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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**Docket No. 13-12**

**Decision and Order: Clair L. Pettinger, M.D.**

On June 5, 2013, Administrative Law Judge Christopher B. McNeil (hereinafter, ALJ) issued the attached Recommended Decision<sup>1</sup> (hereinafter, cited as R.D.) Therein, the ALJ found that the Government had proved that the Respondent issued nine prescriptions for controlled substances “that were not for a legitimate medical need and were not issued in the ordinary course of a professional medical practice,” as well as a prescription for hydrocodone after his DEA registration had been suspended, and that this evidence establishes that “the Respondent’s continued [registration] is inconsistent with the public interest. R.D. at 57. The ALJ further found that the Government “has made a prima facie case in support of the proposed order revoking the Respondent’s registration” and that “Respondent . . . failed to affirmatively acknowledge specific acts of improper prescribing of controlled substances and failed to establish by credible and substantial evidence effected steps taken in remediation.” *Id.* at 58. Accordingly, the ALJ found that “the Government has established cause to revoke the Respondent’s DEA” registration, *id.*, and recommended that his registration be revoked and that any pending applications to renew or modify his registration be denied. *Id.* at 59.

Both parties filed exceptions to the Recommended Decision. Thereafter, the record was forwarded to me for Final Agency Action.

Having considered the record in its entirety, including each party’s exceptions, I have decided to adopt the ALJ’s findings of fact and conclusions of law, except as discussed below.

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<sup>1</sup> All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

While I reject some aspects of the ALJ's discussion, I agree with the ALJ's legal conclusions that Respondent violated federal law in prescribing to each of the undercover officers, and that the Government has established a prima facie case to revoke Respondent's registration on the ground that he has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). I further agree with the ALJ's conclusion that Respondent has failed to produce sufficient evidence to rebut the Government's prima facie case, as notwithstanding the unrefuted evidence that he knowingly and intentionally diverted drugs by issuing unlawful prescriptions, he failed to acknowledge his misconduct. A discussion of each party's exceptions follows.

### **Respondent's Exceptions**

Respondent first takes exception to the ALJ's finding that he authorized a new prescription for 180 dosage units of Norco, a combination drug containing hydrocodone, a schedule III controlled substance, and acetaminophen, for his patient B.D., on December 21, 2012, ten days after he had been served with the Order to Show Cause and Immediate Suspension of Registration. Resp. Exceptions, at 1-4. In support of the allegation, the Government introduced several documents from the Safeway Pharmacy which filled the prescription. These included: 1) a copy of a prescription issued to B.D. by Respondent on October 22, 2012 for 180 dosage units of Norco, which authorized two refills; and 2) a printout from the pharmacy showing B.D.'s medical expenses between August 13 and December 21, 2012. GX 24, at 2, 4. Of note, the latter shows that the prescription, which was assigned the number 4362259, was filled on October 22, 2012, and refilled on November 12 and December 3, 2012. Id. at 4. Of further note, this document shows that on December 21, 2012, the pharmacy

dispensed an additional 180 tablets of Norco to B.D., under a new prescription number and attributed the prescription to Respondent. Id.

The Government also introduced into evidence a copy of a prescription refill request form, which was dated December 20, 2012, and which was faxed by the pharmacy to Respondent and then faxed backed to the pharmacy. Id. at 3; Tr. 91. Under the heading “PRESCRIPTION REQUEST,” the form indicated that the prescription was for B.D. and was 180 tablets of Norco; the form also stated that the prescription was “First Filled” on “Oct 22, 2012,” and “Last Filled” on “Dec 3, 2012.” Id. In the space for the doctor’s signature, the form bore the following notation: “N Pettinger MD Can fill current refill No New Refill.” Id. On the upper right side of the form, were the words “MD and “OK x 1,” each of which was circled; in addition, an arrow was drawn from the latter to the words “No New Refill.” Id.

At the hearing, the Special Agent, who was the Case Agent, testified that upon serving the Order to Show Cause and Immediate Suspension of Registration on Respondent, he told Respondent “that he was unable to dispense, prescribe or otherwise issue controlled substances from that point on” and that Respondent “stated to me that he understood that.” Tr. 87. The Case Agent further explained that while it was illegal for Respondent to authorize a new prescription after his registration was suspended, any refills that had been authorized prior to the suspension could be filled. Id. at 112.

In his testimony, the Case Agent explained that when the Refill Request fax was sent, “the patient had already refilled all the refills that were on the previous prescription”; the Agent also answered “no,” when asked if it would have been necessary to contact Respondent if there had been additional refills remaining on the prescription. Id. at 92. The Case Agent further

testified that as far as he knew, pharmacists call a physician only to verify a new prescription and would not call to verify a refill. Id. at 112-13.

The Case Agent also testified (erroneously) that there was no information on the Refill Request form that showed that all of the previously authorized refills had been dispensed by the pharmacy. Id. at 115. Finally, the Case Agent testified that he could not state that Respondent had “knowingly” issued a new prescription in violation of the suspension order. Id. at 116.

Reviewing the Refill Request form, the ALJ concluded that the circled words “MD” and “No New Refill,” along with the arrow drawn to the words “No New Refill,” “indicat[e] that the pharmacist contacted [Respondent] and was told it was okay to dispense 180 generic Norco tablets, despite the fact that the pharmacy had already dispensed all of the medication authorized by the prescription written by [Respondent] on October 22, 2012.” R.D. at 9. The ALJ thus reasoned that “[w]hile this evidence does not establish that the pharmacist told [Respondent] that B.D. filled this prescription three times already, it does establish that [Respondent] knowingly authorized another 180 unit dispensation after being called by the pharmacist, a condition that would not have existed had there been a refill available under the original prescription.” Id. at 10.

Taking exception to this finding, Respondent asserts that “Exhibit 24 does not establish that Respondent was aware of the prior refills.” Resp. Exceptions, at 3. However, notwithstanding the testimony of the Case Agent and the ALJ’s finding, the Refill Request form actually did contain evidence that the previously authorized refills had been dispensed. Specifically, the form indicates that the prescription had last been filled on December 3, 2012 and been filled in the full amount of 180 tablets. RX 24, at 3. Moreover, the bottom of the form includes the notations: “Remaining Qty: 0” and “Rx Expires On: 04/23/2013.” RX 24, at 3.

These, of course, are references to the previous prescription which had been issued on October 22, 2012, and which, in accordance with DEA regulations, was good for six months. See 21 CFR 1306.22(a). Beyond this, as the ALJ pointed out, had there been any refills remaining on the original (October 22nd) prescription, the pharmacy would have had no reason to send the refill request form.

Respondent nonetheless asserts that his notation on the Refill Request Form used the word “refill” and not “prescription” and further states: “can fill current refill no new refill.” Resp. Exceptions, at 4. He argues that “[t]his contemporaneous handwritten note can only be interpreted as documenting Respondent’s belief that he was confirming the “current” (i.e., existing) refill authorization and specifically declining to authorize a ‘new refill’ (current prescription), just as instructed by” the Case Agent. Id.

However, in his exceptions, Respondent entirely ignores that the Refill Request form also contains the circled notations of “MD” and “OK x 1,” along with the arrow that was drawn towards the words “No New Refill.” As noted above, based on these notations, the ALJ concluded that Respondent “knowingly authorized another 180 unit dispensation after being called by the pharmacist.” R.D. at 10.

The ALJ’s conclusion that Respondent was called by the pharmacist and approved an additional dispensation of Norco is a permissible inference from the evidence.<sup>2</sup> While this may not be the only permissible inference which can be drawn from the notation, it nonetheless constitutes probative evidence of the allegation. Significantly, when called to testify, Respondent invoked his Fifth Amendment privilege. However, as the Supreme Court has explained, “the Fifth Amendment does not forbid adverse inferences against parties to civil

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<sup>2</sup> The Case Agent testified that the documents, which are identified as pages 2-4 of Government Exhibit 24, were obtained from the pharmacist at the Safeway Pharmacy and are “true and accurate cop[ies] of the documentation [he] obtained from the” pharmacy. Tr. 89.

actions when they refuse to testify in response to probative evidence offered against them.” Baxter v. Palmigiano, 425 U.S. 308, 318 (1976). As the Tenth Circuit has noted, “[t]his rule applies with equal force to administrative proceedings.” MacKay v. DEA, 664 F.3d 808, 820 (10th Cir. 2011) (citing Hoxie v. DEA, 419 F.3d 477, 483 (6th Cir. 2005)). See also Keating v. Office of Thrift Supervision, 45 F.3d 322, 326 (9th Cir. 1995). Because Respondent refused to testify in response to the evidence suggesting that he had spoken with a pharmacist and authorized an additional dispensing (notwithstanding his having written “No New Refill” on the Refill Request form), I draw an adverse inference and conclude that he did authorize the December 21, 2012 dispensing, at which time his registration had been suspended. And because there was no reason for the pharmacy to contact him regarding a refill request unless there were no refills remaining, I conclude that Respondent knowingly authorized the dispensing in violation of the Immediate Suspension Order.

Next, Respondent argues that the nine prescriptions which he issued to the undercover officers “cannot possibly be probative of whether [his] continued [r]egistration is inconsistent with the public interest.” Resp. Exceptions, at 5. According to Respondent, “[i]n addressing the public interest question, the key word is obviously the word ‘is[,]’ not ‘was.’” Id.

Respondent thus maintains that because the undercover officers “never intended to consume the medication” and “were never at risk from this medication,” his issuance of the prescriptions is not probative of the public interest. Id. He further asserts that because he issued the prescriptions “over a year before the hearing,” his conduct in issuing them “cannot possibly be probative of whether [his] continued Registration [is] inconsistent with the public interest unless the Government shows either that this conduct “typif[ies] his conduct with actual patients who did consume the medications” or that his “prescribing practices did not improve to the point

that he was in compliance with DEA requirements and the applicable standard of care.” Id. Respondent thus concludes by arguing that “[t]his analysis goes to the heart of the public interest question under 21 U.S.C. §§ 823(f)(4) and 824,” and that “[a]ll of these provisions require an assessment of [his] **current** conduct and compliance.” Id. at 6.

As for his contention that “the key word is . . . ‘is’ [and] not ‘was,’” Respondent ignores, that in section 824(a), Congress granted the Agency authority to suspend or revoke a registration “upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest.” 21 U.S.C. § 824(a)(4) (emphasis added). Thus, while a decision to continue or grant a new registration is prospective in nature, the Agency properly bases the public interest determination on instances of past misconduct, of which, here, there is no shortage.<sup>3</sup> As the Seventh Circuit has explained, and as the Agency has noted in numerous cases, “past performance is the best predictor of future performance.” ALRA Labs, Inc., v. DEA, 54 F.3d 450, 452 (7th Cir. 1995); see also, e.g., Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008), pet. for rev. denied, Medicine Shoppe-Jonesborough v. DEA, 300 Fed. Appx. 409 (6th Cir. 2008).

As for Respondent’s contention that the nine unlawful prescriptions are not probative of the public interest determination, because the undercover agents “never intended to consume the

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<sup>3</sup> Notwithstanding that section 823(f) authorizes the Attorney General to “deny an application for [a practitioner’s] registration . . . if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest,” here again, the provision explicitly recognizes the probative nature of an applicant’s past conduct in making this determination as demonstrated by factor two, which directs the Attorney General to consider “[t]he applicant’s experience in dispensing . . . controlled substances,” and factor three, which directs the Attorney General to consider “[t]he applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. § 823(f)(2) & (3).

While the text of factor four, which directs the Attorney General to consider “[c]ompliance with applicable State, Federal or local laws relating to controlled substances” is not similarly limited to an applicant’s past conduct, (nor limited to the specific applicant, see David A. Ruben 78 FR 38363, 38385 n.47 (2013)), the Agency has long considered an applicant’s record of compliance with laws related to controlled substances under this factor. See Albert Lepis, M.D., 51 FR 17555, 17555-56 (1986) (discussing physician’s dispensings in violation of state law limiting quantity of controlled substances that could be prescribed under factor four (as well as factor two)); Carriage Apothecary, Inc., 52 FR 27599, 27600 (1987).

medication” and thus were “never at risk,” Resp. Exceptions at 5, the evidence clearly showed that Respondent intentionally and knowingly diverted controlled substances. Indeed, as catalogued by the ALJ, the Government’s Expert testified to some twenty-two areas of concern regarding Respondent’s prescribing practices. See R.D. at 30-32. These included his failure to resolve numerous red flags such as statements by the undercover officers that they were either diverting controlled substances or seeking them for recreational use; his falsification of medical records by indicating that he had performed an extensive physical exam when he had not; his failure to even examine the area of the body which was the source of an undercover officer’s purported pain; his – in the words of the Government’s Expert – “[t]rolling for symptomology”; his suggesting to a patient that she claim to have pain radiating from her back into her leg to justify obtaining an MRI, as this was needed to justify his prescribing of oxycodone to her; and his typically rapid fire review with the patients of their medical history. See id. at 30-33. That each of the patients was an undercover agent does not make any of Respondent’s acts of prescribing to them any less a violation of federal law. I thus reject Respondent’s fatuous contention that his prescribing to the undercover officers is not probative of whether his registration is inconsistent with the public interest unless the Government can show that his conduct “can somehow be translated to typify his conduct with actual patients who did consume the medications.” Resp. Exceptions, at 5.

Respondent did allow that his prescribings to the undercover agents would be probative of the public interest determination if the Government could show that his “prescribing practice did not improve to the point that he was in compliance with DEA requirements and the applicable community standard of care.” Id. Here again, Respondent is confused, but not because the Agency’s precedent is unclear. Under Agency precedent, DEA can revoke based on

proof of a single act of intentional or knowing diversion. See Dewey C. MacKay, 75 FR 49956, 49977 (2010); see also Daniel Olefsky, 57 FR 928, 928-29 (1992). Moreover, where, as here, the Government makes out a prima facie case by showing that a registrant has committed acts which render his registration inconsistent with the public interest and which support the revocation of his registration, the registrant bears the burden of producing evidence to show that he accepts responsibility for his misconduct and has taken sufficient remedial measures to assure the Administrator that he will not engage in future misconduct. MacKay, 75 FR at 49977. (collecting cases). Having established its prima facie case by showing that Respondent diverted controlled substances on multiple occasions, the Government was not required to show that his “prescribing practices [have] not improve[d] to the point that he [is] in compliance with DEA requirements and the applicable . . . standard of care.” Resp. Exceptions, at 5.

Next, Respondent argues that “[i]t is significant that the Government failed to introduce any evidence or testimony concerning Respondent’s care of a single current patient, even a ‘drug seeking’ one.” Id. at 6. He also asserts that “[t]he Government seized hundreds of medical charts” when it served the Immediate Suspension Order and yet “failed to introduce a **single one** of these charts, although presumably they were aware that Respondent had drug seeking patients in his practice.” Id.

Because of the extent and egregious nature of his misconduct, Respondent’s registration was Immediately Suspended simultaneously with the commencement of this proceeding. Thus, Respondent is without authority to lawfully dispense controlled substances to any current patient. Respondent does not explain why his care of a single current patient would be probative of his ability to responsibly and lawfully dispense controlled substances.

As for the Government's failure "to introduce a single one of" the patient charts it seized, the Government was not required to provide any such evidence to prove its case. Having conducted the nine undercover visits, the Government could reasonably conclude, based on its review of the evidence obtained during those visits, that Respondent was engaged in the diversion of controlled substances and that it had sufficient evidence to bring this proceeding. See T.J. McNichol, 77 FR 57133, 57146 (2012) (rejecting ALJ's reasoning that the Government was required to review patients charts it had seized "to develop evidence that might enlighten the administrative record of [physician's] positive prescribing practices"; "[h]aving garnered evidence of what it believed to be unlawful prescriptions issued to . . . four undercover officers, the Government was entitled to go to hearing with that evidence").

In a variation on a previous theme, Respondent further argues that his prescribing to the undercover officers "is useless in determining the public interest question" because "all" of the agents engaged in "diverting behavior" by "discussing extraneous matters" with him. Resp. Exceptions, at 7. Respondent asserts that this behavior is atypical of drug seeking patients and that "it tended to divert [his] attention from the symptoms he was asking about so that the recording would contain less evidence of a legitimate examination and history taking" and also diverted his "attention from his note taking which distorted the medical record itself."

Id.

However, as explained above, Respondent did not testify, and thus, there is no evidence to support his assertion that the putatively extraneous conversations diverted his attention from his responsibilities in either questioning his patients regarding their conditions and medical history or his note taking. Moreover, as the ALJ found (see R.D. at 15), while the Agents may have initiated the extraneous conversations, such as when Agent Breeden noted that Respondent

had gone to Nebraska and that “they play Penn State . . . this week,” Respondent perpetuated the conversation by noting “that Joe Paterno thing is so stupid,” that “these politically correct people just piss me off to no end” and continuing to discuss the Penn State/Jerry Sandusky scandal for several minutes thereafter<sup>4</sup>. See GX 5, at 8-12. Furthermore, the extraneous conversation had long ended by the time Agent Breeden and Respondent proceeded to discuss what drugs the former (in his undercover capacity) was using and why he was using them, and during which the following exchange occurred:

Dr: so you use the norcos and?

Agent: uh yes I use pretty much whatever I (unintelligible) whatever I have available.

Dr: ok the opanas are so damned expensive do you notice any high out of the opanas at all they make you dopy for (unintelligible)?

Agent: (unintelligible) well compare to the old the old oxy’s um . . . you know I got some friends who’ve used the um who don’t like ‘em um I personally I like ‘em I mean I (unintelligible).

Dr: which ones?

Agent: the opanas. . . but they’re harder to get for than the . . . roxicodones are . . and they’re way more expensive though.

Dr: yea.

Agent: the opanas are . . . ya know twice as much as the Roxicodone are.

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<sup>4</sup> Respondent asserts that the ALJ’s Recommended Decision “recognized [that] all Agents engaged in this diverting behavior,” by trying to distract him during his evaluation of the patients. Resp. Exceptions, at 7. However, following a review of the recordings, I agree with the ALJ’s finding:

that the conversations engaged in by these agents were [not] designed to divert [Respondent’s] attention or keep him from performing a proper, adequate, physical examination. To the contrary, most of the extraneous dialogue recorded here was occasioned by Respondent himself. The record does, however, make clear that each of the undercover agents tried to act like drug-seeking patients. . . .

Dr: and then you you get the norcos as well?

Agent: some sometimes mostly the Roxicodone and the opanas.

GX 5, at 27-28.

Moreover, a further review of the transcript and recording shows that Respondent was not distracted when he informed the Agent that “for pain medication I would charge you \$200 dollars . . . and then I charge you \$80 dollars a month for your prescriptions,” but that he was “gonna do [the Agent] better than that because . . . I’m gonna give you the cannabis card” for which, “when I do the pain medication prescriptions with the cannabis then you know I charge \$180 for the cannabis recommendation,” but that “on the initial evaluation I charge people half on their prescriptions so instead of charging you \$80 bucks I charge you \$40.” GX 5, at 38. Nor was Respondent distracted by the Agent when the latter explained that he had \$200 on him and Respondent agreed that “for \$200 we’ll just go ahead and do your prescriptions for your norcos and your and stuff” and “do the [cannabis] card for you too.” Id.

Later, after a discussion of various cannabis related issues, Respondent and the Agent proceeded to discuss what prescriptions the latter wanted, with the following exchange occurring:

Dr: . . . what are we gonna do as far as prescriptions for what are you using you say you are using norcos?

Agent: ah mostly the uh opana or the uh roxies um and then if uh I’m not sure if it’d be the same prescription or not (unintelligible) the cough syrup too.

Dr: ok so basically you want to end up getting the oxycodone you want the IR’s the 30 IR’s?

Agent: Ah, yea.

Dr: ok and how many of those . . . are you taking?

Agent: what is it (unintelligible) for a month what is it 120?

Dr: Ok.

Id. at 41-42. Here again, Respondent was not distracted. Nor was he distracted when the Agent also asked for the cough syrup, and Respondent replied: “I’ll give you the promethazine.” Id. at 42.<sup>5</sup>

Finally, Respondent argues that the ALJ failed to give proper weight to his evidence of remediation. Resp. Exceptions, at 8-9. First, he argues that the ALJ failed to recognize that he expressed remorse when he admitted to the Case Agent “that he had been over prescribing in the past.” Id. at 8. Second, he argues that while the ALJ acknowledged “the testimony of two patients (of Respondent) who received appropriate examinations and treatment,” the ALJ “made no finding impugning the veracity of [the clinic employee who testified] about improvements in the practice with respect to controlled substance prescribing.” Id. at 8-9.

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<sup>5</sup> It is noted that Respondent did ask the Agent various questions regarding his medical history. However, he did not ask any questions about the Agent’s purported pain level and how it affected his ability to function. See Tr. 343 (testimony of Government’s Expert: “he’s a tile man, and nowhere in the information that I listened to or read was there any conversation about how his pain conditions [sic] was interfering with his ability to be a tile man. It seems to me it would be very hard to be a tile man if you had knee pain or back pain.”); id. at 344-45 (testimony of Government’s Expert; “nor did I get any impression from the transcript or the recording of the degree of pain that was being suffered on a scale of one to [ten], or even using such words as mild, moderate or severe. None of that language was employed”); id. at 325-26 (Expert’s testimony discussing scope of questioning by a physician in assessing a patient’s pain complaint).

Nor does Respondent explain why these distractions prevented him from examining the Agent’s knee, which was the purported area of the Agent’s pain. See Tr. 133 (Agent’s testimony that Respondent did not at any point look at his knee); see id. at 345-46 (testimony of Government’s Expert: noting that upon review of Agent Breeden’s medical record, there was “a very nondetailed examination of the musculoskeletal system, although that was quite relevant to the pain complaint, the pain complaint being knee pain. One would customarily expect to see a highly detailed knee examination and an examination of the joints on either side of the knee, that being the ankle and the hip”).

I also reject Respondent’s contention that the Government’s Expert’s testimony should be “given very little weight” because she “had never qualified as an expert witness” by testifying in a medical board case on “the “treatment of non-cancer pain.” Resp. Exceptions, at 8. There is, of course, a first time for everything, and the Expert testified that she has reviewed other cases for the state medical board which involved the long-term use of opiates in managing chronic, non-cancer pain. Tr. 320. In addition, the Expert testified that she has been a clinical professor of medicine at the U.C. Davis School of Medicine for nearly thirty years; she also testified that in her prior position, she had evaluated one to five patients each week to determine whether to initiate long term opioid therapy for non-cancer pain and had prescribed oxycodone for one to two patients a week. Id. at 322-23.

