oxycodone 30mg), he nonetheless increased his oxycodone prescription to 300 tablets and the TFO told him that he would ''do whatever it takes'' to get OxyContin. Thus, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing oxycodone to the TFO.

At his final visit, TFO 1 again asked if he could get OxyContin and offered to pay $400 for the visit. Manifesting his awareness that the TFO was not a legitimate pain patient but was engaged in drug-seeking, Respondent's assistant replied that ''[i]t doesn't matter to me how much you pay'' and that he was ''not going to jail just because you need something.'' Moreover, while Respondent asked the TFO if there had been any ''major changes'' since his last visit, the TFO said no but that he ''was going to see if I could get the Oxys 80,'' but ''if not, the Roxies work fine for me.'' After noting that the TFO had been getting oxycodone (the same drug as Roxicodone), Respondent asked the TFO, ''is that what you would like?'' and whether 300 pills ''works for you?''

Notably, at no point did the TFO complain of pain, and other than Respondent's question whether there had been any ''major changes'' since his last visit, neither Respondent nor his assistant questioned the TFO about the nature and intensity of his pain, and its effect on his ability to function. Moreover, Respondent then asked the TFO if he would like Xanax and the TFO asked if he could get 100 tablets. Manifesting that he knew the TFO was a drug abuser, Respondent expressed his concern that he could get in trouble because the ''Xanax is so powerful'' if ''they found [the TFO] on the street unconscious'' with Respondent's name on the bottle in his pocket. Notwithstanding that there was no legitimate purpose for either prescription, Respondent prescribed 300 oxycodone 30mg and 90 Xanax 2mg to the TFO, in violation of 21 CFR 1306.04(a).

TFO 2's Prescriptions

As found above, at TFO 2's first visit, she represented that she had pain in her left arm, that the pain was related to her former work as a cocktail waitress, and that she had had the pain for over six months. However, Respondent made no further inquiry into whether the TFO had suffered an injury, the nature and intensity of her pain, its effect on her physical and psychological function, and whether she had previously been treated for it. Moreover, while the TFO stated that she had used Lortab and Soma for her pain, Respondent made no inquiry as to the TFO's source for these drugs. Furthermore, the TFO then asked Respondent if he would mind if she ''ask[ed] for something for stress?'' While Respondent stated that he thought the TFO would ''sleep better'' if she was relaxed, he conducted no inquiry into what symptoms the TFO had that would warrant prescribing Xanax. Respondent then prescribed 90 Percocet 10/325, 30 Xanax 2mg, as well as Soma. Based on Respondent's clear lack of compliance with the Nevada Board's *Policy,* I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Percocet and Xanax to the TFO.

Moreover, at her second visit, Respondent was not present and the TFO was seen by his assistant, who either called or faxed in prescriptions for 90 Percocet and 30 Xanax. While the TFO had stated that she was ''feeling better and everything,'' Respondent's assistant conducted no inquiry into the nature and intensity of her pain and its effect on her physical and psychological functioning. Nor did Respondent's assistant discuss with the TFO her use of Xanax and whether she even needed a refill. As noted above, while Respondent was not present at his clinic, the TFO's chart noted that he authorized the prescriptions. Accordingly, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in authorizing the prescriptions for Percocet and Xanax and therefore violated 21 CFR 1306.04(a).[8]

Based on the numerous controlled substance prescriptions which Respondent issued in violation of 21 CFR 1306.04(a), I conclude that the evidence relevant to factors two and four supports a finding that he has ''committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further conclude that Respondent's conduct is sufficiently egregious as to warrant the revocation of his registration and the denial of his application to renew his registration. Accordingly, I will order that Respondent's registration be revoked and that his pending application be denied.

[8] Because there is no evidence establishing the substance of what actually occurred during the TFO's third visit with Respondent (other than that she received more prescriptions), I conclude that there is no basis to conclude that these prescriptions also violated federal law.

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 BW5180372, issued to Henri Wetselaar, M.D., be, and it hereby is, revoked. I further order that any pending application of Henri Wetselaar, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.[9]

Dated: August 31, 2012.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–14]

T.J. Mcnichol, M.D.; Decision and Order

On October 27, 2011, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to T.J. McNichol, M.D. (Respondent), of Brandon, Florida. ALJ. Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration FM0624139, which authorizes him to dispense controlled substances in schedules II through V, as a practitioner, and the denial of any pending applications to renew or modify his registration, on the ground that his ''continued registration is inconsistent with the public interest.'' *Id.* at 1 (citing 21 U.S.C. 823(f) and 824(a)(4)).

As support for the proposed action and the immediate suspension, the Show Cause Order alleged that ''[o]n six separate occasions between approximately July 28 * * * and August 25, 2011, [Respondent] distributed controlled substances (oxycodone, a Schedule II controlled substance, and alprazolam, a schedule IV controlled substance) by issuing 'prescriptions' to [four] undercover law enforcement officers [hereinafter, UC or UCs] for other than a legitimate medical purpose or outside the usual course of professional practice.'' *Id.* at 2. More specifically, the Order alleged that on July 28, 2011, Respondent ''distributed'' 180 tablets of oxycodone 30mg and 60 tablets of alprazolam 1mg to UC1 on the

[9] Based on the allegations that led me to order the Immediate Suspension of Respondent's registration, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67

officer's ''first visit to [his] practice'' and that he did so ''after conducting only a cursory medical examination of [the officer] and despite [his] informing the [officer] that [his] physical exam did not correlate to any findings of pain as outlined'' on the officer's MRI, and although ''UC1 provided no history or illness that warranted the distribution of a controlled substance.'' *Id.* The Order further alleged that on August 25, 2011, Respondent distributed another 180 tablets of oxycodone 30mg and 60 tablets of alprazolam 1 mg to UC1, although UC1 ''provided no history of injury or illness that warranted the distribution of a controlled substance'' and after performing ''a cursory physical examination.'' *Id.*

Next, the Show Cause Order alleged that on July 28, 2011, Respondent distributed 150 tablets of oxycodone 30mg and 90 tablets of alprazolam 1mg to UC2 on his initial visit, even though ''UC2 provided no history of injury or illness that warranted the distribution of controlled substances'' and that Respondent ''conduct[ed] only a cursory physical examination'' which lasted ''approximately two minutes'' and ''despite the officer telling [Respondent] that he experienced little pain.'' *Id.* The Order further alleged that on August 25, 2011, Respondent distributed to UC2 an additional 150 tablets of oxycodone 30mg and 90 tablets of alprazolam 1mg after performing '' a cursory medical examination'' which ''consisted only of [Respondent placing his] hands on the mid to lower back area of UC2 and asking if [he] experienced any pain in those areas.'' *Id.* The Order also alleged that ''UC2 provided no history of injury or illness that warranted the distribution of a controlled substance'' and that Respondent's ''total interaction * * * with UC2 lasted approximately two minutes.'' *Id.*

With respect to UC3, the Show Cause Order alleged that on August 25, 2011, Respondent distributed 180 tablets of oxycodone 30mg and 30 tablets of alprazolam 2mg to the UC at his first visit, ''while conducting only a cursory physical examination and despite the officer not providing any information in his medical questionnaire about experiencing any pain.'' *Id.* at 2–3. The Order also alleged that ''UC3 provided no history of injury or illness that warranted the distribution of a controlled substance.'' *Id.* at 3.

