an initial matter, this is not a case of a registrant failing to adhere to the finer points of record keeping. The undisputed evidence of record is that Respondent's record keeping was essentially non-existent.

Pursuant to 21 CFR 1304.03(b), 1304.21(a), 1304.22(a)(2)(iv), 1304.22(a)(2)(ix) and 1304.22(c), a registered individual practitioner is required to maintain records of controlled substances in Schedules II–V that are dispensed and received, including the number of dosage units, the date of receipt or disposal and the name, address and registration number of the distributor. It is unlawful to fail to make, keep or furnish required records.[33] DEA regulations require that ''each registered individual practitioner required to keep records'' shall maintain inventories and records of Schedule II controlled substances ''separately from all of the records of the registrant''; inventories and records of Schedule III–V controlled substances ''shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.'' [34]

One mandatory recordkeeping vehicle is DEA Form 222, the ''official triplicate order form[] used by physicians to order scheduled narcotics'' and other controlled substances.[35] A menu of federal regulations specifies procedures relating to DEA Form 222, such as obtaining, 21 CFR 1305.11, executing, 1305.12, filling, 1305.13, and endorsing DEA Form 222, 1305.14, among other procedures.[36] In addition, 21 CFR 1305.03 requires that a DEA Form 222 be used for each distribution of a controlled substance listed in Schedule I or II, and Section 1305.17 provides that these order forms must be maintained separately from all other records and that they ''are required to be kept available for inspection for a period of 2 years.''

Failing to comply with recordkeeping laws and regulations relating to controlled substances can justify adverse action against a registrant's COR. ''[A] blatant disregard for statutory provisions implemented to maintain a record of the flow of controlled substances and to prevent the diversion of controlled substances to unauthorized individuals, would justify revocation'' of a certificate of registration.[37]

DEA regulations state that a registered individual practitioner is required to keep records of controlled substances in Schedules II, III, IV and V which are dispensed.[38] As a general matter, records are required to be kept by the registrant and must be available for at least two years.[39]

The undisputed evidence of record reflects that Respondent consented to an inspection of his registered location on December 2, 2009, by two DEA diversion investigators. The evidence also reflects that between October 2007 and March 2009, Respondent had received in six separate shipments from his supplier, Harvard Drug Group, several thousand tablets of hydrocodone, and in July 2008, a significant quantity of oxycodone. (Gov't Ex. 5 at 2–5.) Additionally, the evidence reflects Respondent's order and receipt in or before June 2009 of significant quantities of the Schedule IV controlled substances Adipex, Fastin,

[29] That subsection provides that a DEA COR may be revoked upon a finding that the registrant: (1) has materially falsified an application; (2) has been convicted of a felony under the CSA or any other federal or state law relating to any controlled substance; (3) has had a state license or registration suspended, revoked or denied and is no longer authorized by state law to handle controlled substances; (4) has committed such acts as would render his registration under 21 U.S.C. 823 inconsistent with the public interest; or (5) has been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a). It should also be noted that 824(a) contains a reciprocal reference incorporating the public interest factors from 823(f). *See* 21 U.S.C. 824(a)(4).

[30] *Kuen H. Chen, M.D.,* 58 FR. 65,401, 65,402 (DEA 1993) (citing *Serling Drug Co. & Detroit Prescription Wholesaler, Inc.,* 40 FR. 11,918, 11,919 (DEA 1975)); *see also Scott J. Loman, D.D.S.,* 50 FR. 18,941 (DEA 1985); *Roger Lee Palmer, D.M.D.,* 49 FR. 950 (DEA 1984).

[31] *See Chen,* 58 FR. at 65,402.

[32] No further evidence or testimony was offered with regard to the status or outcome of the state review, and I give the allegations contained within the Dental Board Accusation no evidentiary weight for purposes of this Recommended Decision.

[33] 21 U.S.C. 842(a)(5).

[34] 21 CFR 1304.04(g) & (f)(2).

[35] *Robert L. Dougherty, Jr., M.D.,* 60 FR. 55,047, 55,048 (DEA 1995).

[36] *See, e.g.*, 21 CFR 1305.15- .19.