As for the testimony of Respondent's patients that they received appropriate examinations and treatment and were helped by his treatment, neither patient testified that they possess medical expertise. Moreover, because under the CSA, "registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [his] professional career." Jayam Krishna-Iyer, 74 FR 459, 463 (2009). Thus, while Respondent may have treated these two legitimate patients appropriately, this says nothing about his management of persons who seek controlled substances to either abuse or divert them. See MacKay v. DEA, 664 F.3d at 819 ("Although Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to K.D. and M.R. is sufficient to support her determination that his continued registration is inconsistent with the public interest.").

It is acknowledged that the Practice Manager at the urgent care clinic, where Respondent is now employed, testified regarding the new procedures he instituted to screen out non-complying patients. However, to rebut the Government's prima facie case, Respondent was required to produce evidence not only as to his corrective measures, he was also required to acknowledge his misconduct in prescribing to the undercover officers. Medicine Shoppe-Jonesborough, 73 FR at 387 (quoting Samuel S. Jackson, 72 FR 23848, 23853 (2007)); John H. Kennedy, 71 FR 35705, 35709 (2006). As the Tenth Circuit has explained:

. . . The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether continued registration is in the public interest. Without Dr. MacKay's testimony, the Deputy Administrator had no evidence

that Dr. McKay recognized the extent of his misconduct and was prepared to remedy his prescribing practices.

MacKay, 664 F.3d at 820 (citing Hoxie v. DEA, 419 F.3d 477, 483 (2005)).

Here, the only evidence regarding whether Respondent admits fault with respect to anything, was his admission during an interview (on the date the ISO was served) with the Case Agent “that some of his patients were not legitimate” and that “a number of them were receiving too many pills.” Tr. 104. Indeed, as noted above, at the hearing, Respondent invoked his Fifth Amendment privilege. Thus, Respondent has entirely failed to address the multiple acts of intentional diversion which he committed when he prescribed to the undercover officers. Respondent has therefore failed to produce sufficient evidence to rebut the conclusion that his continued registration would be consistent with the public interest. See MacKay, 664 F.3d at 820; Medicine Shoppe-Jonesborough, 73 FR at 387.

### **The Government’s Exceptions**

While the Government apparently agrees with the ALJ’s ultimate conclusion of law and recommended order (i.e., that Respondent’s registration is inconsistent with the public interest and should be revoked), it takes exception to two features of his recommended decision. First, it takes exception to the ALJ’s conclusion that even in a proceeding brought pursuant to section 824(a)(4), it must identify in the Show Cause Order each of the public interest factors it is relying on. Govt. Exceptions, at 1-4. Second, it takes exception to the ALJ’s legal conclusion that factor two (the experience factor) should not be considered “[w]here evidence of the Respondent’s experience, as expressed through his patients and employees, is silent with respect to the quantitative volume of the Respondent’s experience,” R.D. at 56, thus impliedly suggesting that the Government has an obligation to put forward evidence as to the volume of a

registrant's prescribing activities in order to rely on this factor. Gov. Exceptions, at 4-9. Both of the Government's exceptions are well taken.

As for his conclusion that the Government cannot rely on factor two because it did not cite the factor in either the Show Cause Order or its Pre-Hearing Statements, the ALJ cites no authority for this hyper-technical view of the Agency's notice obligation. Contrary to the ALJ's understanding, that the Government did not refer to factor two until its opening statement violated neither federal law nor the Due Process Clause.

Here, the Government set forth that it was proposing the revocation of Respondent's registration "pursuant to 21 U.S.C. § 824(a)(4) . . . because [his] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f)." ALJ Ex, 1, at 1. In addition, the Government set forth specific factual allegations regarding each of the nine undercover visits which it alleged resulted in Respondent issuing prescriptions "outside the usual course of professional practice or for other than a legitimate medical purpose." *Id.* at 2-3. The Government further alleged that Respondent violated 21 U.S.C. § 841(a)(1), which makes it unlawful to intentionally or knowingly distribute a controlled substance except as authorized by the Controlled Substances Act, as well as 21 CFR 1306.04(a), which requires that a controlled substance prescription "be issued for a legitimate medical purpose by [a] practitioner acting in the usual course of his professional practice."

"Pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law." Aloha Airlines v. Civil Aeronautics Bd., 598 F.2d 250, 262 (D.C. Cir. 1979) (quoted in CBS Wholesale Distributors, 74 FR 36746, 36749 (2009)); accord Citizens State Bank of Marshfield v. FDIC, 751 F.2d 209, 213 (8th Cir. 1984). Thus, "the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive and an issue

can be litigated if the Government otherwise timely notifies a [r]espondent of its intent to litigate the issue.” CBS Wholesale, 74 FR at 36570. And while the Agency has held that “the parameters of the hearing are determined by the prehearing statements,” consistent with numerous court decisions, it has also recognized that even where an allegation was not raised in either the Show Cause Order or pre-hearing statements, the parties may nonetheless litigate an issue by consent. Pergament United Sales, Inc., v. NLRB, 920 F.2d 130, 135-37 (2d Cir. 1990); see also Duane v. Department of Defense, 275 F.3d 988, 995 (10th Cir. 2002) (discussing Facet Enterprises, Inc., v. NLRB, 907 F.2d 963, 974 (10th Cir. 1990); “we held that defendant had constructive notice of an alternate theory of liability not described in the formal charge when the agency detailed that theory during its opening argument and at other points during the hearing and when the defendant’s conduct revealed that it understood and attempted to defend against that theory”); Grider Drug #1 & Grider Drug #2, 77 FR 44070, 44077 (2012) n.23 (holding that notwithstanding that the Government did not provide adequate notice of its intent to litigate an allegation in either the Show Case Order or its pre-hearing statements, where respondents “did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it” and “fully litigated the issue,” the allegation was litigated by consent) (citing Citizens State Bank, 751 F.2d at 213; Kuhn v. Civil Aeronautics Bd., 183 F.2d 839, 841-42 (D.C. Cir. 1950); and Yellow Freight System, Inc., v. Martin, 954 F.2d 353, 358 (6th Cir. 1992)).

“The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.” Pergament United Sales, 920 F.2d at 135 (citation omitted). The Government adequately fulfilled this function when it disclosed the legal authority for the

Agency's proposed revocation of Respondent's registration, see ALJ Ex. 1, at 1 (citing 21 U.S.C. §§ 824(a)(4), 823(f)); the factual allegations that Respondent had issued prescriptions for oxycodone to undercover agents on nine different occasions, see id. at 2-3; and the legal basis for its contention that the prescriptions were unlawful. See id. at 2 (alleging that Respondent "issued these prescriptions outside the usual course of professional practice or for other than a legitimate medical purpose, in violation of 21 U.S.C. §§ 823(f)(4),<sup>6</sup> 841(a)(1), and 21 CFR 1306.04(a)").

That the Government did not specifically reference it was seeking an analysis of this evidence under factor two (as well as factor four) until its opening statement did not in any way prejudice Respondent.<sup>7</sup> Respondent neither objected to the Government's argument, nor argued in its post-hearing brief that he was prejudiced by the Government's assertion that his various violations "are grounds for revocation of [his] registration based on" both factors two and factor four. Tr. 70. Indeed, in a section of his post-hearing brief entitled "undisputed matters," Respondent noted that "[t]he Government, in its opening statement set forth its intention to prove, in its case and [sic] chief, that Respondent's DEA registration should be revoked based on the public interest factors set forth in 21 U.S.C. § 823(f) factors 2 and 4 only." Resp. Post-Hrng. Br. 4 (citing Tr. 69-70). Thus, even if the public interest factors created substantive rules of conduct, which they do not, this case stands four square with Facet Enterprises. See 907 F.2d at 972.

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<sup>6</sup> While the Government alleged that Respondent's prescribings to the undercover agents violated section 823(f)(4), this provision cannot be violated because it does not create a substantive rule of conduct. Rather, it is simply a factor which Congress directed the Agency to consider in making the public interest determination under section 823(f). Cf. Bio Diagnostic International, 78 FR 39327, 39330 (2013) (quoting Penick Corp., Inc. v. DEA, 491 F.3d 483, 490 (D.C. Cir. 2007) (other citations omitted) ("the 'enumerated factors represent components of the public interest rather than independent requirements for registration'")).

<sup>7</sup> See Tr. 70 ("These violations of the Controlled Substances Act and DEA regulations are grounds for revocation of the Respondent's DEA registration based on the public interest pursuant to 21 U.S.C. § 824(a)(4) as determined by 21 U.S.C. § 823(f), Factor 2, the registrant's experience at dispensing controlled substances, and Factor 4, compliance with applicable state, federal or local laws relating to controlled substances.").

Even if Respondent had claimed prejudice, I would not find the argument persuasive. This is so because whether the Government's evidence regarding the prescriptions was considered under factor two (the experience factor), factor four (the compliance factor), or both factors together, Respondent knew "what conduct was being alleged and ha[d] a fair opportunity to present [his] defense." Duane v. Department of Defense, 275 F.3d at 995 (quoting Facet Enterprises., 907 F.2d at 972). The allegations that Respondent violated the CSA's prescription requirement and unlawfully distributed controlled substances to the undercover agents, as well as the potential defenses to the allegations, are the same whether the conduct is considered under factor two or factor four. Accordingly, while I agree with the ALJ's conclusion that Respondent waived any objection to the Agency's consideration of the prescription evidence under factor two, I reject the ALJ's conclusion that the Government did not provide adequate notice of "its intention to rely on Factor Two in this hearing." R.D. at 46.

The Government also took exception to the ALJ's legal conclusion that factor two "should not be used to determine whether Respondent's continued registration is inconsistent with the public interest." Gov. Exceptions, at 4-9. In support of this conclusion, the ALJ offered the following reasoning:

In order to establish a basis for revoking a Certificate of Registration based on the provisions of 21 U.S.C. § 823(f)(2) (Factor Two), and assuming Factor Two applies to both applicants and registrants, the Government must present evidence establishing, by at least a preponderance, that the experience of the Respondent in dispensing controlled substances is of such character and quality that his continued registration is inconsistent with the public interest. This requires evidence of both the qualitative and quantitative volume of the Respondent's experience. Where evidence of the Respondent's experience, as expressed through his patients and employees, is silent with respect to the quantitative volume of the Respondent's experience, and requires speculation to support an adverse finding under Factor Two, this Factor should not be used to determine whether the Respondent's continued registration is inconsistent with the public interest.

R.D. at 56. I reject the ALJ's analysis as it entirely ignores relevant precedent and is illogical.

Earlier in his Recommended Decision, the ALJ explained that “in analyzing a registrant’s experience under Factor Two [that] the Administrator should consider the context of a registrant’s entire dispensing practices, notwithstanding that isolated acts against the public interest can outweigh substantial positive experience.” R.D. at 43. As support for this reasoning, the ALJ cited four cases: the Eleventh Circuit’s unpublished decision in Jayam Krishna-Iyer; as well as the Agency’s decisions in Jeffery J. Becker, 77 FR 72387 (2012); T.J. McNichol, 77 FR 57133 (2012); and Rene Casanova, 77 FR 58150 (2012). Notably, the ALJ did not discuss either the Agency’s decision on remand in Krishna-Iyer, 74 FR 459 (2009), or its decision in Dewey C. MacKay, 75 FR 49956 (2010). Nor did the ALJ discuss the Tenth Circuit’s decision in MacKay. See MacKay v. DEA, 664 F.3d 808 (10th Cir. 2011).

On remand in Krishna-Iyer, I discussed at length the role of so-called “positive experience” evidence in Agency proceedings where, as here, the Government has proved that a registrant has committed intentional diversion. Therein, in response to the court’s instruction that I re-consider my findings under the experience factor, giving “particular attention to the entire corpus of [the physician’s] record in dispensing controlled substances [notwithstanding that there was no such evidence in the record], not only the experience [with the] undercover officer[s],” I assumed, without deciding, that the physician’s “prescribings of controlled substances to every other person she has treated constitute ‘positive experience.’” 74 FR at 462-63. However, I explained that the physician’s “prescribings to thousands of other patients do not . . . render her prescribings to the undercover officers any less unlawful, or any less acts which ‘are inconsistent with the public interest.’” Id. at 463 (21 U.S.C. § 823(f)).

Moreover, I then explained that under the CSA, only those persons who are authorized to dispense controlled substances under the laws of the State in which they practice are entitled to

be registered. Id. Continuing, I explained that “[b]ecause under law, registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career.” Id.

I then discussed several cases in which the practitioners had argued that the Agency should ignore their acts of intentional or reckless diversion because they had dispensed controlled substances to thousands of patients legitimately. Id. (discussing Paul J. Caragine, Jr., 63 FR 51592, 51599-600 (1998); Medicine Shoppe-Jonesborough, 73 FR at 386 & n.56). For example, in Caragine, the Agency noted in its discussion of factor two that the physician had practiced medicine for 20 years and had “seen over 15,000 patients.” 63 FR at 51599. While the Agency did not dispute this, it explained that what was “[a]t issue in this proceeding is Respondent’s controlled substance prescribing to 18 patients.” Id. After a lengthy discussion of the physician’s prescribing practices with respect to the patients (some of which rejected the ALJ’s findings of improper prescribing), which was conducted under the auspices of factor two, see id. at 51599-600, the Agency explained “that even though the patients at issue are only a small portion of Respondent’s patient populations, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.” Id. at 51600.<sup>8</sup>

More recently, in Medicine Shoppe-Jonesborough, I concluded that notwithstanding the pharmacy’s argument that it had 17,000 patients, the evidence that it had diverted controlled

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<sup>8</sup> Moreover, in contrast to this case, the Agency acknowledged that the patients at issue all “had legitimate medical problems that warranted some form of treatment.” 63 FR at 51601. It should also be noted there was no evidence that the physician had knowingly or intentionally diverted controlled substances and the physician put on evidence of his rehabilitation.

substances to twelve patients established that its “experience in dispensing controlled substances warrants a finding that its continued registration is inconsistent with the public interest.” 73 FR at 386. Noting that “[t]he fundamental question under the CSA is whether Respondent ‘has committed such acts as would render [its] registration inconsistent with the public interest,’” I concluded that “[n]o amount of legitimate dispensings can render Respondent’s flagrant violations [acts which are] ‘consistent with the public interest.’” Id. n. 56.

In Krishna-Iyer, I also noted that DEA had revoked a practitioner’s registration based on a physician’s presentation, at the same time, of two fraudulent prescriptions to a pharmacy, noting that the physician had “refuse[d] to accept responsibility for his actions and does not even acknowledge the criminality of his behavior.” Id. at 463 (discussing and quoting Alan H. Olefsky, 57 FR 928, 928-29 (1992)). I therefore held that “evidence that a practitioner has treated thousands of patients does not negate a prima facie showing that the practitioner has committed acts inconsistent with the public interest.” Id. And I further explained that “[w]hile such evidence may be of some weight in assessing whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, such evidence is entitled to no weight.” Id.

Thus, in Krishna-Iyer, I adhered to my previous conclusion that the “Respondent’s dispensings to the undercover officers and her pre-signing of prescriptions and unlawful delegation of her prescribing authority to her nurse, establish a prima facie case that her continued registration is ‘inconsistent with the public interest.’” Id. (quoting 21 U.S.C. § 824(a)(4)). I also made clear that had Respondent not acknowledged her misconduct, I would have revoked her registration again.

Subsequently, in MacKay, I found that the evidence that the physician had intentionally diverted controlled substances to two patients and did so on multiple occasions was “sufficient to hold that the government had made a prima facie showing that [the physician] had committed acts which render his registration inconsistent with the public interest.” 75 FR at 49977. Citing the Eleventh Circuit’s unpublished decision in Krishna-Iyer, the physician argued that “[a] better assessment of [his] medical practice and habits can be ascertained from [his] numerous positive experiences in prescribing controlled substances, some of which were recounted by the patients themselves \* \* \* at the hearing.” Id. (quoting Resp. Summation Br. at 3).

Based on my decision on remand in Krishna-Iyer, I rejected Respondent’s argument. See id. As I explained: “even assuming, without deciding, that Respondent’s prescribing practices to all of his other patients (including those whose medical records were reviewed by the Government’s expert) fully complied with the CSA and Utah law, these prescribings do not refute the evidence showing that he intentionally diverted to [the two patients] in violation of both the CSA and Utah law.” Id. I therefore rejected the physician’s “arguments and conclude[d] that the Government ha[d] established a prima facie case that his continued registration is ‘inconsistent with the public interest.’” Id. (citing 21 U.S.C. § 823(f)).<sup>9</sup>

On review of the Agency’s decision, the Tenth Circuit held “that substantial evidence supports the [Agency’s] findings under factors two and four” that the physician had “knowingly diverted controlled substances in violation of state and federal law.” MacKay v. DEA, 664 F.3d at 818. Addressing the physician’s contention that the Agency had failed to consider his “positive experience” evidence, the Tenth Circuit explained:

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<sup>9</sup> The physician also put on the testimony of three fellow physicians and introduced affidavits from sixteen other physicians. 75 FR at 49977. I placed no weight on this evidence because none of the physicians had personal knowledge of the physician’s prescribing with respect to the two patients. Id. at n.37.

None of the evidence presented by Dr. MacKay undermines the evidence relating to [the two patients]. Although numerous patients and colleagues of Dr. MacKay related their positive experiences with him, none had any personal knowledge regarding his treatment of [them]. Notably, Dr. MacKay's medical expert . . . failed to specifically discuss and justify Dr. MacKay's treatment of [the two patients]. As a result, none of Dr. MacKay's evidence contradicts the testimony and evidence presented by the DEA relating to the knowing diversion of drugs to these two patients.

Nor did the Deputy Administrator misweigh the five statutory factors for determining the propriety of revocation, see 21 U.S.C. § 823(f). In light of Dr. MacKay's misconduct relating to factors two and four, the government made a prima facie showing that Dr. MacKay's continued registration is inconsistent with the public interest. See MacKay, 75 FR at 49,977. Although Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to [the two patients] is sufficient to support her determination that his continued registration is inconsistent with the public interest.

Id. at 819. The Tenth Circuit thus denied the physician's petition for review.

As noted above, in his discussion of the experience factor, the ALJ entirely failed to discuss the Agency's decision on remand in Krishna-Iyer, as well both the Agency's and Tenth Circuit's decision in MacKay. However, as these precedents make clear, allegations that a practitioner has violated the prescription requirement (21 CFR 1306.04(a)) are properly considered – for obvious reason – under the experience factor. Moreover, while the respondent-practitioner in a proceeding brought under sections 823(f) and 824(a)(4) may put on evidence as to his experience as a compliant registrant, the Government has no obligation to put forward such evidence.

Thus, as the Tenth Circuit's decision in MacKay demonstrates, where the Government proves that a registrant has violated the prescription requirement, its evidence is still sufficient to make out a prima facie case under 21 U.S.C. § 824(a)(4) even where the registrant has produced evidence of his experience as a compliant registrant. That being the case, it is absolutely clear that, where, as here, the Government has proved that a registrant has violated the prescription requirement, the Government is entitled to a finding that the evidence with respect to the

registrant's experience in dispensing controlled substances establishes that he "has committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4); MacKay, 664 F.3d at 819.

This is so, even where there is no evidence "with respect to [the practitioner's] overall practice history," and "we do not know the number of patients he has served." R.D. at 45.<sup>10</sup> Indeed, notwithstanding various cases which have discussed the volume of a practitioner's dispensing activity as a relevant consideration under the experience factor, no case has ever placed the burden of producing evidence as to the volume of a practitioner's legitimate dispensings on the Agency. This is for good reason, as one of the fundamental principles of the law of evidence is that the burden of production on an issue is typically allocated to the party which is "most likely to have access to the proof." Christopher B. Mueller & Laird C. Kirkpatrick, 1 Federal Evidence § 3:3, at 432 (3d ed. 2007).<sup>11</sup>

I therefore reject the ALJ's conclusion of law that "[w]here evidence of the Respondent's experience, as expressed through his patients and employees, is silent with respect to the quantitative volume of the Respondent's experience, . . . this Factor should not be used to determine whether the Respondent's continued registration is inconsistent with the public interest." R.D. at 56. Consistent with Agency precedent which has long considered violations of the CSA's prescription requirement under factor two (as well as factor four), I hold that the evidence relevant to factor two establishes that Respondent violated 21 CFR 1306.04(a) when he dispensed controlled substances to the various undercover officers, and that this establishes a

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<sup>10</sup> The ALJ further explained that "we do not know . . . the value of [the Respondent's] service to the community, or other similar demographic factors relevant to the issue." R.D. 45. Contrary to the ALJ's understanding, there is no need to know any of this, because the Agency has held that so-called "community impact" evidence is irrelevant to the public interest determination. See Linda Sue Cheek, 76 FR 66972, 66972-73 (2011); Gregory D. Owens, 74 FR 36571, 36757 (2009).

<sup>11</sup> Nor is the Agency required to calculate a ratio of a practitioner's lawful to unlawful dispensings.

prima facie case that he has committed acts which “render his registration inconsistent with the public interest.” 21 U.S.C. § 824(a)(4). See also Carriage Apothecary, 52 FR 27599, 27600 (1987) (holding that evidence that pharmacy failed to maintain proper records and could not account for significant quantities of controlled substances was relevant under both factors two and four); Eugene H. Tapia, 52 FR 30458, 30459 (1987) (considering evidence that physician did not perform physical exams and issued medically unnecessary prescriptions under factor two; no evidence regarding quantity of physician’s legitimate dispensings); Thomas Parker Elliott, 52 FR 36312, 36313 (1987) (adopting ALJ’s conclusion that physician’s “experience in the handling [of] controlled substances clearly warrants finding that his continued registration is inconsistent with the public interest,” based on physician’s having “prescribed enormous quantities of highly addictive drugs to [ten] individuals” without adequate medical justification); Fairbanks T. Chua, 51 FR 41676, 41676-77 (1986) (revoking registration under section 824(a)(4) and citing factor two, based, in part, on findings that physician wrote prescriptions which lacked a legitimate medical purpose; physician’s “improper prescribing habits clearly constitute grounds for the revocation of his . . . [r]egistration and the denial of any pending applications for renewal”).

\* \* \*

In his discussion of factor two, the ALJ also explained that:

[o]n its face, Factor Two does not appear to be directly related to registrants like Dr. Pettinger. By its express terms, Factor Two applies to applicants, and calls for an inquiry into the applicant’s “experience in dispensing, or conducting research with respect to controlled substances.” Thus, it is not clear that the inquiry into Dr. Pettinger’s experience in dispensing controlled substances is warranted, given the limited scope of this factor.