Finally, with respect to UC4, the Show Cause Order alleged that on August 25, 2011, Respondent distributed 210 tablets of oxycodone 30mg and 60 tablets of alprazolam 2mg to the UC at his first visit. *Id.* The Order alleged that Respondent ''conduct[ed] only a cursory physical examination'' and that ''UC4 provided no history of injury or illness that warranted the distribution of a controlled substance.'' [1]

Respondent requested a hearing on the allegations; the matter was placed on the docket of the Office of Administrative Law Judges and assigned to ALJ Timothy D. Wing. Following pre-hearing procedures, the ALJ conducted a hearing on January 17–18, as well as April 10–11, 2012.[2] Upon conclusion of the hearing, the parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On May 17, 2012, the ALJ issued his recommended decision. With respect to factor one—the recommendation of the state licensing board—the ALJ found ''that Respondent currently holds a valid, unrestricted medical license in Florida and has never been disciplined by the Florida Department of Health.'' ALJ at 45. The ALJ thus found that, while this factor is not dispositive, it ''weighs against a finding that Respondent's continued registration would be inconsistent with the public interest.'' *Id.*

With respect to factor three—Respondent's conviction record under Federal or State laws related to the manufacture, distribution, or dispensing of controlled substances—the ALJ found that there was no evidence that Respondent has been convicted of such an offense. *Id.* While noting that this factor also is not dispositive, the ALJ concluded that it ''weighs against a finding that Respondent's continued registration would be inconsistent with the public interest.'' *Id.*

Next, the ALJ considered factors two—Respondent's experience in dispensing controlled substances—and four—Respondent's compliance with applicable laws relating to controlled substances, together. *Id.* at 46–91. The ALJ noted that, under Federal law, a prescription for a controlled substance must be ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.'' *Id.* at 46 (citing 21 CFR 1306.04(a)).

Reasoning that because ''Respondent's prescribing practices with regard to the undercover patients visits [were] not remotely close to 'outright drug deals,''' and that ''the undercover patient visits objectively reflect that Respondent's prescribing practices included, to a degree, a documented medical history, physician examination, documented urinalysis testing, medical record release forms, and pharmacy prescribing profiles, * * * consistent with applicable Florida law,'' the ALJ explained that ''any finding that Respondent's prescribing conduct * * * was not for a legitimate medical purpose and outside the usual course of professional practice under the Florida Standards or standards generally recognized and accepted in the medical community will significantly depend on the evidentiary weight'' given to the opinion testimony of the Government's Expert. *Id.* at 50. The ALJ then explained that, while he found the Government's Expert ''qualified by education and experience generally,'' he did not find the Expert ''qualified to render an expert opinion regarding Florida law and standards of medical practice'' because he was not aware of the current state standards and the ''significant change in the regulations as of October 2010.'' *Id.* at 51.

The ALJ further stated that he found that the Expert's testimony included ''inconsistencies, factual errors, vague or nonresponsive answers to basic questions, and an overall lack of interest or even curiosity in examining all available information relevant to Respondent's prescribing conduct.'' *Id.* at 53. While acknowledging that the Expert's ''testimony at various points did find some support in the evidence, overall his testimony and related opinions repeatedly demonstrated an unwillingness to consider positive conduct by Respondent, or even inquire of any, beginning with his October 24, 2011 report.'' *Id.* The ALJ also cited the Expert's financial interest as a Government Expert and what he characterized as a ''history of near uniformity of opinion testimony on behalf of the Government'' as grounds for his conclusion that the Expert's testimony lacked ''the necessary independence, objectivity, and factual basis to be relied upon.'' *Id.* at 57–58.

Accordingly, based on what he deemed to be the absence of ''credible medical opinion testimony,'' or other ''credible evidence of misconduct by Respondent,'' the ALJ rejected the allegations that Respondent lacked a

[1] Based on the above allegations, I concluded that Respondent's continued registration during the pendency of the proceeding ''constitute[d] an imminent danger to the public health and safety.'' ALJ Ex. 1, at 3. Accordingly, I ordered the immediate suspension of Respondent's registration. *Id.*

[2] While the ALJ noted the amount of time which has passed between the date of service of the Order to Show Cause and Immediate Suspension, ''which was exclusive of any delays attributable to Respondent,'' *see* ALJ at 43 n.72 (citations omitted), the record is devoid of any explanation as to why the hearing did not reconvene until April 10. Indeed, while the ALJ cited ALJ Ex. 26 in support for his calculation, *id.*, this exhibit was not forwarded as part of the record. Nor was the record timely forwarded by the ALJ to this Office following the receipt of the Government's Exceptions.

legitimate medical purpose and acted outside of the usual course of professional practice in prescribing to each of the UCs. *Id.* at 69, 75, 82, 91. The ALJ reached this conclusion notwithstanding his finding that Respondent prescribed Xanax to one of the UCs without any inquiry into ''the medical basis for continuing the prescription'' and that this ''arguably supports a finding that such a prescription lacks a legitimate medical purpose, or is outside the usual course of professional practice.'' *Id.* at 82. The ALJ thus concluded that factors two and four ''weigh heavily against a finding that Respondent's continued registration would be inconsistent with the public interest.'' *Id.* at 91.

With respect to factor five—such other conduct which may threaten public health and safety—the ALJ noted that Respondent, who had been called to testify by the Government, invoked his Fifth Amendment privilege and refused to testify. ALJ at 92. While the Government requested that the ALJ draw an adverse inference based on Respondent's refusal to testify, the ALJ declined to do so explaining that because the Government had failed to establish a *prima facie* case that ''Respondent's conduct was contrary to the public interest,'' his ''testimonial silence with regard to acceptance of responsibility'' was not relevant. *Id.* While acknowledging that an adverse inference may be permissible, the ALJ reasoned ''that the failure to testify alone may not be taken as an admission of wrongdoing, without regard to other evidence.'' *Id.* at 92–93. Noting that ''Respondent is facing uncertain criminal liability,'' the ALJ reasoned that he did ''not find his testimonial silence during this parallel administrative proceeding to make it more likely than not that he would dispute an untrue accusation.'' *Id.* at 93. The ALJ then explained that ''in light of the fact that the Government's evidence was insufficient to establish a prima facie case, particularly given the lack of credible medical expert testimony, Respondent's silence in and of itself does not appreciably tip the balance of evidence in favor of the Government.'' *Id.* The ALJ thus explained that even were he to draw an adverse inference, he would still find the evidence insufficient to conclude that Respondent's prescribing practices were unlawful. *Id.* Because in the ALJ's view, there was no other evidence that Respondent had engaged in conduct which may threaten public health or safety, the ALJ concluded that this factor also supported the continuation of Respondent's registration. *Id.* The ALJ thus recommended that the Order to Show Cause and Immediate Suspension be dismissed. *Id.* at 94.

On June 5, 2012, the Government filed Exceptions to the ALJ's recommended decision. Thereafter, on June 14, 2012, the ALJ forwarded the record to me for Final Agency Action.

I have carefully considered the entire record including the ALJ's recommended decision and adopt his findings with respect to factors one and three. However, I reject his findings with respect to factors two and four because, with respect to many of the prescriptions (especially those for alprazolam) Respondent issued to the undercover officers, expert testimony was not necessary to prove that he lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing them. Indeed, with respect to one of the undercover officers, the ALJ ignored nearly all of the evidence of the conversation which occurred between Respondent and the officer which shows that Respondent knew the undercover officer was a drug abuser and that he engaged in an outright drug deal.

Likewise, with respect to the alprazolam prescriptions Respondent issued to three of the undercover officers, the ALJ entirely ignored relevant evidence and failed to discuss the evidence pertaining to these prescriptions. In other instances, the ALJ mischaracterized the evidence he cited. Finally, with respect to several issues, the ALJ failed to apply properly, or ignored entirely, precedents of both the Agency and federal courts.

Accordingly, as ultimate factfinder, I reject the ALJ's legal conclusion that the Government has not met its *prima facie* burden of showing that Respondent has committed acts which render his continued registration inconsistent with the public interest. *See Reckitt & Coleman, Ltd.,* v. *Administrator,* 788 F.2d 22, 26 (DC Cir. 1986) (citing 5 U.S.C. 557(b) (''On appeal from or review of the initial decision, the agency has all the power which it would have in making the initial decision * * *'')). Because even assuming, without deciding, that the Expert's testimony is not entitled to weight (notwithstanding the ALJ's inconsistent statements regarding the weight he was giving it), the record still contains substantial evidence that Respondent violated 21 CFR 1306.04(a) in issuing several of the prescriptions and he has offered no evidence that he acknowledges his misconduct and will refrain from engaging in similar acts in the future, I will order that Respondent's registration be revoked and that any pending application be denied.