[37] *Robert L. Dougherty, Jr., M.D.,* 60 FR. 55,047, 55,050 (DEA 1995) (citing *George D. Osafo, M.D.,* 58 FR 37,508, 37,509 (1993) (revoking practitioner's registration where ''[r]espondent failed to comply with numerous recordkeeping requirements[, explaining that] * * * it is a registrant's responsibility to be familiar with the Federal regulations applicable to controlled substances'')); *see also Hugh I. Schade, M.D.,* 60 FR. 56,354, 56,356 (DEA 1995) (noting the inventory procedures required by Sections 1304.11 to 1304.13, and 1305.06).

[38] 21 CFR 1304.03(b) (2010).

[39] 21 CFR 1304.04.

phentermine, and Tenuate, referred to collectively as ''diet pills.'' As of December 2, 2009, Respondent had received thousands of tablets of controlled substances, requiring various levels of record keeping. The December 2, 2009 audit of Respondent's registered location, with Respondent present, resulted in the inventory and accounting of only 89.5 tablets of hydrocodone. (Gov't Ex. 8.) Moreover, no copies were found of required DEA Form 222, which should have documented each distribution of the Schedule II controlled substance oxycodone. Nor were any other required records found or produced by Respondent during the inspection, to include biennial inventories, dispensing logs and invoices for controlled substances. (Tr. 139–40.)

Respondent's statement during the December 2, 2009 audit that the dispensing records were located within his patient records was found to be inaccurate. Even if true, the patient records would not substitute for required copies of DEA Form 222 relating to the Schedule II controlled substance oxycodone, among other recordkeeping requirements. Respondent's attempt to produce relevant patient records during the audit to support his claim was also revealing. Respondent initially produced patient records that were outside the scope of the inspection period, and was redirected by the diversion investigators to produce relevant files. (Tr. 142.) Respondent then produced a ''printout of patient names.'' (Tr. 143.) At that point, the diversion investigators identified a random sample of patient files by name within the time frame of the audit, which upon production and review were found to contain no dispensing records. (*Id.*)

I find by a preponderance of the evidence that Respondent unlawfully failed to make, keep or furnish required records relating to his handling of controlled substances, in violation of 21 U.S.C. 842(a)(5) and 827(a) and applicable regulations.[40]

The Government also alleged and offered evidence of Respondent's failure to properly report the theft of controlled substances, in violation of 21 CFR 1301.76(b). During the December 2, 2009 audit, Respondent stated to diversion investigators that there were two separate occasions within the preceding two years in which Respondent believed that hydrocodone which had been placed on his desk had come up missing. (Tr. 148, 150.) Respondent was also certain that neither incident had been reported to DEA. (Tr. 149.) The applicable regulation unambiguously requires a registrant to notify the ''Field Division Office of [DEA] in writing, of the theft or significant loss of any controlled substances within one business day of discovery * * *.'' 21 CFR 1301.76(b). In this case, Respondent's violation was not a *de minimis* one, such as missing the one business day deadline or notifying the wrong office in writing. Rather, Respondent stated that on one occasion he recalls law enforcement was not notified at all, and the second he ''thought law enforcement had been contacted by one of his staff, but he wasn't certain of that.'' (Tr. 149.) Notably, Respondent's failure to maintain any required records precluded DI Windsor from determining the amount of the loss. (Tr. 152–53.)

I find by a preponderance of the evidence that Respondent failed to timely notify DEA of the theft or loss of controlled substances on two separate occasions between 2007 and 2009, in violation of 21 U.S.C. 1301.76(b).

The Government also offered evidence of Respondent's unlawful use of his surrendered DEA registration to issue a prescription for lorazepam in January 2010. This evidence centered on the testimony of patient [GS], along with the testimony of DI Windsor, as corroborated by a pharmacy copy of the filled prescription. The evidence at hearing clearly documented Respondent's voluntary surrender of his DEA registration on December 2, 2009.[41] (Gov't Ex. 2.) In relevant part, the surrender form states: ''I understand that I will not be permitted to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other controlled substance activities whatever, until such time as I am again properly registered.'' (*Id.*)