R.D. at 42. The ALJ nonetheless “assum[ed] [that] Factor Two does indeed pertain to both registrants and applicants.” *Id.* at 42; see also R.D. 56 (“assuming Factor Two applies to both applicants and registrants”).

Contrary to the ALJ’s understanding, there was no need to assume that Factor Two applies to registrants. As demonstrated by the several hundred agency decisions which have considered all five of the public interest factors in revocation proceedings brought against practitioners, it does.<sup>12</sup> See, e.g., Thomas H. McCarthy, 54 FR 20936, 20938 (1989) (revoking registration and holding that “[a]n applicant’s ‘experience in dispensing’ (which includes prescribing and administering), made applicable to registrants by 21 U.S.C. 824(a)(4), is a statutory factor which ‘shall’ be considered as set out in 21 U.S.C. 823(f)(2)” ).

In section 824(a)(4), Congress provided the Agency with authority to suspend or revoke a registration “upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. § 824(a)(4) (emphasis added). In section 823, Congress set for the registration requirements for each category of registrant under the CSA, including practitioners. See 21 U.S.C. § 823(f). With respect to practitioners, the Agency has long and consistently held that all five of the factors set forth in section 823(f) are to be considered in making the public interest determination. See, e.g., McCarthy, 54 FR at 20938.

To be sure, factors two and three refer to “[t]he applicant’s experience” and “[t]he applicant’s conviction record,” rather than “the registrant’s.” *Id.* As for why they do, the answer is obvious: the purpose of section 823 is to set forth the registration requirements, i.e., the criteria for determining whether the granting of an application for registration is consistent with

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<sup>12</sup> In addition to the cases involving practitioners, there are numerous published decisions of revocation proceedings brought against other categories of registrants (such as list I chemical distributors) in which the Agency considered all of the public interest factors applicable to the particular category of registrant.

the public interest. Given that the initial determination of whether “issuance of [a] registration . . . would be inconsistent with the public interest,” *id.*, is made before an applicant is ever registered, it would make little sense to refer to “[t]he registrant’s experience.” Indeed, none of the factors applicable to any of the seven categories of registrant set forth in section 823 refers to “the registrant.”

Implicit in the ALJ’s reasoning is the notion that only those public interest factors which do not explicitly reference “the applicant” should be considered in a proceeding brought under section 824(a)(4). Not only does the ALJ’s proposed construction place undue reliance on literalism while ignoring both the statute’s context and Congress’s purposes in enacting section 824(a)(4), its adoption would lead to strange results.

For example, in the case of a list I chemical distributor, four of the five factors used in making the public interest determination refer to the “the applicant.” *See* 21 U.S.C. § 823(h)(1)-(4). Accordingly, were I to adopt the ALJ’s interpretation, in a revocation proceeding, these four factors would be rendered null and the only factor to be considered would be “such other factors as are relevant to and consistent with the public health and safety.” *Id.* § 823(h)(5) (emphasis added). This begs the question of how the Agency would determine whether the factors asserted to be within this factor were truly “other” without having considered the other four factors.

Moreover, under the ALJ’s interpretation, the factors to be considered in a revocation proceeding brought against a practitioner would vary from case to case, depending upon whether the practitioner had filed any pending applications. Thus, where the practitioner has not filed a renewal application (or an application to modify his registration), only factors one, four, and five could be considered in determining whether the acts he committed render his registration inconsistent with the public interest. However, upon the practitioner’s filing of a renewal

application (or application to modify), he would once again be an applicant and the Agency would then have authority (and be required) to consider all five factors in determining whether he had committed acts which “render his registration . . . inconsistent with the public interest.” 21 U.S.C. § 824(a)(4). This is simply a prescription for inconsistent decisionmaking.

Notably, the Agency has never interpreted the CSA in the manner suggested by the ALJ. Thus, while some of the earlier decisions in cases brought under section 824(a)(4) did not explicitly cite factor two (or the other factors for that matter), the Agency has long considered factor two in revocation proceedings brought under section 824(a)(4). See Tapia, 52 FR at 30459; Elliott, 52 FR at 36312; Chua, 51 FR at 41676-77. And in McCarthy, the Agency made explicit what was previously implicit (but was nonetheless the Agency’s practice), when it held that “[a]n applicant’s ‘experience in dispensing’ . . . [is] made applicable to registrants by 21 U.S.C. 824(a)(4), [and] is a statutory factor which ‘shall’ be considered” in a revocation proceeding. 54 FR at 20938.

The Agency’s interpretation is fully supported by the legislative history of the Drug Enforcement Amendments to the Comprehensive Crime Control Act of 1984. See P.L. 98-473, § 512, 98 Stat. 2068, 2073 (1984). As the House Report explained, the “[i]mproper diversion of controlled substances by practitioners is one of the most serious aspects of the drug abuse problem. However, effective Federal action against practitioners has been severely inhibited by the limited authority in current law to deny or revoke practitioner registrations.” H.R. Rep. No. 98-1030, at 266 (1984), reprinted in 1984 U.S.C.C.A.N. 3182, 3448. Continuing, the House Report explained that:

because of a variety of legal, organizational, and resource problems, many States are unable to take effective or prompt action against violating registrants. Since State revocation of a practitioner’s license or registration is a primary basis on which Federal registration may be revoked or denied, problems at the State regulatory level have had a

severe adverse impact on Federal anti-diversion efforts. The criteria of prior felony drug conviction for denial or revocation of registration has proven too limited in certain cases as well, for many violations involving controlled substances which are prescription drugs are not punishable as felonies under State law. Moreover, delays in obtaining conviction allow practitioners to continue to dispense drugs with a high abuse potential even where there is strong evidence that they have significantly abused their authority to dispense controlled substances.

Clearly, the overly limited bases in current law for denial or revocation of a practitioner's registration do not operate in the public interest.

Id.

Congress thus amended section 823(f) "to expand the authority of the Attorney General to deny a practitioner's registration application" based upon a finding "that registration would be 'inconsistent with the public interest,'" by considering the five factors, which the House Report then set forth. Id. And Congress also amended section 824(a) "to add to the current bases for denial, revocation[] or suspension of registration a finding that registration would be inconsistent with the public interest on the grounds specified in 21 U.S.C. § 823, which will include consideration of the new factors added by section 509, as discussed supra." Id. at 3449 (emphasis added). Notably, nowhere did the report suggest that the Agency should consider only those factors that do not use the words "the applicant."

Accordingly, consistent with the Agency's longstanding interpretation,<sup>13</sup> in future cases brought against practitioners under section 824(a)(4), the ALJ should rest assured that factor two (as well as factor three) applies in making the public interest determination. So too, in any proceeding brought under section 824(a)(4), the ALJ shall, in making the public interest determination, consider all of the public interest factors set forth in the relevant provision of section 823. To the extent the evidence submitted by either party is relevant under a particular factor, the ALJ shall make the appropriate findings.

However, the ALJ's failure to make findings under factor two does not alter the outcome of this matter. Because I agree with the ALJ's conclusions of law that there is substantial evidence that Respondent issued nine prescriptions to the undercover agents in violation of 21 CFR 1306.04(a), because he lacked a legitimate medical purpose and acted outside of the usual course of professional practice, and this conduct is also properly considered under factor four (compliance with applicable laws related to controlled substances), I adopt the ALJ's conclusion of law that "Respondent's continued [registration] is inconsistent with the public interest" and "warrant[s] the revocation of" his registration and the "the denial of any pending application." R.D. 57. And for reasons explained earlier, I also adopt the ALJ's legal conclusion that

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<sup>13</sup> At the close of the hearing, the ALJ explained that while he had "seen court and DEA construction that assumes that factor 2 applies to registrants as well as applicants," he was "in a learning curve here." Tr. 500. The ALJ then explained that "I don't see how factor 2 applies here at all," even though "I have seen cases that tell me that I should be construing factor 2 as though it's written for both the applicant and the registration [sic]." *Id.* at 500-01. The ALJ thus asked the parties to address "what your take is on that." *Id.* The Government complied, yet even after the Government provided applicable precedent, *see* Gov't's Post-Hearing Br. 22-23 (citing Thomas H. McCarthy, 54 FR 20936, 20938 (1989)), the ALJ was apparently still unconvinced. *See* R.D. at 42.

As stated above, there are several hundred Agency decisions which have applied factor two (as well as factor three) in section 824(a)(4) proceedings brought against practitioners. Moreover, having seen court decisions, none of which questioned the Agency's longstanding construction of the statute, there was no reason to require the parties to brief the issue or to ruminate as to whether factor two even applies. It does. *See Iran Air v. Kugelman*, 996 F.2d 1253, 1260 (D.C. Cir. 1993) (quoting Joseph Zwerdling, Reflections on the Role of an Administrative Law Judge, 25 Admin. L. Rev. 9, 12-13 (1973) (an ALJ "is governed, as is the case of any trial court, by the applicable and controlling precedents. These precedents include . . . the agency's policies as laid down in its published decisions . . . Once the agency has ruled on a given matter . . . it is not open to reargument by the administrative law judge")).

Respondent authorized a prescription for hydrocodone after his registration had been suspended, and this conduct is also inconsistent with the public interest.<sup>14</sup> Id. Finally, because Respondent has entirely failed to address the multiple acts of intentional diversion which he committed when he prescribed controlled substances to the undercover officers, I agree with the ALJ's conclusion of law that "Respondent has failed to affirmatively acknowledge specific acts of improper prescribing," id. at 58, and that he has not put forward sufficient evidence to show why he can be entrusted with a registration. See MacKay, 664 F.3d at 820. Accordingly, I will adopt the ALJ's recommendation that I revoke Respondent's registration and deny any pending applications to renew or modify his registration.<sup>15</sup>

### **ORDER**

Pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration Number AP6572716, issued to Clair L. Pettinger, M.D., be, and it hereby is, revoked. I further order that any pending application of Clair L. Pettinger, M.D., to renew or modify the aforesaid Certificate of Registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: September 18, 2013

Michele M. Leonhart  
Administrator

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<sup>14</sup> While I also adopt this conclusion, Respondent's violations in prescribing controlled substances to the undercover agents provides more than sufficient evidence to support the revocation of his registration.

<sup>15</sup> For the same reasons that I ordered that Respondent's registration be immediately suspended, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.



Paul Soeffing, Esq., for the Government

Alan Kaplan, Esq., for the Respondent

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

**Nature of the Case**

Administrative Law Judge Christopher B. McNeil. Respondent Clair L. Pettinger, M.D., is registered with the Drug Enforcement Administration as an individual practitioner authorized to prescribe Schedule II-V controlled substances under DEA Certificate of Registration Number AP6572716, with an office at 4707 Greenleaf Court, Suite A, Modesto, California, 95356. His DEA Certificate of Registration expires by its own terms on March 31, 2015.<sup>1</sup> He also is licensed to practice medicine as a physician and surgeon in the State of California under license number G29874, which will expire by its own terms on March 31, 2015.<sup>2</sup> He has been licensed to practice medicine in the State of California since July 1, 1975 and has, heretofore, never been the subject of disciplinary actions by the DEA or by the State of California.<sup>3</sup>

On December 11, 2012, the DEA served Dr. Pettinger with an Order to Show Cause and Immediate Suspension of his DEA Registration dated December 10, 2012, whereby his DEA Certificate was suspended pursuant to 21 U.S.C. § 824(d).<sup>4</sup> The Government alleged Dr. Pettinger distributed controlled substances to five undercover law enforcement officers outside the usual course of professional practice or for other than a legitimate medical purpose, in

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<sup>1</sup> Per stipulation of the parties, see Order of February 5, 2013, ALJ Exhibit 13, at 1.

<sup>2</sup> Tr. at 481.

<sup>3</sup> Per stipulation of the parties, see Order of February 5, 2013, ALJ Exhibit 13, at 1.

<sup>4</sup> Id.

violation of 21 U.S.C. §§ 823(f)(4) and 841(a)(1), and 21 C.F.R. § 1306.04(a). Further, the Government alleged that Dr. Pettinger prescribed a high volume of controlled substances, particularly oxycodone through September 2012.<sup>5</sup> Based on this set of conditions, the Administrator suspended Dr. Pettinger's Certificate effective immediately and provided Dr. Pettinger with the opportunity to show cause why this immediate suspension should end and why the Administrator should not permanently revoke Dr. Pettinger's DEA Certificate.

While this matter was pending before me, the Government alleged further that after the Immediate Suspension Order was issued and served upon Dr. Pettinger, Dr. Pettinger issued a new prescription dispensing hydrocodone to a patient on December 21, 2012.<sup>6</sup>

### **Statement of the Issue**

The general issue to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes, by substantial evidence, that Dr. Pettinger's continued DEA registration is inconsistent with the public interest, as that term is used in Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824. Under this Act, the DEA may revoke the Certificate of Registration of a Registrant upon sufficient evidence establishing that the Registrant's continued registration is inconsistent with the public interest. Continued registration is inconsistent with the public interest if (among other bases) a Registrant who is otherwise authorized to prescribe controlled substances does so outside the usual course of his or her professional practice, or does so for other than a legitimate medical purpose. The specific issue is thus whether by at least a

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<sup>5</sup> At the hearing, the Government did not present evidence to support allegations in the Order to Show Cause that referred to Dr. Pettinger's prescription history. Order to Show Cause and Immediate Suspension of Registration, at paragraphs 4(a) through 4(e), pages 3-4. These allegations therefore are not currently before me.

<sup>6</sup> Government Prehearing Statement at 4.

preponderance of the evidence the Government has established that Dr. Pettinger prescribed controlled substances to any of the five undercover agents outside the usual course of his professional practice or for other than a legitimate medical purpose.

### **Summary of the Evidence**

The evidence in this record consists of recorded proceedings conducted during a brief hearing held in Arlington, Virginia on February 5, 2013 and a two-day hearing in Sacramento, California held on April 2-3, 2013, along with the documents admitted into evidence during those hearings. Included in the admitted exhibits are five audio recordings and six audio-visual recordings. By agreement of the parties, I listened to and, where appropriate, viewed the recordings after the evidentiary hearing was concluded. The contents of those recordings thus are part of the evidence now before me.

The Government's case is based in part on the testimony of five investigators who presented to Dr. Pettinger under assumed identities. Dr. Pettinger, who goes by Nate Pettinger, M.D., maintained a medical office under the name of Medical Cannabis of Northern California, or MCNC, at 2222 Watt Avenue Suite B1, Sacramento, California.<sup>7</sup> Each of the five government investigators worked for federal agencies, including the DEA, the United States Department of Health and Human Services, and the FBI.

DEA Special Agent Robert Kittrell testified regarding the overall scope of this investigation. Each of the participating undercover agents testified regarding what they heard and saw during their interactions with Dr. Pettinger, describing the discussion and examinations that preceded Dr. Pettinger's issuance of a total of nine prescriptions for controlled substances. The

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<sup>7</sup> Government Exhibit 25 at 1.

Government then presented testimony from an expert medical witness regarding the nature of the examinations that led to Dr. Pettinger prescribing controlled substances to these undercover agents. The Government also called Dr. Pettinger as a witness, but after being sworn in and acknowledging his identity, Dr. Pettinger refused to answer further questions and invoked his Fifth Amendment right to avoid self-incrimination.

Although he did not testify on his own behalf, Dr. Pettinger presented testimony from an employee and two patients, with the intention of demonstrating that it would be improper to make generalizations adverse to Dr. Pettinger's regular practice based on the undercover activity. Without directly admitting to any violation of DEA diversion control regulations, Dr. Pettinger argues that the visits with the undercover agents are not indicative of his ordinary practice, urging that the Government's evidence does not establish that he has in any way endangered the public. Further, Dr. Pettinger urges that I find that he has taken remedial steps appropriate under the circumstances, such that further action by the DEA is not warranted.

After carefully considering the testimony elicited at the hearing, examining the admitted exhibits, evaluating the arguments of counsel, and weighing the record as a whole, I have set forth my recommended findings of fact, conclusions of law, and analysis below. Because I find that a preponderance of the evidence establishes that the Respondent's continued registration would be inconsistent with the public interest, I recommend the Administrator revoke Dr. Pettinger's DEA Certificate and deny any pending application for the same.

### **Testimony from DEA Special Agent Kittrell**

Robert Kittrell is a DEA Special Agent with the Tactical Diversion Squad in the Sacramento District Office.<sup>8</sup> Agent Kittrell has been a criminal investigator with the DEA since 1991. He attended a 14-week training academy at Quantico, Virginia, studying subjects that included a review of drug laws, tactical training, training in the use of firearms, training in investigations, training in the use of undercover agents, and training in financial investigations.<sup>9</sup> He has furthered his studies through continuing education, including recent attendance at an 80-hour course in the investigation of controlled substance diversions involving pharmacies and doctors.<sup>10</sup>

Agent Kittrell described two kinds of controlled substance diversion: one involving drug gangs that send people to doctors' offices with the intent to get prescriptions for controlled substances; and the other involving what Agent Kittrell described as "rogue doctors" who "will prescribe controlled substances to people without medical necessity."<sup>11</sup> He said that characteristics of such rogue doctors include prescribing the controlled substances that patients ask for, with little or no medical evaluation. He explained that these doctors "will not ask for a lot of medical records" and are "just getting the patients in, writing them the script and getting them out."<sup>12</sup>

Agent Kittrell said that he served as the Case Agent – the agent in charge of the DEA's investigation of Dr. Pettinger. He explained that an undercover investigator for the Department of Health and Human Services, Rob Breeden, approached him after Agent Breeden was able to

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<sup>8</sup> Transcript at 75.

<sup>9</sup> Id. at 75-6.

<sup>10</sup> Id. at 76.

<sup>11</sup> Id. at 76-7.

<sup>12</sup> Id. at 77.

obtain controlled substances without medical necessity.<sup>13</sup> In response, the team supervised by Agent Kittrell began investigating Dr. Pettinger.

According to Agent Kittrell, agents in these cases are trained to approach the Certificate holder equipped with recording devices. The agents will sometimes simply ask for pills and may speak vaguely about medical problems. “They’ll try to avoid answering questions. They won’t provide any medical records or, if they do, they’ll be falsified. . . . They won’t complain of any immediate pain. They won’t complain of any pain at all sometimes. They’ll basically give every indication they can that the drugs are going to be diverted or that they’re going to be abused or that there’s no medical need for it.”<sup>14</sup>

On cross examination, Agent Kittrell elaborated on this approach, stating that undercover agents can be “vague” about whether they have any actual pain.<sup>15</sup> When asked whether the agents were instructed to attempt to divert the doctor’s attention during these examinations, Agent Kittrell stated that “[w]e leave a lot of those things up to the undercovers themselves in each individual case because a lot of it has to do with what’s going on at the time. You know, is it possible for an undercover agent to try to be friendly with the doctor when it happens? Absolutely. Does that include extraneous conversations? Absolutely.”<sup>16</sup> He agreed with the premise that during their preparation for undercover assignments, agents are “instructed to not act like a legitimate patient,” but instead are to act the way a drug-seeking patient would act.<sup>17</sup>

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<sup>13</sup> Id. at 77-8.

<sup>14</sup> Id. at 78-79.

<sup>15</sup> Id. at 95.

<sup>16</sup> Id.

<sup>17</sup> Id. at 96.

Supporting the actions of the undercover agents were medical records and patient questionnaires prepared by the undercover officers and identified as Exhibits 25, 26, and 27.<sup>18</sup> According to Agent Kittrell, Agent Breeden completed Exhibit 25, which encompasses the patient questionnaire for a fictional patient named Danny Daly, when he visited Dr. Pettinger.<sup>19</sup> Similarly, FBI Special Agent Neeki Bianchi completed the patient questionnaire for a fictional patient named Nichole Hancock, shown as Exhibit 26.<sup>20</sup> DEA Special Agent Bob Ghazanfari completed the patient questionnaire for a fictional patient named Reza Soltani, shown as Exhibit 27.<sup>21</sup> Each of these records was submitted to Dr. Pettinger by the undercover agents, and was then recovered after Agent Kittrell obtained a search warrant to seize evidence from the doctor's office and residence.<sup>22</sup> According to Agent Kittrell, similar false medical files compiled for use by the other two undercover agents had been delivered to Dr. Pettinger in the course of the agents' visits, but were not located during subsequent searches of Dr. Pettinger's office or home.<sup>23</sup> They were, however, provided by Dr. Pettinger after Agent Kittrell requested them.<sup>24</sup>

Upon execution of the search and arrest warrants Agent Kittrell participated in questioning Dr. Pettinger. According to Agent Kittrell, Dr. Pettinger said that when presented with a pain management patient, "he does a complete physical workup and that includes blood pressure, heart rate, respiration, height, weight, and a complete physical exam."<sup>25</sup> Dr. Pettinger told Agent Kittrell that in these cases he would request the patient's medical records, including

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<sup>18</sup> Id. at 80.

<sup>19</sup> Id. at 81.

<sup>20</sup> Id.

<sup>21</sup> Id. at 82.

<sup>22</sup> Id.

<sup>23</sup> Id.

<sup>24</sup> Id. at 103, and Respondent's Exhibits C and D.

<sup>25</sup> Tr. at 85-6.

any MRIs or x-rays, to evaluate the basis for the prescription being requested by the patient.<sup>26</sup>

Dr. Pettinger told Agent Kittrell he would perform a complete physical exam again on follow-up visits.<sup>27</sup> According to Agent Kittrell, Dr. Pettinger stated “that he knew that he had a soft heart and that he was probably prescribing too much. He stated that about 20 percent of his patients were pill seekers and that 50 percent were probably receiving too many meds. He stated to me that he had received a lot of complaints from pharmacies, but if he was guilty of anything, he was guilty of not calling the pharmacies back, but he had been taking steps to correct that and trying to work with pharmacies so that they would accept his prescriptions.”<sup>28</sup>

According to Agent Kittrell, during this questioning Dr. Pettinger stated that if a patient came to him for pain medication and did not have any medical records, “he would only prescribe Norcos [hydrocodone] to begin with, which is a Schedule III narcotic.”<sup>29</sup> Further, he told Agent Kittrell that he was “taking steps to try to wean out or weed out problem patients . . . [and] if a patient came to him and stated that they were selling the pills, that he wouldn’t write a prescription.”<sup>30</sup> Agent Kittrell stated that, in addition to these efforts, Dr. Pettinger told him he was trying to identify patients who were “double dipping,” in that they were obtaining controlled substances from more than one doctor at the same time.<sup>31</sup> According to Agent Kittrell, Dr. Pettinger reported that he was “really clamping down” on patients who appeared to be misusing medication and that as of July 2011 he had stopped accepting new patients.<sup>32</sup> Asked on cross examination whether that is exactly what the DEA expects doctors to do, Agent Kittrell agreed that if there is abuse of prescription medication, double-dipping, or the use of fraudulent medical

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<sup>26</sup> Id. at 86.