I make the following

Findings of Fact

Respondent Registration and Licensing Status

Respondent is the holder of DEA Certificate of Registration FM0624139, which prior to the issuance of the Order of Immediate Suspension, authorized him to dispense controlled substances in schedules II through V as a practitioner, at the registered location of Quality Care Medical Group (hereinafter, QCMG), 143 Oakfield Drive, Suite 102, Brandon, Florida. GX 1–2. Respondent's registration does not expire until January 31, 2014. GX 2.

Respondent is also the holder of an active medical license issued by the Florida Board of Medicine, which does not expire until January 31, 2014. ALJ at 45 n.76. There is no evidence that Respondent's state license has been the subject of any disciplinary proceedings. *See id.*

The DEA Investigation of QCMG

QCMG first came to the attention of DEA in early 2010, when a Task Force Officer (TFO) received information from various sources including citizens, anonymous callers and a cooperating defendant regarding a QCMG clinic located in Bradenton, Florida. Tr. 50–53. The information included a report that persons were traveling to QCMG from out-of-state locations, that QCMG allowed sponsors to bring groups of people into the clinic, and that persons were presenting fraudulent MRIs and prescription profiles to obtain admission as patients. *Id.* at 53–55.

In June 2011, DEA commenced undercover operations at the Bradenton location and sent in several undercover officers who presented MRIs and patient profiles and were able to see the doctor who worked at that location. *Id.* at 61, 70–71. During the investigation, the officers determined that the owners of QCMG also had a clinic located in Brandon, Florida and decided to conduct undercover operations at the latter location as well. *Id.* at 72. In total, four undercover officers made visits to the Brandon location. *Id.* at 73. Two of the officers, who used the undercover names of Anthony Thompson and Robbie Payne, each made two visits to the Brandon clinic and saw Respondent on both occasions. *Id.* The other two officers, who used the undercover names of Mike Corleone and Eric McMillen, went to the Brandon location and saw Respondent once. *Id.*

The Undercover Visits of Robbie Payne

On some date not specified in the record but shortly before July 28, 2011, a Task Force Officer (TFO) using the undercover name of Robbie Payne went to the QCMG Bradenton clinic but was turned away because he did not have an appointment. Tr. 169–70. During a discussion following the operation, the investigators decided that the TFO would contact the Brandon clinic and make an appointment. *Id.* at 174. The TFO called the Brandon clinic and was able to make an appointment for July 28th. *Id.*

On July 28, the TFO went to the clinic, wearing a recording device, and brought an MRI and a profile purporting to show what prescriptions he had obtained; the latter showed that Payne had last received prescriptions for 210 tablets of oxycodone 30mg, 90 tablets of oxycodone 15mg, and 90 tablets of Xanax 2mg on April 10, more than three and a half months earlier.[3] *Id.* at 174–77; RX 4, at 15; RX 1, at 36–39. The TFO testified that he was required to fill out various forms requiring personal information, waivers, and a questionnaire which included historical information, previous medications, pain levels, and how the pain ''affected'' his life. Tr. at 175. The TFO further testified that the questionnaire used a ''0 through 10'' pain scale and asked him to rate his ''pain at that moment'' and when he was ''on medications.'' *Id.* at 175–76. While the TFO did not remember ''the exact number'' he wrote down for his pain at the present time, he testified that usually writes ''something between 0 and 4.'' *Id.* at 176. With respect to what he wrote as his pain level with medications, Payne testified that he would write ''the same number.'' *Id.*

The TFO did not, however, recall whether the questionnaire had any questions regarding whether he suffered from anxiety. *Id.* Eddie Gomez, Respondent's Medical Assistant, testified that the medical questionnaire which patients were required to fill out contained no information about anxiety. *Id.* at 984. However, Gomez then changed his testimony, explaining that the questionnaires, which were subsequently shredded under the clinic's policy, did ask about anxiety. *Id.* at 985–86.

The TFO also testified that one of the forms had a picture of a human body and that he ''deliberately'' circled a part of the body that was different than his MRI ''to disprove * * * the MRI.'' *Id.* at 180. After turning in his paperwork and paying for the visit, Payne took a seat in the waiting room. *Id.* at 176–77.

The TFO was eventually summoned from the waiting room by Eddie Gomez, who identified himself as the office manager and Respondent's assistant. *Id.* at 178; GX 14, at 4. Gomez took the TFO's height, weight and blood pressure; Gomez then asked him whether he was going to another pain management clinic (with the TFO answering ''no'') and stated that the clinic reported doctor shoppers to the authorities. Tr. 178; GX 14, at 4. Gomez explained that ''[t]hese are Schedule II drugs, C II drugs, uh * * * narcotics. You cannot share them, sell them, okay?,'' and asked the TFO if he was ''abusing pain meds or illegal substances.'' *Id.* at 5.

Gomez then said that he was going to do a drug screen on the TFO and asked him when the last time was that he took his meds. *Id.* The TFO stated that he had been prescribed drugs ''a while ago,'' and Gomez acknowledged that ''April was the last script.'' *Id.* The TFO then added that ''that was the last time * * * that I actually saw a doctor, but I take them here and there, from * * * wherever.'' *Id.* Gomez asked if the TFO had taken drugs ''this morning?'' *Id.* The TFO replied ''[n]o, no, no'' and added that it was ''a week or two.'' *Id.* Gomez then asked how long the TFO had been on pain meds, with the latter replying that he had started about a year and a half to two years ago, but that it was ''kind of sporadic.'' *Id.* at 6. Gomez then asked the TFO what clinic he had gone to; the TFO stated that the clinic was in south Florida and named ''Real Care'' but that he thought the clinic had gone out of business. *Id.*

Gomez gave the TFO a cup for a urinalysis and the TFO provided a sample. *Id.* at 6–7. Gomez then tested the TFO's sample, which ''came back all negative.'' Tr. 179; GX 14, at 8. Gomez, however, prepared a Drug Urinalysis Test form on which he circled that the TFO was ''positive'' for ''Oxy.'' RX 1, at 40. In his testimony, Gomez insisted that the TFO tested positive for oxycodone. Tr. 944–45, 959. However, I find (as did the ALJ) that Gomez falsified this form. Thereafter, Gomez escorted the TFO to an exam room.

The TFO testified that Gomez did not ask him about the source of his pain, or whether he had any problems with anxiety or sleeplessness. *Id.* at 181–82. Gomez testified at the hearing that if the TFO ''was a new patient,'' Respondent (and not himself) would ask the patient if he had pain or anxiety. *Id.* at 959–60. Moreover, Gomez testified that one of his responsibilities was to review the information that the patients provided on their medical questionnaires and enter the information into the clinic's Electronic Medical Record System (EMR). *Id.* at 932, 952.

Gomez testified that after the information was entered into the EMR, ''it was shredded.'' *Id.* at 940, 952.[4] Gomez also testified that in doing the ''review of systems,'' his role was to review the patient's ''past medical history, social history, which was on the initial paperwork, [and] any family history, if they had any family history.'' *Id.* at 942.

Respondent entered the exam room and introduced himself. GX 14, at 9. Respondent noted that the TFO had been in pain management in south Florida but that ''they went out of business.'' *Id.* The TFO said ''yes'' and Respondent surmised that his previous clinic had been ''shut down.'' *Id.* The TFO replied that he did not ''know what happened to them.'' *Id.* at 10.