In addition to the actual notice Respondent received as to his lack of authority to handle controlled substances on and after December 2, 2009, applicable law and regulations provide clear guidance. ''Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally * * * to * * * dispense[] a controlled substance.'' 21 U.S.C. 841(a). Moreover, ''[e]very person who dispenses * * * any controlled substance, shall obtain from the Attorney General a registration,''[42] 21 U.S.C. 822(a)(2), with the exception of ''[a]n agent or employee of any registered * * * dispenser of any controlled substance if such agent or employee is acting in the usual course of his business or employment,'' *id.* 822(c)(1). ''Every person who manufactures, distributes, dispenses, imports or exports any controlled substance or who proposes to [do so] * * * shall obtain a registration unless exempted by law or pursuant to 1301.22–1301.26.'' 21 CFR 1301.11(a) (2010). Although a person may apply for registration at any time, ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1301.13(a) (2010).[43] Respondent did not submit an application for a new DEA registration until approximately January 27, 2010. (Gov't Ex. 1.)

The uncontroverted evidence of record reflects that notwithstanding his lack of DEA registration, Respondent unlawfully prescribed the Schedule IV controlled substance lorazepam to patient [GS] on January 16, 2010. Patient [GS] credibly testified to being treated by Respondent for an infected tooth beginning in December 2009 and further testified that in the latter part of January 2010, Respondent performed a root canal on [GS]. (Tr. 38.) [GS] specifically recalls Respondent prescribing lorazepam on a third office visit, recalling the time frame as the latter part of January or February 2010. (Tr. 39.) Corroborating [GS]'s testimony, the

[40] Respondent argues for the first time in his post-hearing brief that Ms. Muratalla and counsel for the Government had copies at the hearing of Respondent's biennial inventories and invoices for controlled substances. (Resp't Br. 6.) This unsworn assertion by Respondent is neither evidence nor is it supported by testimonial or documentary evidence of record. In fact, evidence of controlled substance shipments to Respondent that post-date Ms. Muratalla's access to the records plainly refutes the assertion. Moreover, Respondent had the opportunity to cross-examine Ms. Muratalla at hearing and declined to offer any evidence to support his claim. I therefore find that Respondent's argument, that required records did in fact exist, is without factual support.

[41] DI Windsor testified in relevant part that Respondent's surrender of his registration included an oral discussion between Respondent and investigators, as well as a written surrender form (DEA–104) that Respondent read and signed. (Tr. 154–59.) DI Windsor also testified in response to Respondent's question about his state of mind at the time of surrender, that he appeared ''overwhelmed'', but Respondent offered no testimony or documentary evidence to contradict the voluntariness of his surrender. I find by a preponderance of the evidence that Respondent's surrender of registration on December 2, 2009, was in fact voluntary.

[42] *See also* 21 CFR 1301.11 (2010).

[43] Applicable California law also prohibits the prescribing of controlled substances without ''current registration from the appropriate federal agency as provided by law. Cal. Health & Safety Code 11155. ''No person shall issue a prescription that is false or fictitious in any respect.'' *Id.* 11157.

evidence included a pharmacy copy of a phoned-in prescription for [GS] issued in Respondent's name dated January 16, 2010, using Respondent's surrendered DEA registration number, prescribing ''Amox'' and ''Lorazepam'', the latter being a Schedule IV controlled substance. (Gov't Ex. 6; Tr. 163.)

I find by a preponderance of the evidence that Respondent violated federal and state law by prescribing a Schedule IV controlled substance on January 16, 2010, knowing that he lacked a DEA registration and was prohibited from prescribing any controlled substance.[44]

Another issue in this case concerns Respondent's prescribing practices with regard to hydrocodone and phentermine, which the Government alleges were not prescribed pursuant to a legitimate medical purpose or within the usual course of professional practice, contrary to 21 CFR 1306.04(a) (2010). (Gov't PHS at 7.) 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 CFR 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 FR. 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 FR. 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).

Turning to the evidence of record, with regard to Respondent's prescribing practices for hydrocodone, no specific evidence was offered other than the evidence discussed above as to a complete lack of documentation. The evidence pertaining to Respondent's prescribing practices for phentermine and related diet pills included Respondent's admission on December 2, 2009, that ''he had ordered diet pills for his wife [Ms. Muratalla] and he had also said that she ordered them for herself.'' (Tr. 146.) The evidence with regard to the 2200 tablets of diet pills that formed the basis of the investigation of Respondent after Harvard's June 11, 2009 Suspicious Order Report was minimal, as DI Windsor testified that she did not recall specifically discussing with Respondent the diet pills Adipex, Fastin, phentermine or Tenuate, with reference to a specific time frame for the orders. (Tr. 146–47.) Ms. Muratalla testified that she ordered diet pills on Respondent's behalf prior to July 2008, but is certain she did not order any after that date. (Tr. 64.) Ms. Savarese testified that she ordered phentermine from Ms. Muratalla, recalling placing two separate orders prior to 2007. (Tr. 94; 99–100.)