<sup>27</sup> Id.

<sup>28</sup> Id.

<sup>29</sup> Id. at 86.

<sup>30</sup> Id. at 87.

<sup>31</sup> Id. at 104.

<sup>32</sup> Id. at 105.

records, a doctor should discharge the patient.<sup>33</sup> When asked whether this constitutes “remediation” by the doctor, Agent Kittrell stated, “Yes, it’s like that,” – but clarified that this was “kind of like shutting the barn door after the cow got out[.]”<sup>34</sup>

On cross examination Agent Kittrell agreed with the proposition that one way to verify whether Dr. Pettinger had engaged in remediation and reduced his prescribing would be to obtain patient activity reports from the California Substance Utilization Review and Evaluation (CURES) tracking system.<sup>35</sup> Agent Kittrell said he obtained “some” reports on Dr. Pettinger’s patients from the CURES system, but he acknowledged that these reports were “not part of the evidence packages here.”<sup>36</sup>

Agent Kittrell stated that he served an order of immediate suspension on Dr. Pettinger, telling him that “he was unable to dispense, prescribe, or otherwise issue controlled substances from that point on.” In response, Dr. Pettinger “stated that he understood that.”<sup>37</sup> Despite acknowledging this bar to further prescribing, Dr. Pettinger did not stop writing prescriptions, according to Agent Kittrell.

According to Agent Kittrell, the order of immediate suspension was delivered to Dr. Pettinger on December 11, 2012.<sup>38</sup> Exhibit 24 is a photocopy of a prescription for patient B.D., directing dispensation of 180 units of Norco 10/325 (indicating 10 mg of hydrocodone and 325 mg of acetaminophen). This prescription predates the December 11, 2012 order, and it allows for two refills. Also in Exhibit 24 is a photocopy of records from Safeway Pharmacy #2242, located

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<sup>33</sup> Id. at 106-7.

<sup>34</sup> Id. at 108.

<sup>35</sup> Id. at 109.

<sup>36</sup> Id. at 110-1.

<sup>37</sup> Id. at 87.

<sup>38</sup> Id. at 80.

in Sacramento, California. The Medical Expenses record (page 4 of Exhibit 24) reflects that the prescription was first filled on October 22, 2012, and then again on November 12, 2012, and on December 3, 2012. Thus, by December 3, 2012, all of the authorized dispensations under this prescription had been filled. According to Agent Kittrell, at this point if a pharmacy were to dispense any additional narcotics, the patient would need to produce a new prescription.<sup>39</sup>

According to Agent Kittrell, despite being prohibited from prescribing controlled substances as of December 11, 2012, Dr. Pettinger authorized B.D. to receive an additional 180 units of Norco on December 21, 2012. Agent Kittrell identified a faxed Prescription Refill Request, shown at page 3 of Exhibit 24, and stated that this was a prescription issued by Dr. Pettinger after the effective date of the suspension order he received on December 11, 2012.<sup>40</sup> Agent Kittrell stated that while doing routine follow-up work regarding Dr. Pettinger, he contacted the pharmacist responsible for dispensing the Norco equivalent to B.D. He testified that the pharmacist told B.D. that there were no remaining refills on the initial prescription, so the pharmacist sent a fax to Dr. Pettinger's office. In response, the pharmacist received what has been marked as page 3 of Exhibit 24, through which Dr. Pettinger authorized the pharmacy to dispense 180 units of Norco to this patient.<sup>41</sup> To support his contention that this dispensation was the result of a new prescription and not simply the refilling of the earlier one, Agent Kittrell stated that a pharmacist would have no obligation to contact the prescribing source if the prescription had valid refills that had not yet been dispensed. Given that the pharmacist here did see the need to contact Dr. Pettinger, it follows that the earlier prescription could no longer serve

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<sup>39</sup> Id. at 92.

<sup>40</sup> Id. at 89.

<sup>41</sup> Id. at 91.

as a basis for dispensing another 180 units of Norco – and that the faxed sheet constitutes a new prescription.<sup>42</sup>

Agent Kittrell added that, about four days after he spoke with the Safeway pharmacist, he got a call from Dr. Pettinger, who asked if he could authorize a new prescription for a patient to whom he had previously prescribed narcotics. Agent Kittrell said he told Dr. Pettinger no, that only prescriptions that were written prior to December 11, 2012 could be filled or refilled, but that Dr. Pettinger could not authorize any new prescriptions.<sup>43</sup>

On cross examination, Agent Kittrell agreed with the premise that there is nothing in Exhibit 24 that establishes that Dr. Pettinger knew D.B. had already filled and refilled the earlier prescription to its limit.<sup>44</sup> There is handwriting on page three of Exhibit 24 that uses the word “refill,” which Agent Kittrell agreed appears to have been written by Dr. Pettinger.<sup>45</sup> This page, captioned “Prescription Refill Request,” appears to have been faxed from Dr. Pettinger’s office on December 21, 2012 (as it bears that designation on the bottom of the page). At the signature block, we see “N Pettinger MD – Can fill current refill No New Refill.” Above that, with an arrow pointing to the “No New Refill” language, there are two circles, one with “MD” and the other with “OK x 1”, indicating that the pharmacist contacted Dr. Pettinger and was told it was okay to dispense 180 generic Norco tablets, despite the fact that the pharmacy had already dispensed all of the medication authorized by the prescription written by Dr. Pettinger on October 22, 2012.<sup>46</sup> Despite the fact that the pharmacists would not have contacted Dr. Pettinger if refills remained on this prescription as of December 21, 2012, and despite the fact that the

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<sup>42</sup> Id. at 92.

<sup>43</sup> Id. at 93.

<sup>44</sup> Id. at 115.

<sup>45</sup> Id. at 116.

<sup>46</sup> Government Exhibit 24 at 3.

December 21, 2012 fax shows the pharmacist did contact Dr. Pettinger and was told it was okay to issue another 180 units of generic Norco, when Agent Kittrell was asked “You can’t state sitting here today that Dr. Pettinger knowingly issued a new prescription on December 21, 2012, in violation of the suspension order?” he responded “Knowingly? No.”<sup>47</sup> While this evidence does not establish that the pharmacist told Dr. Pettinger that B.D. filled this prescription three times already, it does establish that Dr. Pettinger knowingly authorized another 180 unit dispensation after being called by the pharmacist, a condition that would not have existed had there been a refill available under the original prescription.

Agent Kittrell also agreed with the proposition that persons who lie to doctors in order to get prescription medications are committing crimes and that in such cases the doctors are, to a certain degree, victims of those crimes.<sup>48</sup> He agreed also that the five undercover agents who presented to Dr. Pettinger were engaged in acts that would be crimes if committed by private citizens.<sup>49</sup> Consistent with this theory, but after the close of the hearing and after the time set for offering evidence had passed, counsel for the Respondent submitted a copy of a letter sent to GreenLeaf Urgent Care dated April 2, 2013, from the U.S. Department of Justice. The letter is addressed to Dr. Pettinger and contains information provided pursuant to the Department’s Victim Notification System. The letter states that Dr. Pettinger had been identified as a victim during an investigation involving twelve defendants, all of whom were named in the letter. The letter itself is silent with respect to the nature of the charges against these defendants, and does not indicate why or how Dr. Pettinger is regarded as a victim. The nexus between the letter and this administrative hearing is uncertain, but Respondent’s counsel in his cover letter states that

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<sup>47</sup> Tr. at 116.

<sup>48</sup> Id. at 118.

<sup>49</sup> Id.

“[w]e believe that the individuals listed in the letter received or obtained controlled substances in Dr. Pettinger’s name by means of criminal conduct for which they are now being prosecuted and which may also be relevant to the current DEA proceeding.” While not properly before me, this letter will be maintained as a proffer, identified in the record as ALJ Exhibit 22.

### **Evidence from the Undercover Operatives**

Robb Breeden works as a Special Agent for the United States Department of Health and Human Services in its Office of the Inspector General, out of the Sacramento, California field office.<sup>50</sup> He has worked there since 2007, and his training includes attendance at a fifteen week training course at the Federal Law Enforcement Training Center in Glencoe, Georgia, which included 120 hours of specialized tactical training and 120 hours of undercover training that included the identification of pills and drug diversion.<sup>51</sup>

According to Agent Breeden, after receiving an initial complaint regarding Dr. Pettinger, he made the first of four visits to the doctor’s office using the fictitious name of Daniel Joseph Daly on November 10, 2011, using an audio recorder. The recording from that visit appears in the record as Government Exhibit 5, and is accompanied by a transcript of the conversations recorded during that visit.<sup>52</sup>

Acting as Mr. Daly, Agent Breeden appeared for an appointment at Dr. Pettinger’s medical office on Watt Avenue in Sacramento.<sup>53</sup> He stated that upon his arrival at the office, he found the office was locked and that Dr. Pettinger was not present.<sup>54</sup> He stated that he then called

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<sup>50</sup> Id. at 122.

<sup>51</sup> Id. at 123.

<sup>52</sup> Id. at 123-4.

<sup>53</sup> Id. at 124.

<sup>54</sup> Id. at 126.

Dr. Pettinger's cell phone and reached the doctor, who told him he would be at the office in a moment. Upon Dr. Pettinger's arrival, Agent Breeden greeted him while holding in one hand a small, travel-sized bottle of scotch whiskey.<sup>55</sup> Agent Breeden accompanied Dr. Pettinger into the doctor's office, where Agent Breeden gave the doctor some medical records, some paperwork, and an MRI report.<sup>56</sup> According to Agent Breeden, Dr. Pettinger noticed the bottle of scotch, commenting that it was easier to buy alcohol than cannabis.<sup>57</sup>

Agent Breeden identified Government Exhibit 25 as a copy of the patient questionnaire form filled out at Dr. Pettinger's request. The first five pages of this form appear to be designed for a patient to provide identifying data and a medical history. As Agent Breeden noted in his testimony, the first page of Government Exhibit 25 (captioned "The California Compassionate Use Act of 1996, Eligibility Questionnaire") includes a statement requiring the applicant to state whether he or she is a "law enforcement officer, undercover officer or investigator for the Federal Government, State of California, county, city, or any other organization therein here today with the intent of investigating Medical Cannabis of Northern California or Nate Pettinger, M.D."

Pages 6 through 9 of Government Exhibit 25 are labeled "For Physician's Use Only," and consist of a single-page form apparently filled out by Dr. Pettinger on each of the four visits referred to by Agent Breeden: November 10, 2011, December 6, 2011, January 13, 2012, and May 9, 2012. Page 10 of this exhibit is a copy of a Physician Statement and Recommendation dated November 10, 2011 on which is also a copy of a California Driver License issued to Daniel

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<sup>55</sup> Id. and Government Exhibit 5, transcript at 1 ("let me get rid of my lunch here").

<sup>56</sup> Tr. at 126.

<sup>57</sup> Id. and Government Exhibit 5, transcript at 2 (Agent Breeden: "But I can't buy marijuana. It's stupid." Dr. Pettinger: "Right. Well, I mean, that that's [unintelligible] you know, take the scotch and you can do that, but you can't end up getting marijuana. It seems crazy, doesn't it? The thing about it is you can't even kill a baby with marijuana unless you stuff their mouth so full they can't breathe; I mean you can't get enough into 'em to kill 'em.")

Joseph Daly, identifying Mr. Daly as “a patient whose possession and/or cultivation of medical cannabis is permissible” under California law, signed by Dr. Pettinger and Agent Breeden as Daniel Daly. Accompanying this Physician’s Statement is a form captioned “Consent to Assume Risk for Medical Marijuana,” dated November 10, 2011, and signed by both Agent Breeden as Daniel Daly and Dr. Pettinger.

Also included in Government Exhibit 25 are photocopies of four prescriptions, whose dates match the dates of Agent Breeden’s four office visits. In each instance, the prescriptions are signed by Dr. Pettinger under his office letterhead, and are for Oxycodone 30 mg IR [Instant Release]. In the prescription issued on the initial visit (November 10, 2011), Dr. Pettinger prescribed 120 units of this controlled substance. He prescribed 200 units in the prescription dated December 6, 2011, and 220 units for those dated January 13, 2012 and May 9, 2012.

After Agent Breeden completed the requested paperwork, he met with Dr. Pettinger in the doctor’s office. He described the office as lacking things he would normally associate with a doctor’s office: there was no examination table, no eye chart, no scale – only a cuff for taking blood pressure and a stethoscope.<sup>58</sup> Subsequent records, notably the video recordings at Exhibits 15, 17, 20 and 22, established further that the office that served for these examinations consisted of the doctor’s office desk and two upholstered office chairs.

Agent Breeden explained that during this initial visit, he and Dr. Pettinger spoke for quite a while about the use of cannabis.<sup>59</sup> He said at one point in the meeting, Dr. Pettinger did conduct a very brief physical examination, one that lasted “a couple of minutes” and consisted of Dr. Pettinger asking “a dozen or two health history questions very quickly” and then feeling

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<sup>58</sup> Tr. at 127.

<sup>59</sup> Id.

along his spine, and took a reading of his blood pressure.<sup>60</sup> Although Agent Breeden complained of knee pain on his patient questionnaire,<sup>61</sup> Agent Breeden expressly denied that Dr. Pettinger ever actually saw either of his knees – as he never removed his pants during this office visit.<sup>62</sup> He said the only other physical contact with Dr. Pettinger came in the form of frisking the agent: “he patted me down. I think in my report at the time I thought he was patting me down for a weapon. He didn’t focus on the knee. It was basically like a frisk like a law enforcement officer would do.”<sup>63</sup>

The recording of this office visit confirms the substance of Agent Breeden’s testimony: Dr. Pettinger spent a substantial percentage of this visit discussing how cannabis can be used medicinally. Although Agent Breeden told Dr. Pettinger he was experiencing knee pain, this subject did not come up in the conversation until 59 minutes had passed, and even then the topic was only briefly addressed by Dr. Pettinger. There is no evidence suggesting that Dr. Pettinger palpated the knee, checked for range of motion, or in any other way examined either of Agent Breeden’s knees during this visit. Agent Breeden testified that at no time did Dr. Pettinger actually look at his knees.<sup>64</sup>

Further, although the initial prescription written by Dr. Pettinger based on this visit including both oxycodone and cough syrup with promethazine and codeine, there is nothing in this record indicating the patient was experiencing a cough or needed cough syrup. In addition, the “For Physician’s Use Only” notes for the initial visit reflect clear respiration and full range of motion in the musculoskeletal system, indicating no medical basis for prescribing either pain

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<sup>60</sup> Id. at 127-8.

<sup>61</sup> Government Exhibit 25 at 3.

<sup>62</sup> Tr. at 162-3.

<sup>63</sup> Id. at 163.

<sup>64</sup> Id. at 133.

medication or a cough suppressant.<sup>65</sup> The record does show that in the medical records he presented to Dr. Pettinger, Mr. Daly reportedly had told a Dr. Fazeri that he was experiencing esophageal problems, as a basis for obtaining cough syrup.<sup>66</sup> There is, however, no evidence indicating there were any complaints of cough presented during this initial meeting with Dr. Pettinger.

Further, the record shows Agent Breeden mentioned having been treated for a possible plantar wart, which Dr. Pettinger agreed could result in back or knee problems.<sup>67</sup> There is, however, no evidence in the Daly records or in the patient interview by Dr. Pettinger establishing the patient actually had back problems – whether caused by plantar warts or by any other condition.

Agent Breeden was asked about the use of an MRI report in support of his request for pain medication. He said the MRI report is genuine and was based on an MRI he had taken at the Open Advantage MRI company, although instead of having his own name on the original report he altered it so that it appeared to refer to the fictitious Dan Daly.<sup>68</sup> He said he did not actually have anything wrong with his knees, but that the results indicated he had a medial meniscus tear – something he was not aware of, but later learned that “if you take anybody over the age of 30 almost all of them are going to have a torn meniscus.”<sup>69</sup> He testified that during the initial visit he presented this altered report to Dr. Pettinger, who received it and noted its receipt in the physician’s note page (Government Exhibit 25, page 6).<sup>70</sup> Agent Breeden stated that at the start of each of the three subsequent visits to Dr. Pettinger’s office, he was asked to produce the MRI,

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<sup>65</sup> Government Exhibit 25 at 6.

<sup>66</sup> Tr. at 155.

<sup>67</sup> Id.

<sup>68</sup> Id. at 164.

<sup>69</sup> Id. at 166.

<sup>70</sup> Tr. at 133.

suggesting that the office had lost or misplaced the report.<sup>71</sup> Notwithstanding the fact that the MRI was not found in these records, Dr. Pettinger proceeded to prescribe oxycodone to Agent Breeden after each office visit.

During cross examination, Agent Breeden was asked whether he had deliberately attempted to divert attention during the initial office visit with Dr. Pettinger, out of a concern that “the record was starting to show that Dr. Pettinger was genuinely trying to give you medical treatment[.]”<sup>72</sup> That does not, however, appear to be the case. In my review of the record and after listening to all of the audio recordings and watching all of the video recordings, I found the more persistent pattern was that Dr. Pettinger paused for significant periods of time during all of his patient visits, that he tended to speak slowly, quietly, and with deliberation; that the pauses were sometimes prompted by his need to write down observations or other notes in the patient medical files; and that the patients (not just Agent Breeden, but all of the undercover investigators) filled in these gaps by chatting with the doctor, typically discussing extraneous matters to which Dr. Pettinger had earlier referred. Examples of these include Dr. Pettinger’s repeated references to notable football coaches Sandusky and Paterno; his description of using tinctures as a way of ingesting concentrated forms of cannabis; and the negative and hostile feelings he was experiencing after finding that someone had stolen the catalytic converter off of his car.

I cannot conclude that the conversations engaged in by these agents were designed to divert Dr. Pettinger’s attention or keep him from performing a proper, adequate physical examination. To the contrary, most of the extraneous dialogue recorded here was occasioned by

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<sup>71</sup> Id.

<sup>72</sup> Id. at 156.

Dr. Pettinger himself. The record does, however, make it clear that each of the undercover agents tried to act like drug-seeking patients – a point Agent Breeden acknowledged in cross examination.<sup>73</sup>

The record reflects that Agent Breeden’s second visit to Dr. Pettinger’s Watt Avenue office on December 6, 2011 was substantially the same as the first visit.<sup>74</sup> Notable in this context is the absence of evidence demonstrating that Dr. Pettinger performed any kind of physical examination of Agent Breeden’s knee prior to Dr. Pettinger writing a prescription for oxycodone, and that most of the examination was spent discussing the medicinal use of cannabis. Agent Breeden stated that Dr. Pettinger asked no questions about his pain level, made no attempt to palpate Agent Breeden’s knee, “did a quick palpation of my abdomen,” measured his blood pressure, and then ended the exam.<sup>75</sup> Also notable was that at this meeting, after discussing the versatility of cannabis for medicinal purposes, Dr. Pettinger issued a prescription for Marinol as a means for justifying the presence of the active ingredients in cannabis in Agent Breeden’s bloodstream, should he ever have to submit to urinalysis or other drug screening after consuming products containing cannabis.<sup>76</sup>

HHS Special Agent David Kvach accompanied Agent Breeden on his second visit to Dr. Pettinger’s office. Agent Kvach has been a Special Agent for HHS since 2006. He has been trained at the Federal Law Enforcement Center and completed the Inspector General’s investigative training course.<sup>77</sup> In 2008 he also completed the internal special agent course provided by HHS; he completed electronics and technical surveillance training in 2009; he

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<sup>73</sup> Id. at 157.

<sup>74</sup> Id. at 134-6 and Government Exhibit 7.

<sup>75</sup> Id. at 138.

<sup>76</sup> Id. at 137.

<sup>77</sup> Id. at 178.

completed advanced undercover and survival techniques training in 2010; he completed undercover school in 2012; and he completed training in the narcotics, vice, and street crimes supervisor course in 2013.

In many respects, his initial visit to Dr. Pettinger's office resembled that of Agent Breeden. Using audio recording equipment and under the assumed name of Alex Gonza, Agent Kvach presented as a patient seeking medication for back pain.<sup>78</sup> Agent Kvach identified Respondent's Exhibit C, pages 3 through 7, as forms he filled out at this first visit.<sup>79</sup> The recording revealed a meeting that lasted more than an hour, although here again, as was the case with the initial meeting between Agent Breeden and Dr. Pettinger, most of the time was spent discussing medicinal uses of cannabis.<sup>80</sup> Agent Kvach described meeting with Dr. Pettinger after filling out some parts of these forms, and stated parts of the forms he left blank had later been filled in, although he could not say by whom.<sup>81</sup> In both Agents Breeden's and Kvach's reports, they noted that although they left unanswered those questions regarding cannabis use, the forms now show someone (presumably Dr. Pettinger) filled in answers to these questions, presumably based on what was discussed during these initial visits – although I find this was not always the case, and find substantial evidence that Dr. Pettinger included complaints and diagnoses (including insomnia and back pain) that were never raised by the undercover agents or that were flatly denied by the agents.

Agent Kvach confirmed Agent Breeden's description of Dr. Pettinger's office, noting the absence of an examination table and the very limited amount of examination equipment, which

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<sup>78</sup> Id. at 181.

<sup>79</sup> Id. at 182.

<sup>80</sup> Government Exhibit 9, audio recording and transcript.

<sup>81</sup> Tr. at 183-4.

included a blood pressure cuff and a stethoscope, and little else.<sup>82</sup> Unlike Agent Breeden, Agent Kvach brought no medical records with him for this first visit.<sup>83</sup> Agent Kvach noted that Dr. Pettinger wrote on the patient history form that the patient “will be bringing MRI,” but that never actually happened.<sup>84</sup> He explained further, on cross examination, that while Dr. Pettinger did not seek any x-rays, he did ask Agent Kvach to obtain an MRI report: “He informed me that even if the MRI read out normal, he needed my MRI.”<sup>85</sup>

Agent Kvach described Dr. Pettinger’s examination as “a cursory check” that included taking his blood pressure and putting a stethoscope under the agent’s jacket, possibly to listen to his heart and lungs.<sup>86</sup> After this examination, Dr. Pettinger recommended medical marijuana and issued Agent Kvach a prescription for 120 units of oxycodone 30 mg IR, dated December 6, 2011.<sup>87</sup>

Agent Breeden returned for a third visit to Dr. Pettinger’s office on January 13, 2012, the substance of which was recorded by audio recording and is transcribed at Government Exhibit 11. I would note that the first 38 minutes of this recording have not been transcribed. From my review of the audio recording, I understand that this part of the recording was not transcribed because it represents the time Agent Breeden was in Dr. Pettinger’s waiting room, waiting for his appointment with Dr. Pettinger. The discussion recorded on the audio disc but not transcribed appears to be between Agent Breeden and Sean Ledford, the receptionist working in Dr. Pettinger’s office. As Agent Breeden correctly stated, all interactions between himself and Dr.