Respondent reviewed the TFO's MRI, noting that it showed a ''mild disc bulge'' at ''two levels, without significant central canal or neuro.''[5] *Id.* Respondent then told the TFO that ''[t]he reason why they're out of business is cause they've been prescribing inappropriately. Okay?'' *Id.* The TFO replied, ''uh-hum,'' and Respondent stated: ''I can't give you near the pills that you were getting. Not even remotely close. You, I, I haven't even done a physical exam * * * Just based on your MRI here, its * * * I can't do it.'' *Id.*

The TFO replied that ''that's just what they prescribed, that's not what I actually took,'' and after Respondent said ''okay,'' the TFO added: ''So I didn't * * * I didn't, I can't * * * tell, you're the doctors, so I don't know * * * So that's just what they gave.'' *Id.* After acknowledging the TFO's statement, Respondent stated ''you know you got two bulging discs, with, and it doesn't talk about pushing on any

[3] The profile also showed that Payne had filled prescriptions for the same three drugs and strengths on a monthly basis between December 10, 2010 and April 10, 2011.

[4] When asked by Respondent's counsel whether there was ''a possible explanation'' for the various entries that the undercovers had no problems with anxiety and denied problems with mood disturbance, Gomez testified that the EMR system had various default entries, such that ''if something is not input or checked, it'll put whatever is on default.'' Tr. 1004. However, Gomez could not further identify what the default entries were for various sections of the medical record, *id.* at 1004–5, and did not know if there was a default entry for anxiety. *Id.* at 1008. In any event, if any of the undercovers had represented to Gomez or Respondent that he had anxiety, one must wonder why an entry documenting this would not have been made in the chart.

[5] The TFO's MRI stated that he had ''mild diffuse bulge of [the] L4–5 and L5–S1 discs, without any significant central canal or neural foraminal narrowing'' and that ''no other significant abnormality is detected in this study.'' RX 1, at 34.

nerve roots or anything like that, I mean, this is as close to a normal MRI as you can get without it being actually normal. You see what I'm saying?'' *Id.* The TFO replied ''uh-hum,'' and Respondent added: ''I mean the most I can do for you would * * * And I'm telling you this in case you don't want to come here. Okay? Cause I hate for you to spend all of your money, coming here and not get what you need.'' *Id.*

The TFO said ''alright'' and Respondent added: ''Okay? Could, and * * * what you should get, and what you need, often sometimes is two different things cause if you've been on a certain number of pills, for a long time, if you don't get those number of pills, you're going to be sick.'' *Id.* at 11. After the TFO said that he ''got that,'' Respondent stated: ''you know what I mean? So I mean, I'm at the point * * * I mean just by looking at this without even doing the physical exam yet. * * * I mean I'm looking at maybe a hundred and fifty of them.'' *Id.* The TFO replied: ''And honestly that's about where I was.'' *Id.* Respondent proceeded to conduct his physical exam which took all of one minute and thirty-nine seconds. GX 13.

During the physical exam, Respondent asked the TFO various questions regarding the location of his purported pain. GX 14, at 11. For example, Respondent asked the TFO if most of his pain was in his lower back. *Id.* The TFO replied: ''uh-hum.'' *Id.* Next, Respondent asked: ''How about out to the sides, here?'' *Id.* at 12. The TFO again replied: ''uh-hum.'' *Id.* Respondent then asked: Down on this side?'' *Id.* The TFO replied: Yeah. *Id.* Respondent then asked ''anything like that?'' *Id.* The TFO answered: ''a little bit.'' *Id.* Respondent then asked: ''[a]nything on this side?'' *Id.* The TFO replied, ''Uh-hum * * * probably the same as the other side, I guess, yeah.'' *Id.*

Following an apparent test of the TFO's reflexes, Respondent asked him to stick his legs out and whether doing so caused pain; the TFO stated ''not right now.'' *Id.* Respondent then asked the TFO to give him ''a little twist'' and whether this caused pain; the TFO said ''not at the moment.'' *Id.* Respondent said ''that's fine,'' and asked the TFO to give him ''another little twist''; the TFO again denied that the movement caused any pain. *Id.* Respondent then noted that he was done with the physical exam. *Id.*

Following a discussion of the EMR system, Respondent asked the TFO if he had been getting Xanax. *Id.* at 13. The TFO answered ''yes,'' and when Respondent asked ''for anxiety?'' the TFO said ''for sleep.'' *Id.* Respondent noted the TFO's answer and explained that he did not prescribe the two milligram dosage units of Xanax because of its ''a high street value'' and only prescribed the one milligram strength. *Id.* While Respondent told the TFO that he should not double up on the Xanax, he did not engage the TFO in any further discussion regarding his sleep problems. *Id.*

After Respondent and the TFO discussed how the latter made his living, Respondent gave the TFO his ''new patient talk,'' which included telling him to take his medication as prescribed, and that there is ''no such thing in this clinic * * * of running out of medication. *Id.* at 14–16. Respondent further explained that ''one of the reasons why we don't run out here'' is because ''I don't want you taking medication, the way you want to take them, because that will put you in jeopardy of overdose.'' *Id.* at 16. Respondent added that ''I don't want you to do that, that, I don't want you to, risk my license by doing that, and on top of that I want to keep you in the clinic.'' *Id.* Respondent explained that the TFO would be subject to random urine testing and that it was a ''no tolerance clinic.'' *Id.* Respondent also told the TFO not give to give his ''medication to anybody else,'' or ''take any from anybody else,'' and that if his medication was stolen, he needed a police report. *Id.* Respondent then asked the TFO if he had any questions; the TFO said no. *Id.* at 16–17.

Respondent added: ''We're pretty strict here * * * but we do have fun also,'' a point which he reiterated. *Id.* at 17 (''We have fun, we, you know, we're a pretty fun office, uh, but we do, we uh strictly do things by the book.''). Respondent then showed the TFO the window where he would get his prescriptions and said that he would see him ''in a month.'' *Id.* at 17–18. The visit then concluded. *Id.* at 18.

The evidence shows that Respondent wrote the TFO a prescription for 150 tablets of oxycodone 30mg, and a prescription for 90 tablets of Xanax 1mg. GX 15, at 1. In the medical record for the visit, Respondent documented the TFO's pain level as a ''3'' and that it was of mild severity.[6] RX 1, at 26. Moreover, in the physical exam portion of the record, Respondent documented having palpated the TFO's cervical spine as well as paravertebral muscle groups, yet the video recording of the visit clearly shows that this was never done. RX 1, at 28; GX 13. In addition, Respondent documented findings based on range of motion tests (rotation, bending, flexion, and extension) for all three portions of the TFO Payne's spine (cervical, thoracic and lumbar). RX 1, at 28. Here again, the video shows that while Respondent had the TFO twist his torso and do a straight leg raise of both legs, he did not test the TFO's range of motion on bending, extension or flexion. GX 13. Nor did he do any tests of the TFO's range of motion in his cervical spine. *Id.*

In the TFO's medical record, Respondent further recorded a diagnosis of ''generalized anxiety disorder,'' which he deemed to be ''active'' and ''chronic,'' notwithstanding that under the ''psychiatric'' section of the ''review of systems'' section, Respondent noted that ''Patient denied problems with mood disturbance. No problems with anxiety.'' RX 1, at 27–28.

Likewise, under the ''psychiatric'' section of the physical examination, Respondent noted: ''Oriented with normal memory. Mental status, judgment and affect are grossly intact and normal for age.'' *Id.* at 20.[7] *See also* Tr. 190–92 (TFO's testimony that Respondent did not discuss whether he had generalized anxiety disorder and whether he saw another physician for treatment of anxiety'').

In addition, in the ''Instructions'' section of the medical record, Respondent wrote the following:

> Patient appears to understand risks. Patient instructed to RTC/call clinic if patient experiences any non-urgent side effect such as constipation, nausea, itching, rash & etc. Return to clinic as scheduled. Patient instructed to go to emergency room immediately if the patient has any serious symptoms such as SOB, severe allergic reactions, LOC, Syncope, new neurologic deficits, bowel/bladder incontinence, excessive drowsiness and vomiting.