Although the foregoing evidence is vague as to time frames and mixed as to who placed each order, there is no ambiguity in the evidence that Respondent ordered and dispensed the Schedule IV controlled substances phentermine, Adipex-P, Fastin and Tenuate in or before December 2009, without a legitimate medical purpose and not in the usual course of his professional practice. Respondent admitted on December 2, 2009, that he had ordered diet pills for his wife and knew that she had ordered them for herself. Ms. Savarese also credibly testified that she received two separate orders of phentermine from Ms. Muratalla in exchange for cash, without a prescription between 2006 and 2007. The evidence of record reflects a shipment of phentermine, Adipex, Fastin, and Tenuate to Respondent in June 2009, none of which was present or accounted for at Respondent's registered location in December 2009.

Accordingly, I find by a preponderance of the evidence that Respondent violated applicable federal and state law in ordering and prescribing Schedule IV controlled substances without a legitimate medical purpose and outside the usual course of professional practice at various times between 2006 and December 2, 2009. Additionally, Respondent's handling of these controlled substances failed to comply with any of the mandated record keeping requirements under the CSA, discussed above.[45]

Respondent elected not to testify in this case and the Government suggests summarily in its post-hearing brief that ''DEA may draw an adverse interest (sic) that Respondent presented no testimony on his own behalf.'' (Gov't Br. at 20; *see* Tr. 201–05.) Agency precedent permits but does not require the drawing of an adverse inference from a Respondent's silence in the face of accusation, ''since it is assumed in such circumstances [one] would be more likely than not to dispute an untrue accusation.'' *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (citing *United States* v. *Hale,* 422 U.S. 171, 176 (1975)). Although Respondent's decision not to testify could arguably support an adverse inference in the face of accusation as to some allegations, I decline to do so on the facts of this case, other than in the context of Respondent's failure to accept responsibility for his misconduct.[46]

The evidence of Respondent's experience in dispensing controlled substances and compliance with applicable law and regulations weighs heavily in favor of a finding that Respondent's registration would be inconsistent with the public interest under Factors Two and Four.

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

[44] *See* 21 U.S.C. 841(a)(1); 21 CFR 1301.11(a); 1301.13(a); Cal. Health & Safety Code 11155 & 11157.

[45] *See* 21 U.S.C. 841(a)(1), 827(a) and (b); 21 CFR 1306.04(a); Cal. Health & Safety Code 11153(a).

[46] The Government's invitation to draw an adverse inference does not refer to any particular allegation, leaving open to question whether the request was intended to apply to all allegations noticed in the OSC and prehearing proceedings. For example, the Government alleged and proffered that ''Respondent had been hospitalized in August 2008 for alcohol and cocaine abuse.'' (Gov't Supp. Preh'g Statement (SPHS) at 4.) The proffered testimony at hearing by Ms. Muratalla directly contradicted that allegation and was consistent with Respondent's unsworn statements during the hearing that he was hospitalized due to an assault and related trauma. (*Compare* Tr. 67–68, *with* Tr. 74.) Respondent's testimonial silence as to that allegation does not seem to make the allegation any truer. I also note that the Government listed Respondent as a witness, but chose not to call him at hearing. (Gov't PHS at 3; Tr. 201.) In light of the foregoing, I find that drawing an adverse inference in this case is unwarranted, particularly given the lack of focus to the Government's request.

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 FR. 20,727, 20,734 (DEA 2009).[47] A respondent's acceptance of responsibility must be ''clear and manifest.'' *Mark De La Lama, P.A.,* 76 FR. 20,011, 20,020 n.19 (DEA 2011). 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 FR. 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 FR. 10,083, 10,094 (DEA 2009).