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<sup>82</sup> Id. at 185.

<sup>83</sup> Id. at 187.

<sup>84</sup> Id.

<sup>85</sup> Id. at 201.

<sup>86</sup> Id. at 185-6.

<sup>87</sup> Id. and Government Exhibit 8.

Pettinger have been transcribed.<sup>88</sup> Having listened to the discussion between Agent Breeden and Mr. Ledford, I note only that while the exchanges between Agent Breeden and Mr. Ledford have not been included in the written transcript, their absence is not legally significant.

During this third visit, Agent Breeden introduced Dr. Pettinger to DEA Special Agent Daniel Patrick Moriarty, who was using the fictional name of Jason Kelly.<sup>89</sup> Agent Moriarty has worked as a DEA Special Agent since 2004. He completed basic and advanced training at Quantico, Virginia, on subjects including firearms and enforcing narcotics laws.<sup>90</sup> He testified about the one visit he made to Dr. Pettinger's office on January 13, 2012, and identified the video recording and transcript of that visit.<sup>91</sup>

Agent Moriarty testified that he presented to Dr. Pettinger as a patient seeking medication for pain relating to "knee issues."<sup>92</sup> Agent Moriarty said he presented the same MRI report that Agent Breeden had presented at his initial visit with Dr. Pettinger (save for the fact that when Agent Moriarty presented it, the document had been altered using Photoshop to show the name of Jason Kelly instead of Dan Daly).<sup>93</sup> Agent Moriarty identified pages 2 through 6 of Respondent's Exhibit D as the questionnaire he filled out at his visit to Dr. Pettinger's office.<sup>94</sup> As was the case with Agents Breeden and Kvach, Agent Moriarty described filling out parts of these forms, and later finding answers that he himself did not provide – including a claim of

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<sup>88</sup> Id. at 141.

<sup>89</sup> Id. at 146, 241.

<sup>90</sup> Id. at 241.

<sup>91</sup> Id. at 242 and Government Exhibit 13.

<sup>92</sup> Tr. at 247.

<sup>93</sup> Id. at 248, 276.

<sup>94</sup> Id. at 269.

insomnia, which he stated he did not make either when filling out the form or during the patient interview that followed.<sup>95</sup>

Agent Moriarty described his initial visit with Dr. Pettinger in terms similar to those presented by Agents Breeden and Kvach. He said Dr. Pettinger's exam included taking his blood pressure and pulse, and that he then "walked around his desk to where I was seated and kind of I guess pushed my shoulders or touched my shoulders. He had a reflex tool and tapped each knee. That's kind of it. I think he looked in my ears."<sup>96</sup> He said the entire exam was performed while he was seated in the office chair next to the doctor's desk, and that the doctor never required the agent to remove his jeans in the course of this exam.<sup>97</sup> Based on this examination, Agent Moriarty was able to obtain a prescription for 180 units of oxycodone 30 mg IR.<sup>98</sup>

Agent Kvach returned to Dr. Pettinger's office on January 24, 2012, for a second visit, this time accompanied by FBI Special Agent Neeki Bianchi.<sup>99</sup> Agent Bianchi has been a Special Agent with the FBI for nine years.<sup>100</sup> She stated that during this service, she trained for four months in Quantico, Virginia, and has subsequently been trained in counterterrorism, healthcare fraud, and undercover operations.<sup>101</sup> She said she made one undercover visit to Dr. Pettinger's office using the name Nicole Hancock, and identified Government Exhibit 17 as a video recording and transcript of that visit.<sup>102</sup>

According to Agent Bianchi, she and HHS Special Agent Kvach represented to be boyfriend and girlfriend for this visit and met jointly with Dr. Pettinger, with Agent Kvach

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<sup>95</sup> Id. at 270.

<sup>96</sup> Id. at 271.

<sup>97</sup> Id. at 272.

<sup>98</sup> Id. at 273 and Government Exhibit 12.

<sup>99</sup> Tr. at 189.

<sup>100</sup> Id. at 221.

<sup>101</sup> Id.

<sup>102</sup> Id. at 222, 224.

returning in his role as Alex Gonza.<sup>103</sup> Both Agent Bianchi and Agent Kvach recorded this meeting, although for approximately ten minutes Agent Kvach absented himself from the office visit so that he could use the men's restroom and smoke a cigarette. Regrettably, both of those events are part of the video recording offered by the Government as Exhibit 15, although they lend no substance to this report. On the other hand, the recording created by Agent Bianchi (found at Government Exhibit 17) captured without interruption the entire office visit she and Agent Kvach had with Dr. Pettinger on January 24, 2012.

In her testimony, Agent Bianchi summarized her meeting with Dr. Pettinger. She recalled telling Dr. Pettinger she used cannabis recreationally, but that she was meeting with him in order to get a prescription for pain medication.<sup>104</sup> During the joint interview, Agent Kvach in his role as Alex Gonza told Dr. Pettinger that Ms. Hancock had been using his oxycodone, and Agent Bianchi did not dispute this, but instead stated she was there to obtain an oxycodone prescription for her own use.<sup>105</sup> When Dr. Pettinger asked whether she was experiencing pain, she said no; and she gave the same answer when he asked whether she was having difficulty sleeping.<sup>106</sup> When he asked why she needed pain medication, Agent Bianchi responded by saying the medication makes her talkative and happy.<sup>107</sup> In response, Dr. Pettinger told Agent Bianchi that in order to obtain a prescription for oxycodone, she would need to arrange to have an MRI taken and have the results filed with his office.<sup>108</sup> When Agent Bianchi asked Dr. Pettinger how to go about getting an MRI, specifically asking him what kind of pain she needed to report in order to justify getting an MRI that would serve this purpose, Dr. Pettinger told her to report pain in her

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<sup>103</sup> Id. at 224.

<sup>104</sup> Id. at 225 and Government Exhibit 17.

<sup>105</sup> Tr. at 225.

<sup>106</sup> Id. at 226-7 and Government Exhibit 17.

<sup>107</sup> Tr. at 226 and Government Exhibit 17.

<sup>108</sup> Tr. at 226.

back that radiates down to her leg.<sup>109</sup> Before ending this office visit, Dr. Pettinger checked Agent Bianchi's blood pressure and "ran his hand from [her] lower back to [her] upper back[.]"<sup>110</sup> At that point, Dr. Pettinger wrote a prescription authorizing an MRI, recommended her for medical marijuana, and issued a prescription for 90 units of oxycodone 30 mg IR.<sup>111</sup>

As was the case when Agents Breeden and Kvach first met with Dr. Pettinger, Agent Bianchi testified that although she left many of the questions unanswered in the initial patient questionnaire, Dr. Pettinger appears to have filled in answers that had been left blank – in any event, the agent stated she herself did not answer these questions, and assumed the answers were written in by Dr. Pettinger. She expressly denied any complaint of insomnia or back pain, although these ailments were listed as medical complaints in her patient questionnaire.<sup>112</sup>

DEA Special Agent Babak Ghazanfari testified about his visit to Dr. Pettinger's office. Agent Ghazanfari has worked for the DEA for approximately five years, and is currently assigned to the Tactical Diversion Squad in the Sacramento District Office.<sup>113</sup> His training includes completion of approximately nineteen weeks of training at the Justice Training Center in Quantico, Virginia on all aspects of drug enforcement, including surveillance techniques, defensive tactics, and arrest procedures.<sup>114</sup>

Agent Ghazanfari said he went to Dr. Pettinger's Modesto, California office on March 20, 2012, and identified Government Exhibit 20 as the audiovisual recording of that visit. Using the fictional name of Reza Babak Soltani, Agent Ghazanfari completed the patient questionnaire

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<sup>109</sup> Id.

<sup>110</sup> Id.

<sup>111</sup> Id. at 227 and Government Exhibit 16 at 1-2, Government Exhibit 26 at 8-9.

<sup>112</sup> Tr. at 230 and Government Exhibit 17.

<sup>113</sup> Tr. at 279.

<sup>114</sup> Id.

shown in Government Exhibit 27, and met with Dr. Pettinger shortly thereafter.<sup>115</sup> Agent Ghazanfari testified that although Dr. Pettinger’s physician notes indicate a complaint of left knee pain, the agent never made any such complaint to Dr. Pettinger – a point that is confirmed by the recording made during this office visit. To the contrary, when Dr. Pettinger asked “so the knee is what’s bothering you?” Agent Ghazanfari responded “well, used to, used to” and when the doctor followed that with “so the weather gets to you a little bit with it?” the agent responded “nah, it’s not really bothering me all that much.”<sup>116</sup>

The record establishes that Nikki, who was Dr. Pettinger’s assistant at the Modesto office, took Agent Ghazanfari’s blood pressure,<sup>117</sup> and Dr. Pettinger himself used an otoscope to examine the agent’s ears, and used a stethoscope to examine heart and lung sounds.<sup>118</sup> According to Agent Ghazanfari, Dr. Pettinger conducted “a patdown, touched certain parts of my body, rubbed my neck, kind of felt around me, tapped on my knees a little bit, and then he put his stethoscope up to my heart or the area of my heart and began to tell me that I had some irregular heart beat or something to that effect,” all while the agent remained seated.<sup>119</sup> Dr. Pettinger also had the MRI Agent Breeden referred to, this time altered to reflect that it referred to Reza Soltani.<sup>120</sup> When Dr. Pettinger inquired about the medication Agent Ghazanfari was currently taking, he responded by saying he was taking Percocets, Norcos, and oxys, and that “oxys are the ones that do it for me,” but that he was obtaining them from the street, not through any valid

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<sup>115</sup> Id. at 284.

<sup>116</sup> Government Exhibit 20, audio-video recording and transcript at 7.

<sup>117</sup> Tr. at 286.

<sup>118</sup> Government Exhibit 20, audio-video recording and transcript at 17.

<sup>119</sup> Tr. at 288.

<sup>120</sup> Tr. at 285.

prescriptions.<sup>121</sup> At the conclusion of this meeting, Dr. Pettinger presented the agent with a prescription for 150 units of oxycodone 30 mg IR.<sup>122</sup>

Agent Breeden made one final visit to Dr. Pettinger's office, on May 9, 2012.<sup>123</sup> During this visit, much of the time the doctor spent with Agent Breeden was dedicated to discussing problems Dr. Pettinger was having with pharmacists, who were starting to reject his prescriptions.<sup>124</sup> Dr. Pettinger made the point that he "wrote more prescriptions [for oxycodone] than 50 doctors combined," and was irritated by questions presented to him by pharmacists, some of which arose because his first name is Clair, which leads on occasion to uncertainty about whether the prescribing doctor is male or female, resulting in a lot of unnecessary questions.<sup>125</sup>

Agent Breeden described Dr. Pettinger performing a medical exam that was similar to previous exams, in that it was short and involved only a blood pressure check and stethoscope monitoring of the chest area.<sup>126</sup> At one point in this meeting, Agent Breeden told Dr. Pettinger that he had used some of the prior oxycodone prescription to "pay back" a third person, at which point Dr. Pettinger told him that he would not continue to issue prescriptions for oxycodone if the patient was selling or giving pills away.<sup>127</sup> When Agent Breeden assured Dr. Pettinger he would no longer give away or sell his pills, Dr. Pettinger wrote a prescription for 220 units of oxycodone 30 mg IR.<sup>128</sup>

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<sup>121</sup> Id. at 292 and Government Exhibit 20, audio-video recording and transcript at 12.

<sup>122</sup> Tr. at 289 and Government Exhibit 19.

<sup>123</sup> Tr. at 147.

<sup>124</sup> Id. at 149 and Government Exhibit 22.

<sup>125</sup> Id.

<sup>126</sup> Id.

<sup>127</sup> Id.

<sup>128</sup> Tr. at 150 and Government Exhibit 21.

When asked on cross-examination whether he ever felt in danger while in Dr. Pettinger's presence, Agent Breeden said he did indeed feel in danger, noting first that the doctor told him he possessed a .357 handgun and hollow point bullets, and then noting the doctor's agitation when describing how he would use the weapon.<sup>129</sup>

### **Testimony from the Government's Expert Medical Witness**

The Government's expert witness was Barbara Neyhart, M.D. Dr. Neyhart has been a physician for 35 years, and currently works at the University of California – Davis Medical Center.<sup>130</sup> After completing medical school at Rush Medical College in Chicago, Dr. Neyhart completed residencies in internal medicine and family medicine, and has been a clinical professor at the School of Medicine at the University of California – Davis since 1984.<sup>131</sup> She also maintained a family medical practice in both office and clinical settings.<sup>132</sup> Through this course of practice, Dr. Neyhart has often encountered drug-seeking patients as well as patients with legitimate chronic pain symptoms.<sup>133</sup> She has experience treating persons with chronic pain and with prescribing medication for persons with chronic pain.<sup>134</sup> She has provided medical testimony as an expert for the Licensing Division of the State of California for more than ten years, and was a general medical consultant for the Division prior to her service as an expert.<sup>135</sup> In order to prepare for this hearing, Dr. Neyhart read the exhibits presented to her, and reviewed the recordings that are part of our record, spending approximately 16 hours doing so.<sup>136</sup>

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<sup>129</sup> Tr. at 153.

<sup>130</sup> Id. at 312.

<sup>131</sup> Id. at 314.

<sup>132</sup> Id.

<sup>133</sup> Id. at 314-5.

<sup>134</sup> Id. at 315.

<sup>135</sup> Id. at 316.

<sup>136</sup> Id. at 451-2.

After presenting her curriculum vitae (Government Exhibit 28), the Government offered Dr. Neyhart as an expert medical witness in the standard of care for patients with pain complaints who are being treated by general practitioners.<sup>137</sup> During voir dire of the witness, Respondent's counsel established that Dr. Neyhart believes she is "no less [an expert in pain management medicine] than [Dr. Pettinger]."<sup>138</sup> She stated that while she has not testified in medical board cases that focus on the long-term use of opiates for the management of chronic non-cancer pain, she has reviewed such cases.<sup>139</sup> The record shows that Dr. Neyhart currently staffs the Breast Health Clinic, serving women who have recently been diagnosed with a newly manifested breast mass, a position that does not call upon her to decide whether or not to embark on long-term opioid therapy.<sup>140</sup> That being said, however, she stated in the last five years she has been called upon to decide whether to embark on long-term opioid therapy for non-cancer pain between one and five times a week, until she took her most recent position eighteen months ago.<sup>141</sup>

Dr. Neyhart said within the subset of cases where she was called upon to make such determinations, she has prescribed oxycodone possibly one or two times weekly.<sup>142</sup> As such, Dr. Neyhart established she had significant clinical experience treating persons with chronic pain, including experience using oxycodone in those treatment plans. Based on the answers provided during this part of the examination, the Respondent made no objection to my finding Dr. Neyhart to be an expert, asking only that the limitations presented during voir dire be taken into account

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<sup>137</sup> Id. at 317.

<sup>138</sup> Id. at 318.

<sup>139</sup> Id. at 320.

<sup>140</sup> Id. at 321.

<sup>141</sup> Id. at 322.

<sup>142</sup> Id. at 323.

when weighing any opinions rendered by the witness.<sup>143</sup> As a result, I granted the Government's motion to have Dr. Neyhart regarded as a medical expert, under the scope presented by the Government.<sup>144</sup>

Dr. Neyhart began by describing in general terms what the standard of care calls for when a patient presents with a complaint of pain. In these cases, the physician must take a complete medical history with respect to the pain complaint, including “when did it start; was there a trauma that caused this to start; what is the degree of pain that is currently being suffered.”<sup>145</sup> She noted that doctors will sometimes use a numeric scale of one to ten when questioning about the degree of pain at issue.<sup>146</sup> Beyond these metrics, Dr. Neyhart said the history must also include information about the character of the pain (sharp or dull); the frequency of the pain (constant, periodic, or intermittent); the degree of interference with day-to-day activities and with the ability to seek gainful employment and engage in intimate and non-intimate relationships; and whether there is a psychological impact occasioned by the pain. She said the doctor also needs to inquire about the different modalities of relief sought to date: what have other doctors said and done, what surgeries have been proposed, and what physical therapy has been undertaken?<sup>147</sup> Equally important, according to Dr. Neyhart, is the history of medications used thus far: what medications were used, were the medications effective, were there side effects of note?<sup>148</sup>

Dr. Neyhart examined the patient questionnaires presented in the exhibits. She noted that generally, the patient questionnaires she encounters do not call for the prospective patient to disclose whether he or she is a law enforcement officer, and she saw no reason to inquire about

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<sup>143</sup> Id. at 324.

<sup>144</sup> Id. at 325.

<sup>145</sup> Id.

<sup>146</sup> Id.

<sup>147</sup> Id. at 325-6.

<sup>148</sup> Id. at 326.

the birth order of the patient. Nevertheless, Dr. Neyhart did not describe these forms as deficient.<sup>149</sup> She acknowledged that the forms are designed for use in cases involving medicinal cannabis use under the California Compassionate Use Act, and stated she has testified in cannabis cases and found these forms to be similar to those she has seen in those cases, but that such forms would be considered nonstandard in the course of a family practice.<sup>150</sup>

Dr. Neyhart next examined the Physician Notes form found in these patient records, describing the form itself as “a fairly standard document on which a physician would record elements of the history that were not recorded in the questionnaire and also the objective physical exam findings.”<sup>151</sup> Each of these lines has a specific significance, according to Dr. Neyhart. She explained the role each plays in the examination, noting the significance of objective findings – findings not dependent on the stated history, but on objectively determined data. These include vital sign measurements – blood pressure, pulse rate, respiration rate, and weight.<sup>152</sup> They also include physical examination of the head, eyes, ears, nose and throat; the respiratory system including the lungs; the cardiovascular system including the heart and peripheral pulses; the abdomen, the musculoskeletal system, and the integumentary system (skin surfaces).<sup>153</sup>

According to Dr. Neyhart, the objective exam calls for the use of objective measurements: blood pressure would be taken by a standard blood pressure cuff; pulse counts would be taken by counting the pulse bounds; and weight would be taken by a scale.<sup>154</sup> She said

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<sup>149</sup> Id. at 326-7.

<sup>150</sup> Id. at 328.

<sup>151</sup> Id. at 329.

<sup>152</sup> Id. at 332-3.

<sup>153</sup> Id. at 333-4.

<sup>154</sup> Id. at 334.

that a cursory exam could be taken in as little as five minutes, while a more thorough exam could take as long as half an hour.<sup>155</sup>

Next on the form is “Impression,” which affords the physician an opportunity to take the history and physical exam information and render a diagnosis or, more commonly, a range of diagnoses.<sup>156</sup> Thus, an impression is not a recapitulation of the chief complaint – instead, it is the result of the physician digesting both the subjective history and objective facts, resulting in a diagnosis.<sup>157</sup> Later, Dr. Neyhart explained that “[t]he ‘chief complaint’ is really and truly what the patient says. It’s not what is determined after an extensive history is taken. Most of the time actually the chief complaint is determined by a medical assistant, not by a highly trained clinical professional such as a physician.”<sup>158</sup>

The Recommendation line provides a place for the physician to describe the plan for this patient: “so, for a complaint of pain . . . there are many ways to relieve pain. They can involve physical therapy. It can involve application of ice, the change in the activity that is causing the pain. There are many different things. But it can also involve the prescribing of therapeutics and there is a range of therapeutics that can be prescribed.”<sup>159</sup>

Addressing next the records she reviewed, Dr. Neyhart said she read the patient records and listened to and watched the recordings obtained by the undercover agents in preparation for her testimony. Based on this, Dr. Neyhart was asked a series of questions about the events depicted in these recordings.

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<sup>155</sup> Id.

<sup>156</sup> Id. at 334.

<sup>157</sup> Id. at 335.

<sup>158</sup> Id. at 432.

<sup>159</sup> Id. at 336.

In her review of the first visit by Agent Breeden to Dr. Pettinger's office, Dr. Neyhart noted first the language used by the agent in offering his MRI to Dr. Pettinger. She observed that in a "standard medical visit," a patient would offer a complaint of pain, saying something like "I hurt my knee," whereas here, the agent said words to the effect that he was giving the doctor a copy of his MRI because "I knew you needed something for your records."<sup>160</sup> Dr. Neyhart explained that ordinarily a history of present illness "would tend to go along the lines of 'Have you had any previous testing? May I review that previous testing so I can use it in the course of formulating the diagnosis?' Not in order of justifying a later prescription."<sup>161</sup>

Dr. Neyhart next considered Agent Breeden's discussion with Dr. Pettinger regarding sleep. She described sleep difficulty as "a very common complaint," and one that "doesn't really stand out as a unique thing."<sup>162</sup> According to Dr. Neyhart, if sleep disorder is a "dominant complaint, a physician operating within the standard of care would inquire [in] more detail what strategies had been employed by this individual to solve their sleep problems that did not involve the use of medication."<sup>163</sup> This would include questions such as "[d]o they calm down at the end of the day? Do they not eat huge meals at the end of the day? Alcohol commonly can interfere with sleep, and [the character Agent Breeden was playing] was of a misuser of alcohol. So alcohol would factor rather significantly into any inquiry into sleep."<sup>164</sup>

Dr. Neyhart next considered the colloquy between Agent Breeden and Dr. Pettinger regarding the putative patient's admission that he "basically uses whatever opioids he can get his hands on rather than a more systematic fashion as would customarily be used for somebody who

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<sup>160</sup> Id. at 336-7.

<sup>161</sup> Id. at 337.

<sup>162</sup> Id.

<sup>163</sup> Id. at 338.