RX 1, at 29. At no point during this visit, however, did Respondent discuss with the TFO any of these instructions. *See* GX 13–14. Most significantly, at no time did Respondent ask the TFO what caused his pain or injury and how he gotten by when his last prescriptions were issued more than three months earlier, or why he had tested positive for oxycodone given when he had purportedly last filled prescriptions for the drug.

[6] Mr. Gomez testified that the pain levels recorded in the EMR were with medications. Tr. 964–65. However, the TFO testified that he wrote the same pain number for his pain both with and without medications. *Id.* at 176. Notably, there is no evidence that Respondent addressed this with the TFO.

[7] Respondent also diagnosed the TFO as having lumbar disc displacement, lumbar lumbosacral disc degeneration, and backache unspecified, which was chronic and active. RX 1, at 28.

On August 25, the TFO, again wearing a recording device, returned to the Brandon clinic. Tr. 192. Upon his arrival, the TFO checked in with the receptionist and paid the fee for the visit. RX 4, at 21–22. Before even seeing Respondent, the receptionist gave the TFO an appointment for a follow-up visit. *Id.* at 22.

After about twenty-five minutes, Eddie Gomez called the TFO back to the triage room and took his weight and blood pressure. GX 17, at 2–3. Gomez then told the TFO to return to the waiting room and that he would be called next. *Id.* at 3. After a short wait, Gomez told the TFO to go to an exam room. RX 4, at 22–23.

Respondent entered the exam room and asked the TFO ''what's going on''; the TFO replied: ''How you doing?'' GX 17, at 4. Respondent answered, ''All right, what's up? How did your month go?'' *Id.* After the TFO said that ''everything is good,'' Respondent asked: ''Medication treatin[g] your pain well?'' *Id.* The TFO answered ''Yeah,'' and added that he had ''no problems or issues.'' *Id.* Respondent asked: ''No questions?'' The TFO replied: No, mm-mm. Everything is good.'' *Id.*

Respondent then stated that he would ''be feeling [the TFO's] lower back and get you going''; Respondent then asked: ''[a]ny pain down in this areas here, how about here?'' *Id.* The TFO replied: ''Mm-mm.'' Respondent then asked: ''Anything out on the sides at all?'' The TFO answered: ''Nothing that was, uh, * * * any different than the last.'' *Id.* Respondent asked: ''Nothing was—nothing like this, right?'' *Id.* The TFO replied: ''Mm-mm.'' *Id.* Respondent then said ''all right. Questions? Nope, you are all set.'' *Id.* The TFO then thanked Respondent. *Id.* At the conclusion of the visit, Respondent issued the TFO prescriptions for another 150 oxycodone 30mg and 90 Xanax 1mg. GX 18.

The entire interaction between the TFO and Respondent lasted less than two minutes. GX 17. As the TFO wrote in his report for the visit:

> [Respondent] asked the UC ''are the meds treating your pain well?'' to which the UC replied ''yes, no issues.'' [Respondent] asked if the UC had any questions, and the UC replied that he did not. [Respondent] then got up and walked toward the door. Before exiting, [Respondent] stated ''let me feel your lowerback and get you going.'' The UC scooted forward in his chair and [Respondent] placed his right hand on the UC's lower back. [Respondent] asked, ''pain down here in this area?'' to which the UC stated ''uh-huh.'' [Respondent] then moved his hand to the right and left of the UC's spine and asked ''anything over here?'' to which the UC stated ''nothing is different than last time.'' [Respondent] removed his hand from the UC's lower back and stood straight up, asked if there are any more questions, to which the UC stated ''no,'' and then [Respondent] told the UC he was all set.

RX 4, at 23.

Here again, evidence shows that Respondent made findings in the medical record notwithstanding that he never performed various tests. For example, the medical record for the visits noted that there was ''no change'' in the pain's ''status,'' noted that it radiated into his ''upper back,'' that the ''timing'' of the pain was ''constantly, during the day and EVENING,'' and that its ''quality'' was ''radiating and dull.'' The record further listed ''sleep and physical activity'' as ''affected daily activities.'' RX 1, at 30.

Respondent also documented that he had done a neurologic examination, in which he found that the TFO had ''[n]ormal and symmetrical deep tendon reflexes with no pathological reflexes.'' RX 1, at 31. Likewise, Respondent made findings that he had palpated the TFO's cervical spine and the surrounding areas, as well as that he had had the TFO perform various range of motion tests of various portions of his spine. *Id.* at 31–32. However, as the TFO's report makes clear, Respondent did not do anything other than palpate his lower back area. RX 4, at 22–23.

The Undercover Visits of Anthony Thompson

On July 27, 2011, a Special Agent, who used the name of Anthony Thompson, attempted to see a doctor at the QCMG clinic Bradenton. Tr. 240. While the Agent was turned away because he was not thirty years of age and his MRI could not be verified, a staff member advised him to go to the Brandon clinic because it was not ''as strict as the Bradenton clinic.'' *Id.* at 240–41.

The next day, the Agent, who was wearing a recording device, went to the Brandon clinic and presented an MRI[8] and a prescription profile. *Id.* at 240–41. The Agent filled out various forms covering his personal information, past history and family history of illnesses, and a questionnaire regarding his pain levels. *Id.* at 243. The Agent did not recall the actual numbers he had written on the pain questionnaire, but stated that he would have written a five or below. *Id.* The Agent did not recall whether any of the questionnaires asked if he had anxiety. *Id.* at 244. According to the medical record, the Agent's pain was of ''mild'' severity and was ''4 on pain scale,'' and that it radiated into the ''neck and upper back.'' RX 1, at 15. In addition, while the medical record indicates that the Agent complained that his pain occurred ''frequently and nocturnally'' and was aggravated by sleeping, walking and standing for a long period of time,'' the Agent denied that he told this to either Mr. Gomez or Respondent. Tr. 282–83; RX 1, at 15.

Mr. Gomez called the Agent and identified himself as the doctor's assistant. GX 7, at 3. Mr. Gomez proceeded to review the rules of the pain contract, told the Agent that the clinic reported doctor shoppers, asked if he was taking ''any illegal substances,'' and what pain management clinic he was going to. *Id.* The Agent replied that he had seen a Dr. Barton, who had since died. *Id.* Mr. Gomez then asked the Agent about Dr. Burns, a physician who was listed as the Agent's physician on the MRI. *Id.,* RX 1, at 23. The Agent replied that Burns was ''somebody that the MRI place referred me to,'' noting that he ''had to get a new MRI.'' GX 7, at 3. Gomez then asked the Agent when he had last gotten his pills and when he had last taken them; the Agent replied that he thought he had filled his prescriptions ''in the middle of June.'' *Id.* Gomez then said: ''So you shouldn't have anything in your system,'' and the Agent answered: ''Right, I don't have anything; I've been out for a while.'' *Id.* at 3–4. Gomez then said he was going to do a drug screen on the Agent. *Id.* at 4.