The Government alleged ''other conduct'' relevant to Factor Five during the course of prehearing procedures in the form of a February 24, 2011 Motion to Include Dental Board of California Complaint. The proposed document is entitled: ''In the Matter of the Accusation Against'' [Respondent], brought on behalf of the Dental Board of California, and dated January 31, 2011. (Gov't Ex. 10.) The California Dental Board allegations relevant to Factor Five include obtaining, possessing or administering to oneself, cocaine between May and October 2008, and marijuana between March and April 2010, citing California Health and Safety Code 11054 and 11055; and using alcohol in a dangerous manner in or about January 8, 2010, citing California Business and Professions Code 1681(b). The Government's prehearing notice of evidence to support the above issues consisted of a supplemental prehearing statement dated January 21, 2011, stating in relevant part ''Ms. Murutalla (sic) will testify that she told the DEA that the Respondent had been hospitalized in August 2008 for alcohol and cocaine abuse.'' (Gov't SPHS at 4.)

At hearing, I excluded Ms. Muratalla's proposed testimony on the limited issue of alcohol and cocaine abuse based in part on lack of adequate notice, particularly given the brevity of the noticed testimony and variance from allegations of the California Dental Board. I did allow the Government to proffer in detail Ms. Muratalla's proposed testimony, which produced even greater variance from the alleged conduct.[48] Even if Ms. Muratalla's proposed testimony had been adequately noticed, her proffered testimony at hearing provided no substantive basis to support the allegations by the California Dental Board pertaining to cocaine, alcohol and marijuana. (*See* Tr. 73–74.) I do take note of Respondent's admission in a February 9, 2011 prehearing filing that he used marijuana one time ''during a dark day in April'' of 2010, while intoxicated, which he states he did while unemployed and not seeing patients.[49]

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 FR. 49,979, 49,989 (DEA 2010). Respondent's admitted misuse of marijuana while intoxicated is a relevant consideration as to whether granting Respondent a DEA COR would be consistent with the public interest. *See David E. Trawick, D.D.S.,* 53 FR. 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 substance abuse).

Although I have considered Respondent's prehearing admission of a single instance of marijuana use while intoxicated in April 2010, I give it little overall weight for purposes of this Recommended Decision, particularly given the absence of any other credible evidence of record to support allegations of other drug or alcohol abuse by Respondent at any other time.

Conclusion and Recommendation

I find by a preponderance of the evidence that the Government has met its burden to establish a prima facie case based on substantial evidence of record. After considering all of the relevant factors, the evidence is fully consistent with a denial of Respondent's application for a DEA COR as a practitioner, because Respondent's registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(f) and 824(a)(4). 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 FR. 20,727, 20,734 (DEA 2009).

Respondent has not sustained his burden in this regard. Respondent did not testify and did not accept responsibility for his past misconduct. Moreover, Respondent presented no credible evidence to demonstrate that he has learned from his past mistakes or to demonstrate that he would now handle controlled substances properly if granted a registration.

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 strongly weighs in favor of a finding that Respondent's registration would be inconsistent with the public interest.

Accordingly, 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 Respondent's registration would be inconsistent with the public interest.

Dated: May 19, 2011

Timothy D. Wing,

Administrative Law Judge.

[FR Doc. 2011–27985 Filed 10–27–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on April 5, 2011, Research Triangle Institute, Hermann Building, East Institute Drive, P.O. Box 12194, Research Triangle Park, North

[47] *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.'')

[48] *See* Gov't SPHS at 4. At hearing and consistent with Respondent's prehearing objection to the issue, Respondent timely objected to the testimony related to his hospitalization. (Tr. 65.) I requested the Government to proffer the proposed testimony of Ms. Muratalla given the very limited disclosure of proposed testimony contained in the Government's SPHS. The proffer was similarly brief in content and varied somewhat from the SPHS insofar as the proffer lacked a reference to alcohol. (Tr. 69.) Following argument, I excluded the testimony based on notice and relevance issues. (Tr. 71.) At the Government's request, I did allow the Government to question Ms. Muratalla by way of proffer regarding the alleged August 2008 hospitalization. Notably, Ms. Muratalla's proposed testimony made no reference to cocaine, alcohol or any other substance abuse, nor was any other testimonial evidence on the topic offered by the Government at hearing. (Tr. 73–74.)

[49] Respondent's Reply Regarding Government Request for Motion dated February 9, 2011.