<sup>164</sup> Id.

is under treatment for chronic pain condition.”<sup>165</sup> Such a patient presentation would, in Dr. Neyhart’s opinion, constitute a red flag for abuse.<sup>166</sup> She said another red flag arose when the agent was vague about treatment in the past, locations for such treatment, and providers of such treatment. She explained that such vagueness gives rise to a concern for doctor shopping.<sup>167</sup> Similarly, where the agent told Dr. Pettinger words to the effect that he could not recall whether he had knee pain or back pain, she was “not very clear from this exchange whether or not the pain is driving the clinical encounter or the desire for a preconceived prescriptive opioid is driving that encounter.”<sup>168</sup>

During the initial medical examination, Dr. Pettinger asked Agent Breeden if he had any of the following conditions: nosebleeds, sore throat, difficulty swallowing, respiratory problems, asthma, bronchitis, pneumonia, irregular heartbeat, chest pain, [something that was unintelligible], fever, scarlet fever, GI problems, nausea, vomiting, diarrhea, hepatitis, pancreatitis, urinary difficulties, kidney stones, or blood in the urine.<sup>169</sup> I listened to this recitation, and found it to be presented with such great speed and lack of interest as to be almost a sham. Dr. Neyhart was more charitable in her description, stating that, “I listened to this recording and what was impressive to me was how rapidly this particular array of symptoms was recited by Dr. Pettinger. I would not have been able to follow it myself, and I consider myself a person who is familiar with medical language.”<sup>170</sup> The words followed one to the next without pause and without distinction. As Dr. Neyhart explained, “[t]he standard practice would be to separate it out. Do you have any problems with your eyes, nose or throat? Pause for response. Do

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<sup>165</sup> Id.

<sup>166</sup> Id.

<sup>167</sup> Id. at 339.

<sup>168</sup> Id.

<sup>169</sup> Government Exhibit 5, recording and transcript at 33.

<sup>170</sup> Tr. at 340.

you have any problems with lumps or bumps in your neck or problems with your thyroid? Pause for response. Do you have any problems with breathing or shortness of breath or asthma or wheezing? Pause for response.”<sup>171</sup> Having listened to this presentation of symptoms, I too found Dr. Pettinger’s questions to have been perfunctorily presented in a manner not designed to elicit a meaningful response.

Next, Dr. Neyhart was asked about the exchange between Agent Breeden and Dr. Pettinger during which Dr. Pettinger asked whether the patient intended to grow cannabis. In response, the agent stated “um, probably not. Really, um, I just wanted to get, ah the – my meds; that’s the main thing I was trying, ‘cause we talked on the phone and you said, um, the discount.”<sup>172</sup> Dr. Neyhart stated that in this exchange, the agent “was really getting down to his agenda, and his agenda was to obtain a prescription.”<sup>173</sup> This, she said, would be “a red flag for most clinicians for a patient to come in with a complaint but really direct the encounter towards obtaining the specific remedy for the complaint, especially if said remedy is a controlled substance.”<sup>174</sup>

Dr. Neyhart next considered the exchange between Agent Breeden and Dr. Pettinger in which Dr. Pettinger asks “Okay. So basically you want to be given oxycodone?”<sup>175</sup> Dr. Neyhart explained that after listening to the audio recording and reading the transcript, “this seemed more of a business negotiation than a clinical encounter to me. A clinical encounter would be, ‘Let’s get back to your knee pain and what is the best way to relieve your knee pain.’ This . . . had more

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<sup>171</sup> Id.

<sup>172</sup> Government Exhibit 5, recording and transcript at 37.

<sup>173</sup> Tr. at 341.

<sup>174</sup> Id.

<sup>175</sup> Id. at 342, quoting Government Exhibit 5, at 41 (Dr. Pettinger: “ok so basically you want to end up getting the oxycodones. You want the IRs, the 30 IRs?” Agent Breeden: “ah yea.”)

of a flavor of, ‘So what is it that you want from me in terms of a prescription?’”<sup>176</sup> She expressed a similar concern regarding the exchange between Agent Breeden and Dr. Pettinger in which Dr. Pettinger explained that prescriptions for Norco could include refills, but those for oxycodone cannot. She said “[t]hat should not factor into the decision of what is the most appropriate treatment.”<sup>177</sup>

Dr. Neyhart was asked to offer her impressions about the responses found in the patient questionnaire for this encounter. One red flag, according to Dr. Neyhart, is that the patient indicates he works as a “tile man,” but after listening to the patient interview and exam, she said “nowhere is the information that I listened to or read was there any conversation about how his pain condition was interfering with his ability to be a tile man. It seems to me that it would be very hard to be a tile man if you had knee pain or back pain.”<sup>178</sup> In addition, Dr. Neyhart observed that while the patient reported drinking ten drinks per week, and while that amount itself is not excessive, the character being portrayed by Agent Breeden “disclosed that there was a much greater use of alcohol” than was reported in the questionnaire.<sup>179</sup> Elaborating on this point, Dr. Neyhart said that if a patient presented to her in her office holding a bottle of alcohol, as was the case with Agent Breeden, this would have caused a concern on her part, “because that is so inappropriate . . . in the middle of a clinical encounter.”<sup>180</sup> She also noted that the patient (on page five of the questionnaire) reported “an array of different opioid medications that are listed as presently using,” but that the patient “had purportedly not seen a physician since his days in Florida except for perhaps one encounter with a physician in Sonoma County. So there is

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<sup>176</sup> Tr. at 342.

<sup>177</sup> Id. at 343.

<sup>178</sup> Id.

<sup>179</sup> Id.

<sup>180</sup> Id. at 346.

an inconsistency about how these substances would have been obtained in the course of a legitimate medical encounter.”<sup>181</sup>

Dr. Neyhart next described her impressions of the physician notes found on page six of this patient’s records. She identified several areas of concern:

[T]he first thing that stood out for me is there is really not much detail with regard to the history of present illness recorded there. There is no indication about how long knee pain has been present, no indication of whether or not other modalities of treatment have been employed or prior imaging or prior consultations. There’s just not a lot of detail. I don’t get the idea from what is recorded there, nor did I get any impression from the transcript or the recording of the degree of pain that was being suffered on a scale of one to ten, or even using such words as mild, moderate or severe. None of that language was employed. I also don’t get an impression from this form of whether or not there is periodicity to the pain or an intermittent nature to the pain, or how it is interfering with occupational work. I mean, it’s just not there. The next thing that came up for me on this is that the weight is recorded, and my understanding was that there was not a scale in Dr. Pettinger’s office because there is much interchange about what is your weight, and then Dr. Pettinger would record whatever number the agent posing as a patient would state. So the weight as recorded here, it is implied that it was actually objectively determined, but actually it wasn’t. It was actually a piece of history and . . . in the customary course of medical practice you might write up under review of systems ‘Patient states weight is X’.

The next thing that shows up for me is a very detailed examination of the HEENT, although that was not really relevant to the pain complaint, and a very non-detailed examination of the musculoskeletal system, although that was quite relevant to the pain complaint, the pain complaint being knee pain. One would customarily expect to see a highly detailed knee examination and an examination of the joints on either side of the knee, that being the ankle and the hip. With a complaint of back pain, there would be a full examination of the back, and that would involve a palpitation of [the] entire spine by range of motion of the entire spine, [the] integrity of the nerve roots emanating from the spine. These are not evaluations that can be made in a fully clothed patient seated on a standard chair,

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<sup>181</sup> *Id.* at 344.

and it was my impression of little snippets of video that I was able to see that there was no exam table in Dr. Pettinger's office, nor were the characters asked to remove their clothing.<sup>182</sup>

Dr. Neyhart was asked considering the recording and transcript, and considering the medical records presented regarding this encounter, whether (in her expert opinion) the issuance of prescription medications recorded here was legitimate. In response, Dr. Neyhart stated "there is no evidence that this prescription was provided in the course of usual medical care for a pain condition."<sup>183</sup> She explained that "[t]he agent comes to Dr. Pettinger with a complaint of pain. There was a very limited history taken pertaining to the pain complaint. There was no examination that I could see, that I could discern was done in the area of the pain complaint. Thus, no diagnosis could be rendered beyond 'patient states pain.' While 'patient states pain' is commonly the case, there are many ways to address a complaint of pain that do not involve the prescribing of controlled substances."<sup>184</sup>

In her evaluation of each of the other patient encounters presented her, Dr. Neyhart found similar areas of concern. These included:

- Prescribing a synthetic form of cannabis (Marinol) not for treatment purposes but to help the patient (Agent Breeden) avoid problems with employers or law enforcement personnel;<sup>185</sup>
- Failing to maintain control over the MRI provided by Agent Breeden, and failure to request a replacement copy during the course of his treatment;<sup>186</sup>

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<sup>182</sup> Id. at 344-6.

<sup>183</sup> Id. at 347.

<sup>184</sup> Id.

<sup>185</sup> Id. at 349.

<sup>186</sup> Id.

- Failing to adequately inquire in follow up visits, to determine whether prescribed medications worked as intended and whether they caused any adverse reactions for the patient (Agent Breeden);<sup>187</sup>
- Describing in written physician’s records a “quite extensive” physical examination, where the actual time that elapsed (as revealed in the audio recording) “was very, very brief, so it’s impossible . . . to imagine how such a complete physical examination had been performed”;<sup>188</sup>
- Failing to resolve inconsistency in Agent Breeden’s report that he was working out and running on the one hand, with his complaint of knee pain on the other hand;<sup>189</sup>
- Failing to address information provided by Agent Breeden that he diverted some of the previously prescribed units of oxycodone for profit or to pay off a debt;<sup>190</sup>
- Failing to address red flags associated with self-reported substance abuse in a patient (Agent Kvach) presented to Dr. Pettinger for the purpose of obtaining controlled substances for a third person;<sup>191</sup>
- Failing to inquire further regarding prior prescriptions that had been issued to a patient (Agent Kvach) outside of the course of a medical encounter;<sup>192</sup>
- Failing to resolve the red flag that arose when a patient asked for a particular prescription by brand name, by milligram amount, and by quantity (Agent Kvach);<sup>193</sup>
- Requesting that a patient (Agent Kvach) obtain an MRI not to address or relieve suffering, but so that the doctor can justify providing the patient with the prescription being sought by the patient, and negotiating with the patient by offering to continue prescribing or increase the amount of controlled substances prescribed, provided the patient produces an MRI;<sup>194</sup>
- Failing to resolve the red flag that arose when a patient (Agent Kvach) was vague about the amount of medication prescribed and taken in the past, in order to determine the medical validity of past use of controlled substances;<sup>195</sup>
- Failing to obtain a sufficient medical history of treatment for back pain in a patient (Agent Kvach);<sup>196</sup>

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<sup>187</sup> Id. at 353.

<sup>188</sup> Id.

<sup>189</sup> Id. at 355.

<sup>190</sup> Id. at 356.

<sup>191</sup> Id. at 363.

<sup>192</sup> Id. at 364.

<sup>193</sup> Id. at 366.

<sup>194</sup> Id. at 366-8.

<sup>195</sup> Id. at 367.

- Failing to examine the specific area in issue, failure to render a specific diagnosis, failure to inquire about alternative treatments, and representing to perform a complete physical examination during a time that was too short to permit such an exam of a patient (Agent Kvach);<sup>197</sup>
- Prescribing pain medication under conditions where the patient (Agent Bianchi) reported having no pain symptoms, under conditions where it was clear the patient intended to use the medication recreationally;<sup>198</sup>
- Failing to resolve medical concerns with a patient’s possible substance abuse through the recreational use of cannabis, prior to prescribing pain medication for the patient (Agent Bianchi and Agent Ghazanfari);<sup>199</sup>
- Failing to resolve the red flag that arose when it appeared one patient (Agent Kvach) was sharing his controlled substance medication with another patient (Agent Bianchi), without any medical indication;<sup>200</sup>
- “Trolling for symptomatology,” by concluding a patient (Agent Bianchi) had anxiety based on the fact that she feels good when taking cannabis or oxycodone, in order to justify prescribing oxycodone, and suggesting the patient claim that she has pain radiating from her back to her leg, in order to justify obtaining an MRI that would then be used to justify prescribing pain medication;<sup>201</sup>
- Failing to resolve the red flag that arose when a patient (Agent Ghazanfari) who sought pain medication also abused alcohol;<sup>202</sup>
- Failing to resolve the red flag that arose when a patient seeking pain medication (Agent Ghazanfari) was vague about where and when he had knee surgery, vague about pain medication prescribed after that surgery, and suggested that the surgery was performed by his general practitioner;<sup>203</sup>
- Failing to resolve the red flag that arose when a patient (Agent Ghazanfari) acknowledged selling oxycodone, prior to issuing a prescription for the same;<sup>204</sup>
- Failing to include the examination of knees in the course of an examination based on a complaint of knee pain by a patient (Agent Ghazanfari);<sup>205</sup>

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<sup>196</sup> Id. at 368.

<sup>197</sup> Id. at 368-9, 372-3.

<sup>198</sup> Id. at 374-5, 377.

<sup>199</sup> Id. at 376-7, 406-7.

<sup>200</sup> Id. at 378.

<sup>201</sup> Id. at 378-81.

<sup>202</sup> Id. at 407, 409.

<sup>203</sup> Id. at 408-9.

<sup>204</sup> Id. at 411.

<sup>205</sup> Id. at 412.

- Concluding that a patient (Agent Ghazanfari) needed four oxycodone tablets daily, without first waiting for the patient to indicate what his past daily use had been, and then failing to resolve the red flag that arose when the patient stated that if the number was too high, he would be able to get rid of any excess units.<sup>206</sup>

Based on her review of each of these examination records, Dr. Neyhart expressed the expert medical opinion that the prescriptions for controlled substances reflected in this record were not rendered because of a determination of a legitimate medical condition.<sup>207</sup> In one instance, however, Dr. Neyhart stated that “an argument could have been made for the legitimacy” of the prescription. She explained that in the case of Dr. Pettinger’s treatment of Agent Moriarty (under the assumed name of Jason Kelly), she noted the agent’s character was “vague on the details” about past prescriptions and past treatment, both of which raised red flags the doctor should have resolved.<sup>208</sup> Dr. Pettinger noted that the past prescriptions for oxycodone appeared to be “out of proportion to the degree of disability it caused”.<sup>209</sup> Dr. Neyhart, however, described Dr. Pettinger’s questions along these lines to be generally sufficient: “It was a reasonable exchange and there was some vagueness in terms of how disabling this particular condition was, but it appeared that it had been going on for some time. History seemed reasonable, that the pain comes and goes, and that’s what happens with knee pain. It does come and go. This is all consistent with usual medical practice, this exchange.”<sup>210</sup>

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<sup>206</sup> Id. at 413.

<sup>207</sup> Id. at 354 (prescription at Government Exhibit 25 at 14); 357-8 (prescription at Government Exhibit 25 at 13); 361-2 (prescription at Government Exhibit 25 at 12); 369-70 (prescription at Government Exhibit 8); 372-3 (prescription at Government Exhibit 14); 385 (prescription at Respondent Exhibit B at 8); 406 (Government Exhibit 12); 414 (prescription at Government Exhibit 19).

<sup>208</sup> Id. at 402.

<sup>209</sup> Id. at 403.

<sup>210</sup> Id.

Left unclear, however, was whether there had been a specific injury, what kinds of diagnostics were utilized, what treatment modalities were tried, or why those modalities were changed.<sup>211</sup> Also of concern, according to Dr. Neyhart, was the “rapid-fire review” of possible medical conditions seen here, as in the other cases, and the fact that Dr. Pettinger prescribed oxycodone after recognizing that the patient’s use was “out of proportion to the amount of functional disability or pain that he was suffering.”<sup>212</sup>

Asked to summarize her findings, Dr. Neyhart stated that it was her expert opinion that in eight of the nine prescriptions, there was no medical indication that would support issuing those prescriptions, and that in the prescription issued to Agent Moriarty, this was a “soft call.”<sup>213</sup> She expanded on this during cross examination, stating that the agent “did present with a history that made sense. He presented with an MRI report that made sense relative to his history. He stated that he was using oxycodone for this medical condition. And so the holes in the Swiss cheese kind of lined up, and that’s what made it a softer call than, for instance, the agent who presented herself as Hancock.”<sup>214</sup> She also agreed that the fact that three of the agents all used the same MRI (save for altering the names thereon) would not be something a doctor would likely notice, and that if someone were to give her this MRI, she would likely be fooled into believing it was real.<sup>215</sup>

During cross examination, Dr. Neyhart agreed that a physician, when presented with Agent Moriarty’s claim that he took 180 oxycodone tablets a month, could reasonably believe such a statement; however, Dr. Neyhart stated that it would be “a big assumption” to assume

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<sup>211</sup> Id. at 404.

<sup>212</sup> Id. at 405-6.

<sup>213</sup> Id. at 415.

<sup>214</sup> Id. at 417.

<sup>215</sup> Id. at 418-9.

such a prescription was medically indicated, because in her experience “if somebody requires 180 oxycodone a month or more, there are more appropriate long-acting medications that could be used.”<sup>216</sup> When asked to address the premise that Dr. Pettinger was trying to “titrate down” this patient to where he used only 90 units a month, Dr. Neyhart stated there was no documentation in the medical record supporting such a premise – only documentation proposing “a future tapering. There is no agreement entered into between Dr. Pettinger and this patient. Thus it is impossible for me to conclude that this was step one of a plan.”<sup>217</sup>

Also on cross examination Dr. Neyhart agreed with the premise that, with some patients suffering from acute intractable pain, the patient will sometimes take medication that is not prescribed to them, and on occasion will get medication from relatives or others, without waiting for an appointment to see a doctor. She said such behavior is “not an all-in-all deal breaker, but it is a red flag.”<sup>218</sup> She also agreed with the premise that, after an initial diagnosis calling for pain medication is made, the failure to administer a physical exam in a follow up visit with the doctor is not in and of itself problematic, but here “[w]hat is problematic is the documentation of the physical exam that did not occur.”<sup>219</sup>

Dr. Neyhart said she has experience treating patients who exhibit drug-seeking behavior. She agreed that this population of patients will make a great effort to try to convince physicians to prescribe controlled substances, and will sometimes provide false information or vague answers when asked about their medical history.<sup>220</sup> In addition, while it is not a typical experience, Dr. Neyhart has had patients in this population attempt to divert her attention when

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<sup>216</sup> Id. at 423-4.

<sup>217</sup> Id. at 430.

<sup>218</sup> Id. at 435-6.

<sup>219</sup> Id. at 437.

<sup>220</sup> Id. at 444.

she was inquiring into the patient's medical history, to avoid answering the questions presented.<sup>221</sup>

### **Testimony by Dr. Pettinger and Evidence Regarding Remediation**

Dr. Pettinger testified briefly, on direct examination as a witness for the Government.<sup>222</sup> After responding to questions establishing his identity, Dr. Pettinger declined to answer questions regarding the substance of the charges against him, invoking the privilege against self-incrimination.<sup>223</sup>

On his own behalf, Dr. Pettinger offered the testimony of two patients and a member of his staff. Dr. Pettinger began treating Tammy Gouthro in December 2010.<sup>224</sup> According to Ms. Gouthro, she sought Dr. Pettinger's help for pain management, and continued treatment with him through June 2012.<sup>225</sup> She explained that she had a work-related back injury seventeen years earlier that required fusing the L4 and L5 vertebrae.<sup>226</sup> She said this fusion and damage to her right sciatic nerve led to a 91 percent disability rating and created significant chronic pain, leaving her bedridden for much of the time.<sup>227</sup>

Due to a lack of insurance, Ms. Gouthro had no doctor at the time she visited Dr. Pettinger, and "pain medicine wasn't an option for me. It didn't work[.]"<sup>228</sup> When asked to describe Dr. Pettinger's office, Ms. Gouthro said she was examined in the office where Dr. Pettinger has his desk and file cabinets. She said the room had a stethoscope and "reflection

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<sup>221</sup> Id.

<sup>222</sup> Id. at 303-4.

<sup>223</sup> Id. at 304.

<sup>224</sup> Id. at 252-3.

<sup>225</sup> Id. at 253.

<sup>226</sup> Id. at 254.

<sup>227</sup> Id.

<sup>228</sup> Id. at 255.

gadgets” – possibly referring to a reflex hammer used to strike the patellar ligament when testing the synapses at the L4 level of the spinal cord. She said Dr. Pettinger took her blood pressure, asked her about her pain level, had her stand, “and asked me if I’d walk on my heel and walk on my toes and performed pressure points and did the actual just the exterior of my back. That’s all that he examined was the exterior where the injury and all that is, and then, like I said, he had me see how I walked forward on tippy-toes and walked back on my heel to see balance[.]”<sup>229</sup>

Dr. Pettinger did not offer any medical records to support Ms. Gouthro’s testimony. In addition, Ms. Gouthro said she told Dr. Pettinger she had x-rays of the areas needing treatment, but she never provided them because he did not require them.<sup>230</sup> When asked how this examination was different than others she has had, Ms. Gouthro said “my normal doctors have a lounge, a bed that you lay on if they wanted further extension, but other than that this is pretty much basically the same as I get from my doctors.”<sup>231</sup>

Following this examination, Dr. Pettinger prescribed cannabis for Ms. Gouthro, and then prescribed Norco, which Ms. Gouthro said did not work for her.<sup>232</sup> Ms. Gouthro praised Dr. Pettinger for helping her end her use of opiates, stating that by using cannabis she has been free of other pain medication since December 4, 2010.<sup>233</sup>

Brenda Sue Martin testified on Dr. Pettinger’s behalf, stating that Dr. Pettinger began treating her at the end of 2011 or the beginning of 2012.<sup>234</sup> She explained that she sought treatment for degenerative disc disease following neck surgery, in the hope that she might avoid

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<sup>229</sup> Id. at 257, 260.

<sup>230</sup> Id. at 266.

<sup>231</sup> Id. at 257-8

<sup>232</sup> Id. at 255.

<sup>233</sup> Id. at 259.

<sup>234</sup> Id. at 390.

back surgery.<sup>235</sup> She said while she has a regular doctor, she went to Dr. Pettinger for pain management, understanding that he specializes in that field.<sup>236</sup> Ms. Martin testified that during the first office visit, Dr. Pettinger examined “my back, my neck, my range of motion with my arms, the bending over, different things like that.”<sup>237</sup> Dr. Pettinger did not, however, offer any medical records documenting this examination.

Ms. Martin said she had already been diagnosed, so “[i]t wasn’t like he had to diagnose me.”<sup>238</sup> She explained that when she first met with Dr. Pettinger, she was taking methadone 10 mg units, 480 units a month, 90 Norco units, 90 Soma units, and clonazepam as needed for panic attacks.<sup>239</sup> She said she did not want to continue taking these medications, and Dr. Pettinger agreed to take steps to reduce her dependence on these, first by reducing the amount of methadone she took each day.<sup>240</sup> This proved effective, allowing her to reduce her daily dose of methadone from 480 to 360 units.<sup>241</sup>

Dr. Pettinger sought to present testimony from three other patients: Kim Parham, Lorenzo Watkins, and Jean Kea.<sup>242</sup> According to the Respondent’s prehearing statement, these three witnesses were called for the same reasons Ms. Gouthro and Ms. Martin were called. All five, according to the prehearing statement, would testify that, beginning in September 2012, before becoming aware of the DEA investigation, Dr. Pettinger modified his medication protocols, drastically reduced his prescribing patterns, and instituted new procedures designed to minimize diversion and improper use of scheduled substances. They would also testify that Dr. Pettinger’s

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<sup>235</sup> Id.