After taking the Agent's weight and blood pressure, Gomez asked him about his employment status, education level, marital status, and whether he had kids; whether he smoked, used alcohol or caffeine; whether he had any blood transfusions; whether he had body piercings or tattoos; whether he exercised; and whether he had any significant family history. *Id.* at 5–6. Gomez then tested the Agent's urine sample. *Id.*

According to the Drug Urinalysis Test form, the Agent tested positive for benzodiazepines and oxycodone. RX 1, at 24. At the hearing, however, the Agent testified that he did not take either benzodiazepines or oxycodone; that in his position, he was subject to drug testing; and that he could not take these medications unless they were prescribed to him. Tr. 301. While Gomez insisted in his testimony that the Agent had tested positive for these

[8] The MRI findings included: A ''[l]eft posterolateral disc herniation at L5–S1 with moderate ventral effacement of thecal sac and moderate effacement of the left S1 nerve root''; a ''[c]entral and left posterolateral disc herniation at L4–5 with moderate secondary central spinal stenosis''; ''[s]mall central disc herniation'' at both L2–3 and L1–2; and a ''[d]iffuse central disc bulging at L3–4.'' RX 1, at 23. The MRI included a notation that it was verified on ''7/28/11.'' *Id.*

drugs, and noted that the form was signed, Tr. 943–44, 962–63; the ALJ noted that the Agent did not recall signing the form and that both the recording and the Agent's report concerning the visit show that Gomez had confirmed that the test was negative. ALJ at 71. Accordingly, the ALJ did not find Gomez's testimony credible and I adopt this finding.

Following a discussion of the clinic's recordkeeping system, Gomez took the Agent to an exam room. GX 7, at 7. Respondent eventually entered the room, introduced himself, and proceeded to look at the Agent's MRI. *Id.* at 7–8. Respondent then asked the Agent if most of his pain was in his lower back. *Id.* at 8. The Agent replied: ''Um kinda up towards the mid back too.'' *Id.* Respondent replied ok, and asked how the Agent ''hurt [his] back.'' *Id.* The Agent answered that ''[i]t's just something that, it's over time.'' *Id.* Respondent asked if it had ''gotten worse?'' and the Agent said ''Ah huh.'' *Id.*

Respondent said ''ok,'' and proceeded to conduct a physical exam which lasted less than two minutes. *Id.* During the exam, Respondent placed a stethoscope on the Agent's back and stomach and asked him to breath, tested the reflexes in the Agent's knees, and had him sit on the edge of an exam table and extend his legs out straight and asked if this caused pain in his back; the Agent replied: ''It's ok.'' *Id.* Respondent then placed his hands on the Agent's shoulder, and pressing downward, asked the Agent to turn his torso to each side and whether this was painful. *Id;* RX 4, at 4–5. The Agent replied ''mmm,'' to which Respondent said ''mmm? You don't have to; it doesn't mean anything it just helps me assess.'' GX 7, at 9. The Agent said ''ok,'' and the physical exam ended. *Id.*

The Agent then asked Respondent how long he had been at the clinic; Respondent said that he had been there since February and that when he started there, the doctors who had come before him ''would basically give anything to anybody.'' *Id.* Respondent also stated that the clinic had had an employee, who ''was doing shady things'' but had since been fired and reported to DEA. *Id.* Respondent further maintained that he had ''clean[ed] the practice up a bit'' by ''dropping people down to reasonable levels on their medications, that * * * what the state and medical personnel would deem what is appropriate.'' *Id.* He also stated that ''it seemed like everyone was on'' the ''trifecta'' of Oxycodone, Xanax, and Soma, which was ''just asking for trouble'' in the form of overdose deaths. *Id.* Respondent noted that Soma metabolizes into a substance, which reacts and magnifies the effect of oxycodone and Xanax, which ''are respiratory suppressants to begin with.'' *Id.* Respondent then stated that ''we want to comply with all of the laws, we want to do things appropriately, and not piss the DEA or any law enforcement agency off.'' *Id.* Respondent added that ''we're naïve to think they haven't sent people through here as fake patients'' but that he was fine with this because he doesn't ''do anything I'm not supposed to do.'' *Id.* at 9–10.

Respondent then told the Agent that his physical exam did not ''one hundred percent correlate with [the] finding on your MRI,'' and that his ''physical exam [wa]s a lot better than your MRI,'' but that ''there is some stuff on your MRI that would justify you having pain.'' *Id.* at 10. Respondent then asked ''why were they giving you 30's and 15's?'' *Id.* The Agent replied, ''That's what he had prescribed.'' *Id.*

Respondent replied that ''that's very odd'' because ''the 30's and 15's are * * * both break through medications'' and ''do the same thing.'' *Id.* After the Agent interrupted, asking ''splitting them up like that?,'' Respondent stated that this was ''a common way for doctors to hide more medication.'' *Id.* Respondent then explained that ''I wouldn't say hide'' but that ''the unofficial max is like 240, 210, 240 on 30's,'' and that doctors would write ''a prescription for 240 then they'll throw in a 120 15 * * * instead of writing 300 or so'' in the event ''they get investigated.'' *Id.* Continuing, Respondent added that he would ''rather not do both types of medications,'' meaning the 30s and the 15's. *Id.*

Respondent then told the Agent that based on the latter's MRI and physical exam, he would give him 180 tablets of oxycodone 30mg but not the 15s. *Id.* The Agent replied ''ok,'' and Respondent added: ''Just to give you essentially the same amount of milligrams all along, * * * what I'd like to do is taper you down as far as we can go, where that you're still comfortable.'' *Id.* at 11. Respondent then noted that the Agent was ''fairly young, your [sic] 29'' and that most people under the age of 30 don't need to be on pain management.'' *Id.*

Next, Respondent said: ''I take it you have some anxiety as well is that what's going on with you?'' *Id.* After the Agent replied, ''Yeah, that's the Zanny's help out,'' Respondent said: ''Ok, first of all let me tell you we don't call them Zanny's or bars or any of the street terms in here, ok, we call them Xanax or alprazolam, whichever one you want to call them.'' *Id.* Respondent then explained that ''I don't typically give the two milligrams out[,] I give the ones * * * the twos have too much of a street value.'' *Id.*

Respondent then observed that ''on July 1st[,] the law states now that if the patient has a psychiatric um problem along with being on pain management the law states we have refer you to psychiatry.'' *Id.* After the Agent said ''ok,'' Respondent said ''that doesn't necessarily mean you have to follow up with that, that just means I have to tell you to go, which is I am telling you to go.'' *Id.*

Respondent did not, however, provide the Agent with the name of any psychiatrist to see. Tr. 255. Moreover, in the psychiatric section of the ''review of systems,'' Respondent noted: ''Patient denies problems with mood disturbance. No problems with anxiety.'' RX 1, at 16. Likewise, in the psychiatric portion of the physical examination, Respondent documented: ''Oriented with normal memory. Mental status, judgment and affect are grossly intact and normal for age.'' *Id.* at 17. Respondent nonetheless recorded a diagnosis of ''Generalized Anxiety Disorder'' which was ''active'' and ''chronic.'' *Id.*

Respondent then gave the Agent his ''new patient speech'' and the visit ended. *Id.* at 11–12. According to the medical record, Respondent diagnosed the Agent as having lumbar disc displacement, lumbar lumbosacral disc degeneration, and backache unspecified, all of which were ''active'' and ''chronic.'' RX 1, at 17. At the conclusion of the visit, Respondent issued the Agent prescriptions for 180 tablets of oxycodone 30mg and 60 tablets of Xanax 1mg. GX 8, at 1.

On August 25, 2011, the Agent returned to the clinic, and again wore a recording device. Tr. 256. The Agent met the receptionist, paid the fee for the visit and sat down in the waiting room. RX 4, at 10–11. After approximately thirty minutes, the Agent was called by Mr. Gomez for triage, who took his weight and blood pressure. GX 10, at 6; RX 4, at 11. Mr. Gomez did not, however, ask the Agent any questions regarding his health. GX 10, at 6; RX 4, at 11. The Agent then returned to the waiting room. RX 4, at 11. Moreover, the Agent testified that he did not recall filling out any forms at this visit. Tr. 295.

Shortly thereafter, Mr. Gomez called the Agent and took him to an exam room. Respondent entered the exam room, and after exchanging pleasantries, asked the Agent if the ''medication is

working ok?'' GX 10, at 7. The Agent answered: ''Yep, great.'' *Id.* Respondent asked: ''Questions for me at all?'' *Id.* The Agent replied, ''No, I'm good.'' *Id.* Respondent then asked: ''The medications are controlling your pain well?'' *Id.* The Agent replied: ''Yeah, everything's great.'' *Id.*

Respondent then had the Agent stand up and explained that ''[t]he state makes me do a physical exam each time.'' *Id.* Respondent placed his hand on the Agent's mid to lower back and asked: ''Most of the pain in here at all? Is this where it is or is it down further.'' *Id.;* RX 4, at 12. The Agent stated: ''Right around that whole area.'' GX 10, at 7. Respondent replied: ''Right around this whole area? All right.'' *Id.* Respondent ''then directed the [Agent] out of the'' exam room and the two walked up to the receptionist's counter, where Respondent obtained two printed prescriptions, which he signed and gave to the UC. RX 4, at 12. The prescriptions were for 180 tablets of oxycodone 30mg and 60 tablets of Xanax 1mg. GX 11.

The medical record for this visit indicates that the Agent presented with low back pain, with a severity which was ''mild'' and a ''4 on the pain scale,'' that there was ''no change'' in the pain's status, and that the pain radiated into the Agent's ''neck and upper back.'' RX 1, at 19. In the review of systems section, the record again states: ''Patient denied problems with mood disturbance. No problems with anxiety.'' *Id.* And, as before, in the psychiatric section of physical examination portion, the record states: ''Oriented with normal memory. Mental status, judgment and affect are grossly intact and normal for age.'' *Id.*

The medical record further documents various tests as having been performed which clearly were not. For example, under the neurologic findings for the physical exam, the record states ''normal and symmetrical deep tendon reflexes with no reflexes.'' *Id.* Yet there is no evidence that Respondent tested the Agent's reflexes.

Likewise, with respect to the Agent's lumbar spine, the record states: ''Full active ROM with rotation, Full active ROM with bending. Full active ROM with flexion and Full active ROM with extension.'' RX 1, at 21. And with respect to the Agent's thoracic spine, the record states: ''Full active ROM with extension. Full active ROM with flexion. Full active ROM with bending. Full active ROM with Rotation.'' *Id.* at 21. Here again, the evidence shows that these tests were not performed.

The Undercover Visit of Eric McMillen

On August 25, 2011, another Special Agent, using the name of Eric McMillen, saw Respondent at the Brandon Clinic. However, on July 21, 2011, the Agent had seen a Dr. Mosley at the QCMG Bradenton clinic. GX 20; Tr. 348–55. The Agent acknowledged that he had provided a pharmacy profile and MRI,[9] *id.* at 385 & 353; filled out a medical questionnaire at this clinic, which asked that he rate his pain, *id.* at 349–50; that a physician's assistant had asked him some questions about the nature of his pain, as well as why he was in Bradenton when his driver's license indicated that he was from Fort Lauderdale, *id.* at 352; that he had complained of pain in his ''lower back, specifically the lower back right side,'' *id.* at 355; and that it was possible that he had noted on the paperwork that when the pain was at its worst, he had ''some trouble sleeping.'' *Id.* at 356. The Agent further testified that he ''probably'' saw the doctor at the Bradenton clinic for ''at least thirty minutes,'' and on cross-examination agreed that Mosley's exam was ''pretty thorough.'' *Id.* at 413. At the conclusion of the visit, the Agent obtained prescriptions from Dr. Mosley for 180 tablets of oxycodone 30mg and 30 tablets of Xanax 2mg. *Id.* at 356–58; GX 20.

The Agent's medical record also includes a chart for his initial visit with Dr. Mosley. RX 1, at 60–61. While the chart lists Dr. Mosley's prescriptions to include ''Xanax 2 mg qhs PRN Anxiety #30,'' notably the chart contains no findings pertinent to the Agent's having anxiety (or sleeping problems) and Mosley did not list anxiety as one of his diagnoses in the diagnosis/assessment section of the chart. *See id.* Indeed, on the first page of the chart, under ''Psych Hx,'' the block for anxiety (as well as other mental health conditions) is blank, and in the portion of the form for noting whether the patient had a family history of various conditions including ''mental health,'' Mosley wrote ''none.'' *Id.* at 61.

On August 25, 2011, the Agent, who wore a recording device, went to the Brandon clinic where he saw Respondent. Tr. 358–59, 363. While the Bradenton clinic was supposed to fax over the Agent's medical record, it had not done so; the Agent was subsequently required to fill out a medical questionnaire which asked about the location of the pain, how it had occurred, and what medications he was on. *Id.* at 365. However, the forms did not include a pain chart with a numeric scale. *Id.* at 366.

The Agent was eventually called by Mr. Gomez, who asked how tall he was and took his weight and blood pressure. *Id.* at 366; GX 22, at 3. Mr. Gomez then took him to an exam room. GX 22, at 4.

After a short hiatus, Respondent entered the room, introduced himself, reviewed the Agent's paperwork, and began making entries on a touch screen computer monitor. RX4, at 44. Respondent asked if ''[m]ost of the pain [wa]s in his lower back'' and ''[h]ow it all happened?'' GX 22, at 7. The Agent replied that he ''use [sic] to work in a warehouse lifting boxes and moving stuff'' but didn't ''remember the exact day.'' *Id.* Respondent asked: ''Wear and tear over time?'' *Id.* The Agent replied: ''Yeah.'' *Id.*

Following a discussion of the EMR system, Respondent asked the Agent to lean forward, placed his stethoscope on the Agent's back and asked him to take a deep breath followed by a normal breath, and asked if the pain was ''down here in your lower back?'' *Id.* at 8. The Agent replied, ''Yeah, right around there.'' *Id.* Respondent then said he was going to press various places and instructed the Agent to tell him if he had pain; according to the Agent, Respondent proceeded to press various parts on the Agent's lower back. RX 4, at 44; GX 22, at 9. The Agent stated that he had ''a little bit'' on the left and that ''in the middle it's a little worse.'' GX 22, at 9. Respondent then asked: ''[h]ow about over here?'' *Id.* The Agent replied: ''Yeah,'' Respondent noted that ''[i]t's significantly tighter right there''; the Agent stated: ''Yeah, on the right side.'' *Id.*

Respondent then asked: ''How about over here?'' *Id.* The Agent replied: ''Yeah a little more * * * right around there.'' *Id.* Respondent asked: ''How about down in this area?'' *Id.* The Agent answered ''No.'' *Id.*

Respondent stated ''okay'' and that he had ''just left [the Agent] on everything that you were on down there.'' *Id.* The Agent stated, ''Okay, that's fine.'' *Id.* Respondent added: ''Okay, I usually don't try to mess with it * * *. you know, try to play with it * * * unless I'm trying to increase it or whatever.'' *Id.* The Agent replied: ''No problem.'' *Id.*

[9] The pharmacy profile showed that McMillen had filled prescriptions for 180 tablets of oxycodone 30mg and 60 tablets of Xanax 2mg issued by a Dr. Malcom Foster on March 14, April 12, May 11, and June 10, 2011. RX 1, at 50–51.

The MRI report noted a ''[s]mall posterocentral protrusion of L5–S1 disc, with annular tear, cause mild narrowing of the central canal,'' and a ''[m]ild diffuse bulge of L4–5 disc, with left extraforaminal annular tear, without any significant central canal or neural foraminal narrowing.'' GX 19. The MRI includes a notation that it was verified on the date of the Agent's Bradenton visit. RX 1, at 46.

Respondent then stated: ''Alright we have to have a plan at some point, okay? Cause you're not going to be able to be on these meds for the rest of your life. You know what I mean?'' *Id.* at 10. The Agent stated: ''Okay, yeah sure * * * I hope * * * I hope not,'' and Respondent told the Agent ''[y]ou're all set.'' *Id.* Respondent then escorted the Agent to the receptionist's desk and the receptionist gave the Agent prescriptions for 180 tablets of oxycodone 30mg and 30 tablets of Xanax 2mg, each of which bore the signature of Respondent. RX 4, at 45; GX 23.