<sup>236</sup> Id. at 391.

<sup>237</sup> Id. at 392.

<sup>238</sup> Id. at 393.

<sup>239</sup> Id.

<sup>240</sup> Id. at 394.

<sup>241</sup> Id.

<sup>242</sup> Id. at 395-6.

actions were within the ordinary course of medical practice, and that his prescriptions were for a legitimate medical purpose.<sup>243</sup> In none of these cases did Dr. Pettinger offer copies of his physician notes or medical records of treatment.

I sustained the Government's objection to allowing testimony from Ms. Parham, Mr. Wakins, and Ms. Kea.<sup>244</sup> In his oral proffer of what these three witnesses would say, Respondent's counsel represented that each witness "has a different medical condition. Some of them were experiencing a need to reduce dependence on pain medication. . . . Also, some of them have different experiences regarding history taking, diversion of a conversation, that type of thing[.]"<sup>245</sup>

By the time this proffer was made it was clear – based on the testimony provided by Ms. Gouthro and Ms. Martin – that these witnesses lacked any knowledge about any "new procedures designed to minimize diversion and improper use of scheduled substances," as had been averred in the Respondent's Prehearing Statement. It was clear Dr. Pettinger would offer no written documentation reflecting his treatment of these patients. It was also clear the witnesses were being presented to describe the manner in which Dr. Pettinger treated patients who were not engaged in drug-seeking behavior. Given the nature of the charges in the Order to Show Cause, the testimony of Ms. Martin and Ms. Gouthro was tangential at best, and of little evidentiary value. The testimony of three additional patients would not have contributed in a meaningful way to the record and was for that reason excluded.

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<sup>243</sup> Respondent's Supplemental Prehearing Statement at 3-5.

<sup>244</sup> Tr. at 396.

<sup>245</sup> Id.

Dr. Pettinger's final witness was Nancy McGowan, Practice Manager at Greenleaf Urgent Care.<sup>246</sup> She explained that Greenleaf Urgent Care is a medical office owned by Jim Daniels and operated by Dr. Pettinger.<sup>247</sup> Ms. McGowan stated that she began her job as the office manager at Greenleaf in August 2012, and understands that, prior to that time, the focus of the office had been pain management.<sup>248</sup> She explained that when she arrived, Dr. Pettinger was not accepting any new patients "because he was scaling his business down, scaling the pain management part of it down, and we were going to transition to more of an urgent care."<sup>249</sup> There was no testimony regarding Dr. Pettinger's operation of the medical office known as Medical Cannabis of Northern California, nothing to indicate what happened with the two medical offices (in Sacramento and Modesto) visited by the five undercover agents, nor was there any testimony establishing that MCNC was now operating as Greenleaf Urgent Care.

Ms. McGowan did state that Dr. Pettinger wanted to scale down the pain management practice because some of his patients "were just not complying well, and he wanted to get out of that business."<sup>250</sup> She explained that in some cases, patients were asked to produce medical records such as test results, MRIs, x-rays, and medication histories, and when a patient could not produce needed documentation, Dr. Pettinger would no longer treat them.<sup>251</sup> She said these patients also needed to provide referrals from primary care physicians, indicating the need for pain management, along with progress notes from those referring doctors.<sup>252</sup>

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<sup>246</sup> Id. at 459.

<sup>247</sup> Id.

<sup>248</sup> Id. at 460.

<sup>249</sup> Id. at 461.

<sup>250</sup> Id. at 462.

<sup>251</sup> Id.

<sup>252</sup> Id. at 462-3.

Ms. McGowan stated that even before she began working at the office, Dr. Pettinger had developed a pain management consent form which he had his patients sign – although no such form has been presented in this matter.<sup>253</sup> She stated that the agreement prohibits sharing medications and includes a requirement that the patient agree to use only one pharmacist, so that the patient doesn't “doctor-shop”.<sup>254</sup> Rather than accept the patient's word about referring sources, the office will require enough information to permit the doctor or staff to contact the referring source to confirm the patient's diagnosis and note the existing course of treatment.<sup>255</sup>

According to Ms. McGowan, efforts to address non-compliant patients were being made even before she arrived in August 2012. She said she saw records of patients who had been discharged from Dr. Pettinger's practice due to noncompliance in her review of charts once she started working there.<sup>256</sup> Further, she said she and Dr. Pettinger discussed applying these same standards to new patients, if at some point he decided to resume that part of the practice.<sup>257</sup> Ms. McGowan was aware of instances where a pharmacist would call to inquire about customers who presented prescriptions from both Dr. Pettinger and another doctor, for the same medication. In those cases, a termination letter had been developed and would be used to terminate the patient from Dr. Pettinger's practice.<sup>258</sup> She said similar steps were taken when it appeared that multiple prescriptions for the same controlled substances were being presented from people living in the same household.<sup>259</sup>

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<sup>253</sup> Id. at 463.

<sup>254</sup> Id. at 465-6.

<sup>255</sup> Id. at 464.

<sup>256</sup> Id. at 468.

<sup>257</sup> Id. at 469.

<sup>258</sup> Id. at 470.

<sup>259</sup> Id. at 471.

According to Ms. McGowan, efforts to determine whether a patient was obtaining prescriptions for pain medication from more than one doctor could have been aided by reports under the CURES system, which is used by pharmacies and doctors to reflect patient prescription use.<sup>260</sup>

Ms. McGowan said that at this time, a patient who produced nothing more than an MRI would not qualify for treatment, and that during the time she has been with the office, Dr. Pettinger has reduced the amount of scheduled medications he prescribes.<sup>261</sup> When asked whether the owner's instructions to her regarding patient noncompliance changed at all between August 2012 and now, Ms. McGowan said no; the only changes she noted were that "we were terminating patients a lot more" and "decreasing the amount of medications significantly."<sup>262</sup>

There was, however, no evidence or other testimony establishing that Dr. Pettinger has ever acknowledged writing prescriptions for controlled substances without conducting a sufficient medical examination, without requiring objective medical documentation relevant to the patient's report of pain, or in the course of an office visit that resembled more a negotiation by a drug-seeker than a legitimate medical examination.

### **Analysis**

This administrative action began when the DEA's Administrator issued an Order suspending Dr. Pettinger's DEA Certificate of Registration and ordering him to show cause why that Certificate should not be revoked. The Order alleged that Dr. Pettinger distributed controlled substances by issuing prescriptions under conditions that violated provisions in sections

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<sup>260</sup> Id. at 473.

<sup>261</sup> Id. at 477.

<sup>262</sup> Id. at 478-9.

823(f)(4) and 841(a)(1) and 842 of Chapter 21 of the United States Code, and provisions of section 1306.04(a) of Chapter 21 of the Code of Federal Regulations. Thus, in order to revoke Dr. Pettinger's Certificate of Registration, the Government has the burden of establishing, by at least a preponderance of the evidence, that allowing Dr. Pettinger to continue to issue prescriptions for controlled substances is contrary to the public interest. If the Government meets this burden, the burden of production then shifts to the Respondent, who has the opportunity to present evidence that he accepts responsibility for his misconduct, and has taken appropriate steps to prevent misconduct in the future.<sup>263</sup>

Under the registration requirements found in 21 U.S.C. § 823(f), the Administrator should consider five factors in determining the public interest when presented with the actions of a physician engaged in prescribing controlled substances<sup>264</sup> These factors are:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.<sup>265</sup>

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<sup>264</sup> Government's Proposed Findings of Fact and Conclusions of Law at 27.

Any one of these factors may constitute a sufficient basis for taking action against a registrant.<sup>266</sup> Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether a registration should be rejected.<sup>267</sup> Moreover, the Administrator is “not required to make findings as to all of the factors[.]”<sup>268</sup> The Administrator is not required to discuss each factor in equal detail, or even every factor in any given level of detail.<sup>269</sup> The balancing of the public interest factors “is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest[.]”<sup>270</sup> In this case, the Government does not contend there is a history of professional discipline by a licensing board, nor did it offer evidence of a criminal conviction pertaining to Dr. Pettinger. Accordingly, Factors One and Three are not presented as bases for revoking this Certificate.

### **Factors One, Two, Three and Five**

There is some question regarding whether Factors Two and Five are properly before me. In its post-hearing brief, the Government initially posits that the issue in this matter is whether the Respondent’s registration “is inconsistent with the public interest, as that term is used in 21

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<sup>265</sup> 21 U.S.C. § 823(f) (2005), current through P.L. 112-207 approved 12-7-12.

<sup>266</sup> Robert A. Leslie, M.D., 68 Fed. Reg. 15227-01, 15230 (March 28, 2003).

<sup>267</sup> Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005); JLB, Inc., d/b/a Boyd Drugs, 53 Fed. Reg. 43945-02, 43947 (October 31, 1988); see also David E. Trawick, D.D.S., 53 Fed. Reg. 5326-01, 5327 (February 23, 1988).

<sup>268</sup> Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

<sup>269</sup> Trawick v. DEA, 861 F.2d 72, 76 (4th Cir. 1988).

<sup>270</sup> Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459-01, 462 (January 6, 2009).

U.S.C. §§ 824(a)(4) and 823(f).”<sup>271</sup> As noted above, the citation to section 824(a)(4) calls for the Administrator to consider the “public interest” by examining the Respondent’s “[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.” The specific federal law relied upon by the Government is found in 21 C.F.R. §1306.04(a), which prohibits a practitioner from writing a prescription for controlled substances unless the prescription is “issued for a legitimate purpose by an individual practitioner acting in the usual course of his professional practice.”

Guided by this language, the Government contends that Dr. Pettinger departed from the usual course of his professional practice by prescribing oxycodone to the five undercover agents, and that the prescriptions were not issued for a legitimate purpose.<sup>272</sup> As will be addressed below, the evidence pertaining to the issuance of these prescriptions does indeed lend itself to a finding that the prescriptions in question were not issued for a legitimate purpose and were not issued by a medical doctor who was acting in the usual course of his professional practice. Thus, an analysis under Factor Four appears warranted both by the express terms of the Order to Show Cause and by the nature of the evidence now before me.

In its post-hearing brief, however, the Government contends that the public interest issue also should include an analysis of this evidence under Factors Two and Five.<sup>273</sup> On its face, Factor Two does not appear to be directly related to registrants like Dr. Pettinger. By its express terms, Factor Two applies to applicants, and calls for an inquiry into the applicant’s “experience in dispensing, or conducting research with respect to controlled substances.” Thus, it is not clear

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<sup>271</sup> Government’s Proposed Findings of Fact and Conclusions of Law at 1.

<sup>272</sup> *Id.* at 15.

<sup>273</sup> *Id.* at 18-20.

that the inquiry into Dr. Pettinger's experience in dispensing controlled substances is warranted, given the limited scope of this Factor.

Assuming, however, that Factor Two does indeed pertain to both registrants and applicants, the record here does not include any substantial notice to Dr. Pettinger that the Government intended to rely on Factor Two as justification for revoking his Certificate of Registration. As the Respondent points out in his post-hearing brief, the first time the Government asserted it would seek an analysis under Factor Two was during the opening statement given during the hearing. From my review of the record, there was no clear mention of the Government intending to rely on the provisions of 21 C.F.R. § 823(a)(2) in the Order to Show Cause, nor was it brought forward in either the initial or supplemental prehearing statements filed by the Government. The same is true with respect to the Government's reliance on Factor Five – and in this instance the Government raised Factor Five only after the hearing, in its post-hearing brief.

From this set of circumstances, Dr. Pettinger argues that I have “no alternative but to conclude that factors 1, 3 and 5 all militate in favor of respondents [sic] continued registration.”<sup>274</sup> I reach another conclusion, at least regarding Factor Five. I do agree that I should take into account, and regard as evidence favorable to Dr. Pettinger, the fact that the board licensing him has permitted him to renew that license, notwithstanding these pending administrative actions. Factor One calls for me to consider the “recommendation of the appropriate State licensing board or professional disciplinary authority.” Implicit in the fact that the California state licensing authority renewed Dr. Pettinger's medical license is a tacit

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<sup>274</sup> Respondent's Post-Hearing Brief at 4.

endorsement by the medical board of his continuing ability to safely and professionally serve his community.

Further, and although it may be faint praise, the fact that Dr. Pettinger has not been charged or convicted of any crime does fall within the scope of Factor Three, which requires that I consider “[t]he applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.” As is the case with Factor Two, Factor Three does not appear, on its face, to apply to registrants like Dr. Pettinger. Assuming, however, that this Factor applies with equal force to applicants and registrants alike, the evidence does reflect an absence of criminal convictions.

As noted above, the Government did not identify Factors Two or Five as bases for taking action against Dr. Pettinger when it issued its Order to Show Cause and its Order of Immediate Suspension. Dr. Pettinger correctly notes that the first time Factor Two was mentioned was during the Government’s opening statement.<sup>275</sup> Apart from making this observation, however, the Respondent does not make any objection to a Factor Two analysis, and as such any issue based on lack of notice is waived.

The Administrator may consider evidence of positive experience under Factor Two; however, this evidence does not necessarily outweigh acts against the public interest, particularly where those acts are done intentionally. As stated in Holiday CVS: “In some (but not all) cases, viewing a registrant’s actions against a backdrop of how she has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest. In this regard, however, the Agency has applied

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<sup>275</sup> Id. at 4.

principles of reason, coupled with its own expertise in the application of this factor. For example, the Agency has taken the reasonable position that this factor can be outweighed by acts held to be inconsistent with the public interest.”<sup>276</sup>

Assuming Factor Two applies equally to applicants and registrants, in analyzing a registrant’s experience under Factor Two the Administrator should consider the context of a registrant’s entire dispensing practices, notwithstanding that isolated acts against the public interest can outweigh substantial positive experience. This premise is explained as follows:

- In Krishna-Iyer, the Agency, “[i]n considering Petitioner’s experience in dispensing controlled substances under [F]actor 2, [ ] identified only four visits by three undercover patient[s], who were all attempting to make a case against [the Respondent]. The DEA failed to consider [the Respondent’s] experience with twelve patients whose medical charts were seized by the DEA, or with thousands of other patients. In short, the DEA did not consider any of [the Respondent’s] positive experience in dispensing controlled substances.”<sup>277</sup> In an unpublished opinion, the Eleventh Circuit found the Agency’s failure to consider the Respondent’s positive experience “arbitrary and unfair.” The Court “vacated the [Final] Order and remanded the case for reconsideration, directing that ‘DEA should pay particular attention to the entire corpus of Petitioner’s record in dispensing controlled substances, not only the experience [with the] undercover officer.’ The Court further ordered that ‘[t]he five factors should . . . be re-balanced.’”<sup>278</sup>
- But in T.J. McNichol, M.D.,<sup>279</sup> the Administrator declined to adopt the “positive experience” arguments offered by the ALJ, “who ignored both the Agency’s subsequent decision on remand in Krishna-Iyer, which addressed the role of ‘positive experience’ evidence in cases where the Government has proved intentional or knowing diversion, subsequent Agency cases applying this rule, and several court of appeals’ decisions (including that of the Eleventh Circuit), which have since upheld the Agency’s position”.
- Further, in Becker, the Administrator reaffirmed that “evidence [of a] significant level of sustained activity within the scope of the registration for a sustained period can be a relevant and correct consideration, which may be accorded due weight. The registrant’s knowledge and experience regarding the rules and regulations applicable to practitioners also may be considered. . . . Experience which occurred prior or subsequent to proven

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<sup>276</sup> Holiday CVS, LLC, 77 Fed. Reg. 62316, 62340 (October 12, 2012) (adopting the ALJ’s recommended decision).

<sup>277</sup> Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 459 (January 6, 2009) (citing Krishna-Iyer v. DEA, No. 06-15034 (11th Cir. 2007), Slip Op. at 3).

<sup>278</sup> Id.

<sup>279</sup> T.J. McNichol, M.D., 77 Fed. Reg. 57133, 57144 (September 17, 2012).

allegations of malfeasance may be relevant. Evidence that precedes proven misconduct may add support to the contention that, even acknowledging the gravity of a registrant's transgressions, they are sufficiently isolated and/or attenuated that adverse action against his registration is not compelled by public interest concerns."<sup>280</sup>

- And most recently, in Casanova, the ALJ properly considered evidence of the Respondent's positive prescribing practices, alongside evidence of diversion to undercover agents. The Division Investigator testified that the Respondent's practice was "not a pill mill, and that aside from the absence of a biennial inventory . . . [the practice] appeared to be within the scope of a normal medical practice. . . . Additionally, Respondent offered testimony that he gained experience dealing with acute and chronic pain patients and treating them with opioids, and familiarized himself with the [applicable state medical standards]. . . . Finally, Respondent testified that . . . he turned away a large number of patients [who exhibited signs of drug-seeking behavior]."<sup>281</sup>

In the record now before me, we have evidence establishing multiple instances where Dr. Pettinger improperly issued prescriptions for oxycodone. The record, however, is silent with respect to his overall practice history: we do not know how long he has practiced medicine in the type of office reflected in this record; we do not know the number of patients he has served, or the value of that service to the community, or other similar demographic factors relevant to this issue. We know he was highly regarded by the two patients who testified, and we can assume the same can be said regarding the three patients who appeared and were willing to give testimony on the day of the hearing.

We know from his office manager that by the time she began working for Dr. Pettinger, he was operating out of medical office using the name Greenleaf Urgent Care. It is not clear that

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<sup>280</sup> Jeffery J. Becker, D.D.S., 77 Fed. Reg. 72387, 72404 (December 5, 2012) (adopting the ALJ's recommended decision, which noted that, "[w]hile the Respondent's level of professional achievement is undeniably impressive, he has offered no affirmative evidence regarding his experience dispensing controlled substances from peers, co-workers, or even himself. Still, his professional experience and contributions to his field have been considered in this recommended decision").

<sup>281</sup> Rene Casanova, M.D., 77 Fed. Reg. 58150, 58168-9 (Sept. 19, 2012) ("carefully consider[ing] the evidence of Respondent's past positive experiences in dispensing controlled substances," yet "find[ing] those experiences are considerably outweighed by the substantial evidence of Respondent's repeated misconduct in issuing controlled substance prescriptions to undercover law enforcement officers . . . [and] diminished by Respondent's failure on the whole to admit or accept responsibility for any wrongdoing").

this office was the successor to Dr. Pettinger's medical office known as Medical Cannabis of Northern California, but we are expected to believe this is the case. Assuming this is true, both practices had an active caseload of patients, although there is no evidence with respect to the actual numbers of patients treated either before or after the Order to Show Cause was issued. We know from his office manager that Dr. Pettinger reportedly no longer seeks new patients in need of pain management, and has taken steps to identify drug seeking patients and terminate his professional relationship with them. We cannot, however, point to substantial evidence establishing that the nine instances leading to the prescriptions of record are either isolated or are instead typical of Dr. Pettinger's past or present practice.

To the extent the Government would have me determine Dr. Pettinger's experience in distributing controlled substances, it has given me little to permit me to compare the volume of Dr. Pettinger's history of compliant service with the nine incidents of record here. Given the lack of evidence that would permit such an analysis, and given the lack of notice provided by the Government regarding its intention to rely on Factor Two in this hearing, I conclude Factor Two neither supports nor contradicts a finding that Dr. Pettinger's continued registration is inconsistent with the public interest.

Our record establishes that the Government did not indicate its reliance on Factor Five until after the hearing was over. Moreover, the factual allegations appearing in the Order to Show Cause do not, in and of themselves, suggest the Government intended to rely on theories that fall within the ambit of Factors Two or Five. The theories identified in the Order to Show Cause remained generally intact in the presentation of issues and summaries of witness testimony presented by the Government in both its initial and supplemental prehearing statements.

The exception to this, as noted by the Respondent, is that fewer bases for action were presented during the hearing than had been alleged in the Order to Show Cause.<sup>282</sup> In the Order to Show Cause, the Government noted that records provided by the California Department of Justice Controlled Substance Utilization Review and Evaluation System (CURES) suggested a pattern of prescribing a sufficiently high volume of oxycodone to warrant finding his continued registration with the DEA inconsistent with the public interest. As the Respondent correctly noted, the Government presented no evidence concerning data from the CURES system, apparently abandoning this evidence as a basis for action under the Order to Show Cause.

Action based on Factor Five requires evidence of “[s]uch other conduct which may threaten the public health and safety.”<sup>283</sup> Accordingly, if the conduct falls within the scope of Factors One through Four, it would not be “other” conduct and would be addressed by those Factors, and not through a Factor Five analysis.

The Order to Show Cause and the evidence presented at the hearing both focused almost exclusively on the actions recorded during the nine occasions described by the five undercover agents. The one exception to this is the evidence establishing that Dr. Pettinger wrote a prescription for Norco after acknowledging receipt of the order that he issue no further controlled substance prescriptions. As will be discussed below, this presentation of evidence establishes by at least a preponderance that the prescriptions appearing as exhibits in this record were issued outside the usual course of professional practice and were issued for other than a legitimate medical purpose. As such, when he wrote these prescriptions Dr. Pettinger violated 21 U.S.C. §

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<sup>282</sup> Respondent’s Post-Hearing Brief at 5.

<sup>283</sup> 21 C.F.R. § 823(f)(5).

841(a)(1). Given that the primary basis for taking action against Dr. Pettinger is conduct that falls within the scope of Factor Four, an analysis under Factor Five would be unwarranted.

I am mindful of the evidence introduced during the hearing establishing that Dr. Pettinger misrepresented his office practice when he was questioned by DEA Special Agent Kittrell. Summarized, this evidence includes Agent Kittrell recalling what Dr. Pettinger told him during his initial inquiry into Dr. Pettinger's standard operating procedures. In his testimony, Agent Kittrell credibly stated that Dr. Pettinger assured him that he conducted a full physical examination prior to prescribing any controlled substances, and that he did so whether the patient was presenting for the first time or for a follow up visit. As evaluated by the Government's expert medical witness, the evidence establishes that this was a false statement by Dr. Pettinger. The evidence establishes that Dr. Pettinger failed to perform a full physical examination in each of the cases reported by the undercover agents, leading to the conclusion that (as the Government suggests in its post-hearing brief) Dr. Pettinger lied to Agent Kittrell when he described his standard operating procedures in cases involving the prescription of controlled substances.<sup>284</sup> Similarly, the evidence establishes that Dr. Pettinger lied to Agent Kittrell when he represented that if a patient presented seeking pain medication but had not medical records, all Dr. Pettinger would prescribe was Norco (hydrocodone) – a claim that was patently contradicted during the initial meetings with Agent Kvach and Agent Bianchi.<sup>285</sup>

Lying to a DEA agent in the course of the agent's investigation into diversion of controlled substances is not conduct that falls within the scope of Factors One through Four, but it does fall squarely within the scope of Factor Five. Of concern here, however, is the fact that

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<sup>284</sup> Government's Proposed Findings of Fact and Conclusions of Law at 20.

<sup>285</sup> Id., and citations therein.

throughout its pre-hearing notices, the Government made no mention of its intention to raise such a claim. I have reviewed the Order to Show Cause and both the initial and supplemental prehearing statements and find no suggestion that the Government intended to confront Dr. Pettinger with evidence about his statement to Agent Kittrell regarding his practice of performing full physical examinations. The question thus is whether the Administrator should take disciplinary action based on evidence of improper conduct that was not disclosed to the Respondent until the hearing had begun.

The Government's failure to notify a responding party of the theory of the Government's case becomes a critical issue in cases, such as the present case, that are brought under the Administrative Procedure Act. For example, in Bendix, the FTC "violated § 5 of the Administrative Procedure Act, 5 U.S.C. § 554, when it decided the case on a theory of illegality which was never charged, raised, nor tried during the administrative hearing; never presented for consideration by the Hearing Examiner; and not raised as an issue or discussed by Complaint Counsel in the appeal to the Commission from the order of the Hearing Examiner dismissing the complaint. Bendix had no notice that it was charged under [this] theory of illegality and was accorded no opportunity to present evidence in defense against this theory."<sup>286</sup>

The court remanded the case, affording the parties a second opportunity to offer evidence. In Bendix, Government counsel presented three theories of illegality, each rejected by the Hearing Examiner. Thereafter, the Commission based its final decision on a wholly separate legal theory.<sup>287</sup> "This [was] not a case where the initial complaint was couched in broad generalities but subsequently was tried on the specific theory that ultimately justified [the

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<sup>286</sup> Bendix Corp. v. FTC, 450 F.2d 534, 537 (6th Cir. 1971)

<sup>287</sup> Id. at 537.

Commission’s] finding[s].”<sup>288</sup> Indeed, “[c]ounsel for Bendix specifically asked both the Hearing Examiner and the [Government’s] Counsel for the theory upon which the case would be tried.” Government counsel expressly limited the legal theories at issue: “[r]epeated statements by counsel, witnesses, and the [Hearing] Examiner showed that everyone believed [these] to be the only issue[s]” in contention.<sup>289</sup> At the conclusion of the hearing, Government counsel submitted a final brief to the Commission, which omitted any mention of alternative legal theories.<sup>290</sup> “Bendix’s case was prepared and presented in response to certain enumerated theories. . . . The witnesses were questioned and cross-examined in terms of these issues. The documentary proof was keyed to these theories.”<sup>291</sup> Because “different defenses and proofs would be used in defending” the Commission’s alternate legal theory, Bendix was entitled to a remanded hearing.<sup>292</sup>

Similarly, the court remanded where it found on review that the NLRB did not afford the respondent a full and fair opportunity to litigate the issues comprising the final decision.<sup>293</sup> After an administrative law judge conducted a hearing on the charges set forth in the Board’s complaint, the Board adopted the ALJ’s decision, but did so based on an “alter-ego” theory of corporate liability.<sup>294</sup> Although the NLRB found “sufficient connection to the complaint for Respondent to anticipate” the newly-articulated legal theory, the Court of Appeals determined that the respondent was not accorded his due process rights as to the alter ego claim.<sup>295</sup>

“Respondent was unaware that the [ ] alter ego claim was raised in the proceeding. Even during

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<sup>288</sup> *Id.* at 541.

<sup>289</sup> *Id.*

<sup>290</sup> *Id.*

<sup>291</sup> *Id.* at 542.

<sup>292</sup> *Id.* at 541-2.

<sup>293</sup> *NLRB v. I.W.G., Inc.*, 144 F.3d 685 (10th Cir. 1998)

<sup>294</sup> *Id.* at 687.

<sup>295</sup> *Id.*

the course of the evidentiary hearing, Respondent received no notice of the claim that [its subsidiary] was an alter ego[.]" and "[t]he ALJ never advised the parties that he would consider an alter ego claim."<sup>296</sup> Because the respondent never received notice of the alter ego claim through the pleadings, the Court of Appeals determined that first time the respondent was informed that an alter ego claim was alleged was in the post hearing brief filed prior to the ALJ's decision.<sup>297</sup>

During the review by the Court of Appeals, the NLRB argued that the alter ego claim was fully and fairly litigated because "considerable evidence relevant to" the claim was presented and challenged at the hearing.<sup>298</sup> However, the Court of Appeals noted that "the simple presentation of evidence important to an alternative claim does not satisfy the requirement that any claim at variance from the complaint be 'fully and fairly litigated' in order for the Board to decide the issue without transgressing [Respondent's] due process rights."<sup>299</sup>

Given the substantial evidence of Dr. Pettinger's violation of regulations controlling the distribution of oxycodone under Factor Four (thereby rendering a Factor Five analysis superfluous), given Dr. Pettinger's failure to rebut the Government's prima facie case (as will be addressed below), and given the Government's failure to disclose in advance of the hearing its intention to rely on a Factor Five analysis, I cannot recommend relying on a Factor Five analysis, even as an alternative theory of the case.

#### **Factor Four**

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<sup>296</sup> Id. at 688.

<sup>297</sup> Id.

<sup>298</sup> Id.

<sup>299</sup> Id. (internal citations omitted). See also Soule Glass and Glazing Co. v. NLRB, 652 F.2d 1055 (1st Cir. 1981) (noting that "even if such an argument appeared explicitly in the General Counsel's post-hearing brief, such post-hoc characterizations of the case would not be relevant in determining whether the employer had notice of the issue and a meaningful opportunity to defend against it at the hearing").

Although it is unfortunately blended with a discussion of Factor Two, the Government's post-hearing brief discussing Factor Four cogently summarizes the facts and the legal issues that lead me to conclude the Government has met its prima facie responsibilities in this case.<sup>300</sup>

While the overarching question is whether Dr. Pettinger's continued certification is inconsistent with the public interest, the specific question under Factor Four is whether the behavior captured by the undercover agents reveals action by the Certificate holder that violates drug diversion laws. I find that it does.

The specific instances of misconduct cited by the Government at pages 15 through 20 of its brief have been established by at least a preponderance of the evidence. Without attempting an exhaustive inventory here, these included failing to conduct a sufficient physical examination of each of the five undercover agents on each of their office visits; prescribing oxycodone without first resolving material medical issues suggesting the putative patients had serious alcohol, cannabis, and addictive painkiller problems; prescribing oxycodone to patients who were diverting oxycodone to help pay off debts and to share with friends; prescribing oxycodone to patients who had presented no medical records that would support their self-reported medical histories; and prescribing oxycodone to patients based on complaints of pain and sleep disorders despite the fact that those complaints were absent from the patient's self-reported medical histories. The Government in its post-hearing brief aptly notes that in her review of these nine patient encounters with the five undercover agents and Dr. Pettinger, it appeared to the medical expert that Dr. Pettinger was more interested in negotiating the amount of oxycodone and related controlled substances that would be dispensed through his prescriptions, than he was in actually diagnosing the medical conditions of the agents.

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<sup>300</sup> Government's Proposed Findings of Fact and Conclusions of Law at 14 – 19.

As the Respondent correctly notes, it is clear from the evidence that Dr. Pettinger encouraged these patients to avoid the use of oxycodone and other highly addictive painkillers. Both in his presentation to the Government's undercover agents and in his treatment of his own patients, it is clear Dr. Pettinger sought to wean his patients off of oxycodone, and sought to discourage resorting to oxycodone wherever possible. That being said, however, it is also clear that he abandoned his own professed requirements when he issued the prescriptions at issue, by authorizing the dispensation of oxycodone without first requiring medical records and without ever evaluating treatment modalities that did not include narcotics.

The testimony of the Government's medical expert, Dr. Neyhart, provides substantial credible evidence establishing that the prescriptions shown in our record were not "issued for a legitimate medical purpose," and were not issued "by an individual practitioner in the usual course of his professional practice."<sup>301</sup> In his post-hearing brief, Dr. Pettinger notes that Dr. Neyhart's credentials do not include operating a pain management clinic and asserts that the weight to be given to her opinions should be tempered by the fact that the expert "is not a pain management specialist and had not even practiced primary care for at least eighteen months."<sup>302</sup> This can be duly noted, but from the presentation of Dr. Neyhart's credentials and from her very credible testimony, I find substantial evidence establishing that the actions recorded during these nine patient visits did not constitute the "usual course" of the professional practice of medicine, irrespective of whether the practitioner has or has not limited his practice to pain management.

On the point of such limitation, I note that Dr. Pettinger's cannabis practice, M.C.N.C., appears not to be a pain management clinic, but rather a clinic specializing in dispensing

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<sup>301</sup> See Sun & Lake Pharmacy, 76 Fed. Reg. 24,530, 24523 (quoting 21 C.F.R. § 1306.04(a)).

<sup>302</sup> Respondent's Post-Hearing Brief at 7.

prescriptive cannabis. One of Dr. Pettinger's patients stated she saw nothing that would indicate the office specialized in pain management, and the letterhead and signage in our record indicates Dr. Pettinger used the name "Medical Cannabis of Northern California" or the initials "M.C.N.C." The impression I got from the evidence as a whole is that the practice focused not on pain management but on the medicinal use of cannabis. This is not to be critical of the practice but only to state that the practice bore few of the markings found in practices dedicated exclusively to the management of pain.

This impression is primarily based on what I observed as I listened to the undercover patient visits and on the testimony of Dr. Pettinger's three witnesses. A consistent pattern in the recorded visits by undercover agents was the thorough explanation Dr. Pettinger gave regarding the medicinal use of cannabis, along with his very clear exhortation that the patients do all they can to avoid the use of oxycodone and similar narcotic painkillers. That being said, however, the record also establishes a factual basis for Dr. Neyhart's observation that Dr. Pettinger failed to engage in medical examinations of the type needed to diagnose these patients' medical conditions or to explore treatment modalities other than the use of either cannabis or oxycodone.

In his closing brief, Dr. Pettinger argues that "the undercover agents conduct is highly atypical and therefore cannot be extrapolated to the general population of drug seeking patients and therefore cannot demonstrate that Respondent's prescribing constituted a danger to the general public (as opposed to the miniscule subset of hypothetical patients represented by the undercover agents)."<sup>303</sup> The evidence from Dr. Neyhart did establish that drug seeking patients will attempt to divert attention and to ingratiate themselves with their potential prescribing sources. Agent Kittrell confirmed the same in his very credible testimony on this point. Further,

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<sup>303</sup> Id. at 9.

nothing in the behavior of these undercover agents was so clearly incredible or outlandish as to warrant dismissing their actions as being “atypical”. To the contrary, testimony from Dr. Neyhart and Special Agent Kittrell establishes that the means by which these agents sought to procure controlled substances were well within those employed by persons seeking to illegally divert controlled substances through this kind of office visit.

It also should be noted that, even if I were to accept the premise that this was either outlandish or atypical behavior, I would nonetheless reach the conclusion that such behavior should have prompted a more studied response by Dr. Pettinger, rather than his capitulation or accommodation when the agents asked him to prescribe oxycodone. His failure to resolve the many red flags shown here compels the conclusion that his decision to prescribe dangerous narcotics put the public at risk and constitutes action “outside the usual course of his professional practice.”<sup>304</sup>

Because it was thorough, internally consistent, consistent with the evidence presented generally, and not contradicted by any professional opinion to the contrary, I place great weight in the medical expert’s opinions regarding Dr. Pettinger’s practice. I find that the failure to resolve the multiple red flags present with each of the five undercover agents constitutes action outside the usual course of medical practice, and I find Dr. Pettinger’s decision to issue prescriptions based on a negotiation with these five patients, rather than based on a properly rendered medical diagnosis, compels the conclusion that the prescriptions in evidence here were not issued for a legitimate medical purpose. Upon these findings, the Government has met its burden of establishing a prima facie case in support of the Order to Show Cause.

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<sup>304</sup> 21 C.F.R. § 1306.04(a).

In his discussion about remediation, Dr. Pettinger posits that his decision to stop treating pain patients should be taken into account, and that he should be credited for improving his approach to drug seekers.<sup>305</sup> First, as aptly pointed out by the Government in its post-hearing brief, the significant drop in prescriptions issued by Dr. Pettinger was doubtlessly precipitated, in part at least, by the fact that the Administrator suspended his Certificate.<sup>306</sup> Beyond this, however, Dr. Pettinger did present evidence through his office manager, who testified that Dr. Pettinger has implemented measures to reduce “double dipping,” is accepting no new patients, is discharging problematic patients, refuses to prescribe to patients who appear to be trafficking, and is discharging patients who appear to be providing falsified records.<sup>307</sup>

As Dr. Pettinger correctly notes, all of these steps are steps that every practitioner should undertake when operating under a DEA Certificate. The record does not, however, include an express or implied acknowledgement by Dr. Pettinger that his actions with respect to the five undercover agents put the public at risk. The practices described by Dr. Pettinger’s office manager do not establish remedial efforts taken to correct the mistakes that have been revealed by the undercover action. Instead, they suggest Dr. Pettinger tired of having to negotiate with patients who came to know that he was willing to prescribe oxycodone without requiring medical justification.

As noted above, Dr. Pettinger elected not to give sworn testimony on the issue of remediation, depriving the Administrator and the public with a clear demonstration of contrition and remediation. His silence also permits a negative inference to be drawn with respect to factual

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<sup>305</sup> Respondent’s Post-Hearing Brief at 11.

<sup>306</sup> Government’s Proposed Findings of Fact and Conclusions of Law at 21.

<sup>307</sup> Respondent’s Post-Hearing Brief at 11 and citations to the transcript therein.

issues presented, as noted by the Government in its post-hearing brief.<sup>308</sup> Instead of hearing from Dr. Pettinger, we have the testimony of his office manager, who stated that many of the steps she described had been in place for some time, making it impossible to determine whether any of the steps were actually remedial in nature. It also must be noted that most of the measures listed as remedial in Dr. Pettinger's post-hearing brief require him to act in a specific manner,<sup>309</sup> but as we have only Ms. McGowan's testimony on this point we have no clear record from Dr. Pettinger himself to confirm that he will in fact do what his office manager says he will do. Accordingly, I find insufficient evidence of remediation as to counter the Government's prima facie case.

### **Findings of Fact**

1. Respondent is registered with DEA as an individual practitioner in Schedules II-V under DEA Certificate of Registration Number AP6572716, at 4707 Greenleaf Court, Suite A, Modesto, California, 95356. Respondent's Certificate of Registration expires by its own terms on March 31, 2015.
2. The Respondent's DEA Certificate of Registration expires by its own terms on March 31, 2015. He is licensed to practice medicine as a physician and surgeon in the State of California under license number G29874, which will expire by its own terms on March 31, 2015.
3. On December 12, 2012, DEA served Respondent with an Order to Show Cause and Immediate Suspension of Registration dated December 10, 2012, whereby Respondent's DEA Certificate of Registration Number AP6572716 was suspended.

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<sup>308</sup> Government's Proposed Findings of Fact and Conclusions of Law at 20-1.

<sup>309</sup> *Id.* at 12.

4. Between November 10, 2011 and May 9, 2012, undercover agents employed by the DEA, the FBI, and the U.S. Department of Health and Human Services represented to be patients seeking controlled substances from the Respondent at the Respondent's medical offices in Sacramento and Modesto California. In each of nine instances reported here, the Respondent wrote prescriptions for controlled substances regulated by the DEA, including oxycodone, promethazine with codeine, and hydrocodone.
5. Prior to issuing these nine prescriptions, the Respondent did not conduct sufficient medical examinations to be able to diagnose the medical conditions for which these controlled substances were sought. In addition, the Respondent inappropriately counseled a patient on how to obtain a prescription for oxycodone where there were no objective signs or findings that would support such a prescription; counseled a patient on the use of Marinol as a means by which the patient could avoid adverse legal consequences if found to have the active ingredients of cannabis in his blood or urine; and failed to resolve issues arising when the undercover agents presented facts in the course of the medical examinations that warranted further inquiry, including the failure to produce objective signs and findings through MRIs and other medical sources to substantiate the need for pain medication; the failure to inquire into abuse of alcohol, opioids and cannabis when presented with evidence of the same; the illegal acquisition, diversion, and distribution of controlled substances; the failure to make appropriate inquiries and take appropriate action when presented with drug-seeking behavior by these five agents; the failure to follow his own reported diagnostic and treatment procedures when presented with patients who lacked objective medical evidence supporting pain diagnoses; and the failure to reconcile

inconsistencies between symptoms being reported by the undercover agents and reports of symptoms and conditions appearing in the physician's notes from these patient visits.

6. On December 11, 2012, Special Agent Robert Kittrell served upon the Respondent the Administrator's Order to Show Cause and Immediate Suspension of DEA Registration. After receiving this Order, the Respondent was prohibited from dispensing controlled substances under his DEA Certificate of Registration. Despite acknowledging this prohibition, the Respondent thereafter issued a prescription for hydrocodone for a patient who had exhausted an earlier prescription for the same.

### **Conclusions of Law**

1. When it proposes to revoke a DEA Certificate of Registration or deny any pending applications for such a Certificate, the Government is required to establish by at least a preponderance of the evidence that the holder's continued registration is inconsistent with the public interest. 21 U.S.C. §§ 823(f) and 824; and 21 C.F.R. §§ 1301.36 and 1301.37.
2. Five factors must be considered when determining the public interest in this case:
  - (1) The recommendation of the appropriate state licensing board or professional disciplinary authority.
  - (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

- (3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
  - (4) Compliance with applicable state, federal, or local laws relating to controlled substances.
  - (5) Such other conduct which may threaten the public health and safety. 21 U.S.C. § 823(f).
3. Under 21 U.S.C. § 823(f)(1) (Factor One), where the evidence establishes the Respondent's California medical credentials were renewed by the state medical authority while DEA administrative proceedings were pending, the renewal of those credentials constitutes evidence that is consistent with continued Registration by the DEA. Such evidence is not, however, dispositive of the question whether the Respondent's continued DEA Certification is or is not consistent with the public interest.
  4. In order to establish a basis for revoking a Certificate of Registration based on the provisions of 21 U.S.C. § 823(f)(2) (Factor Two), and assuming Factor Two applies to both applicants and registrants, the Government must present evidence establishing, by at least a preponderance, that the experience of the Respondent in dispensing controlled substances is of such character and quality that his continued registration is inconsistent with the public interest. This requires evidence of both the qualitative manner and quantitative volume of the Respondent's experience. Where evidence of the Respondent's experience, as expressed through his patients and employees, is silent with respect to the quantitative volume of the Respondent's

- experience, and requires speculation to support an adverse finding under Factor Two, this Factor should not be used to determine whether the Respondent's continued registration is inconsistent with the public interest.
5. In order to establish a basis for revoking a Certificate of Registration based on the provisions of 21 U.S.C. § 823(f)(3) (Factor Three), and assuming Factor Three applies to both applicants and registrants, the Government must present evidence of the Respondent's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances. As this Factor is neither alleged by the Government nor suggested by the evidence, and as there is evidence that the applicable licensing authority renewed the Respondent's license while these administrative proceedings were pending, the Factor may be considered as supporting the Respondent's continued registration.
  6. Under 21 U.S.C. § 823(f)(4) (Factor Four), the Administrator must consider the Respondent's compliance with applicable state, federal, or local laws relating to controlled substances. A prescription for a controlled substance is unlawful unless it has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.<sup>310</sup>
  7. Under the conditions presented in the record, the Respondent issued nine prescriptions for controlled substances regulated by the DEA that were not for a legitimate medical need and were not issued in the ordinary course of a professional medical practice. Upon such evidence, the Government has established by at least a preponderance that the Respondent's continued DEA Certification is inconsistent

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<sup>310</sup> Sun & Lake Pharmacy, 76 Fed. Reg. 24520, 23523 (May 2, 2011)(quoting 21 C.F.R. § 1306.04(a)).

- with the public interest, warranting the revocation of that Certification and the denial of any pending application for such a Certification.
8. Under the conditions presented in the record, the Government has established by at least a preponderance of the evidence that the Respondent issued a prescription for hydrocodone on December 21, 2011, at a time when his DEA Certificate had been suspended. Because such prescription activity requires a DEA Certificate, the actions attributed to the Respondent constitute noncompliance with applicable federal laws relating to controlled substances. Upon such proof, the Government has established by sufficient evidence that the Respondent's continued DEA Certification is inconsistent with the public interest, warranting the revocation of that Certification and the denial of any pending application for such a Certification.
  9. Under 21 U.S.C. § 823(f)(5) (Factor Five), the Government may base its determination to revoke a DEA Certification on "such other conduct which may threaten the public health and safety." Such a determination thus may not be based on circumstances falling within the scope of Factors One through Four, but rather must be based on circumstances not otherwise addressed in this section of the regulation. In this matter, the Government presented evidence that the Respondent falsely reported to Special Agent Kittrell that prior to dispensing controlled substances, the Respondent conducted appropriate medical examinations. This contention was raised for the first time in the Government's post-hearing brief, and the Respondent has objected to the late introduction of this Factor as a basis for revocation. Under the Due Process Clause of the Fifth Amendment to the United States Constitution, the Government must provide adequate notice of the factual allegations it intends to

- prove.<sup>311</sup> Where the Order to Show Cause and all prehearing statements provided to the Respondent did not include notice that the Government intended to apply Factor Five in these proceedings, and where such intention was not made known to the Respondent until after the end of the evidentiary hearing, the provisions of Factor Five should not be used as a basis for taking adverse action against the Respondent.
10. Upon such evidence as is now before the Administrator, the Government has under Factor Four met its burden and has made a prima facie case in support of the proposed order revoking the Respondent's DEA Certificate of Registration.
11. Upon a review of the record as a whole, including all claims made in the Respondent's post-hearing brief, where the Respondent has failed to affirmatively acknowledge specific acts of improper prescribing of controlled substances and failed to establish by credible and substantial evidence effective steps taken in remediation, there is insufficient evidence of remediation. Accordingly, the Government has established cause to revoke the Respondent's DEA Certification.

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<sup>311</sup> CBS Wholesale Distribs., 74 Fed. Reg. 36746, 36749 (2009) (“The Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's Action.”).

## **Recommendation**

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

Dated: June 5, 2013.

**CHRISTOPHER B. MCNEIL**

Administrative Law Judge

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