The oxycodone prescription listed diagnoses of ''[l]umbar lumbosacral disc degeneration'' and ''lumbar disc displacement.'' GX 23. The Xanax prescription listed a diagnosis of ''GENERALIZED ANXIETY DISORDER.'' *Id.* These diagnoses are also documented in the medical record as ''chronic'' and ''active.'' RX 1, at 43.

However, in the psychiatric portion of the review of systems section of the medical record for the visit, Respondent wrote: ''Patient denies problems with mood disturbance. No problems with anxiety.'' RX 4, at 41. Likewise, in the psychiatric portion of the physical examination section, Respondent noted: ''Oriented with normal memory. Mental status, judgment and affect are grossly intact and normal for age.'' *Id.* at 42.[10] Notably, at no point during the Agent's visit with Respondent, did Respondent (or Gomez) ask the Agent whether he had anxiety or suffered from sleeplessness.[11] GX 22; Tr. 372, 377–78.

The Undercover Visit of Michael Corleone

On August 25, 2011, a TFO, using the name Michael Corleone, also visited Respondent at the Brandon clinic. Tr. 447, 464. The TFO had made two previous visits to the QCMG clinic in Bradenton (June 15 and July 20, 2011), and saw Dr. Mosley on each occasion. GX 25; RX 4, at 25 & 30.

At his first visit (to Bradenton), the TFO provided his driver's license, an MRI, and a prescription profile to the receptionist and was given several forms to complete including a patient questionnaire. RX 4, at 30–31. On the patient questionnaire, the TFO noted that he had ''pain in the lower back and right shoulder,'' that his ''[c]urrent pain level was at a two'' and that his ''average maximum pain level was at a five'' on a one to ten scale, that the pain was ''a sharp ache,'' which ''occurs on a weekly basis,'' that it affected his ''sleep and physical activity,'' and that ''helpful treatments * * * included heat/ice and physical therapy.'' *Id.* at 31. The TFO further noted that the receptionist had verified his MRI. *Id.* at 31–32.

Shortly after paying the $300 office visit fee, the TFO was summoned by a nurse, who questioned him about his driver's license which listed his address as being in Orlando. *Id.* The nurse further told the TFO about the penalties for trafficking and doctor shopping, and that the clinic conducted urine drug tests, and that marijuana remains in the body for thirty days but that the clinic gave patients the option to reschedule their appointment if they tested positive. *Id.* at 31–32. Subsequently, the TFO was required to provide a urine sample, and after doing so, was told to return to the waiting room. *Id.* at 32.

Later, the nurse called the TFO to another room where he proceeded to take the TFO's vital signs, asked various personal questions, and then asked about the location of his pain, his previous clinic and his current medications. *Id.* Upon completion of these tasks, the nurse escorted the TFO to Dr. Mosley's office. *Id.*

Following a discussion of various non-medical subjects, Mosley asked the TFO where his pain was, with the TFO responding that it was in his lower back and right shoulder and that the pain was caused by playing softball. *Id.* at 32–33. Mosley proceeded to perform a physical exam, during which Mosley stated that the TFO's back felt tight. *Id.* at 33. However, while Mosley had the TFO perform several movements, the TFO did not express any discomfort with the exception of one exercise when he said his back was sore. *Id.* at 33–34. Mosley then had the TFO sit on the exam table and placed his stethoscope on various portions of the TFO's back and chest and told the TFO to breath. *Id.* at 34. Thereafter, Mosley tapped the TFO's knees and then used a light to look into the TFO's eyes, mouth and nose. *Id.* According to the TFO, during this time, he was turning his upper body, with no discomfort, while he conversed with Mosley. *Id.* However, during direct examination, the TFO testified that he believed that he told Dr. Mosley that he ''had some trouble sleeping.'' Tr. 454. He also testified that Mosley's exam ''was fairly thorough.'' *Id.* at 455.

Mosley returned to his desk and began completing paperwork. RX 4, at 34. Mosley then advised that he would not write the TFO prescriptions for 240 oxycodone and 90 alprazolam, which were the amounts the TFO had reported that he had previously received. *Id.* Mosley completed the paperwork, gave the file to the TFO, and told him to take it to the front desk, which the TFO did. *Id.* Upon arriving at the front desk, the receptionist opened the file and gave the TFO two prescriptions which were signed by Mosley: one for 199 tablets of oxycodone 30mg, with the notation ''PRN pain,'' and one for 60 tablets of alprazolam 2mg ''PRN anxiety.'' *Id.; see also* GX 25.

However, in the medical record for the TFO's initial visit, Dr. Mosley made no findings in the section for psychiatric history and did not check the line for anxiety. RX 1, at 5. In the family history section, which included a prompt for ''mental health,'' Mosley wrote ''none.'' *Id.* Moreover, in the diagnosis section of the chart, Mosley wrote: ''mild diffuse bulge + small ® paracentral tear L5–S1 disc,'' and ''diffuse bulge L4–5 disc.'' [12] Id. at 8. No diagnosis of anxiety was listed.

On July 20, 2011, the TFO returned to the Bradenton clinic and signed in. RX 4, at 25. After a short wait, the TFO was called by the receptionist, who collected the payment for the visit and gave him an appointment card for his next visit. RX 4, at 26. The receptionist also gave the TFO forms to complete, including one that asked about his current medications and pain level. *Id.* The TFO completed the forms and returned them to the receptionist. *Id.*

Thereafter, the TFO was called to a room by a nurse, who took his weight

[10] The ALJ noted that the medical record for the August 25 visit lists ''sleep, work, and physical activity'' as daily activities affected by the Agent's back pain, and that the Agent testified that he filled out a medical questionnaire but that ''[t]he record is unclear on exactly what information [the Agent] provided in answering the medical questionnaires on August 25, 2011 on the issue of anxiety, sleep disturbance, or pain.'' ALJ at 82. However, as noted above, the evidence showed that the questionnaires were shredded by Respondent's staff. And in any event, one would expect that a doctor would review with the patient his answers to questions pertinent to various conditions before prescribing a controlled substance to treat a condition.

[11] During cross-examination, Respondent's counsel engaged in the following colloquy with the Agent:

Respondent's counsel: ''And you presented to them [i.e., the Bradenton clinic], a patient profile that showed that you had a history of having pain controlled by narcotic pain medication, correct?

Agent: ''Yes sir.''

Respondent's counsel: ''And alprazolam to help you with the anxiety or sleeping, right?''

Agent: ''Yes sir.''

Tr. 397. Notwithstanding the Agent's answers, a patient pharmacy profile does not establish that the drugs were prescribed for any legitimate medical condition.

[12] The MRI presented by the TFO had listed as its ''impression,'' a ''[m]ild diffuse bulge and small right paracentral annular tear of L5–S1 disc, causing mild narrowing of the central canal and neural foramina, bilaterally,'' and a [m]ild diffuse bulge of L4–5 disc, without any significant central canal or neural foraminal narrowing.''

and blood pressure, and confirmed his name. *Id.* The nurse asked the TFO what his pain levels were with and without medication on a one to ten scale; the TFO replied that his pain was six or seven without medications and three with medications. *Id.* The nurse also asked the TFO if he had adverse reactions and if he used tobacco. *Id.* Upon completing the TFO's paperwork, the nurse took him to an exam room, which was across from Dr. Mosley's office, and left the exam room door open and placed the TFO's file in a tray on the door. *Id.* at 26–27.

After a patient left Dr. Mosley's office, Mosley told the TFO to enter his office and bring his file; the TFO did as instructed and gave his file to Mosley, who was seated at his desk facing a computer. *Id.* at 27. Mosley and the TFO had a conversation in which they discussed the TFO's clothing, beard and tattoos. *Id.* Mosley asked the TFO a single question about his medication and did not perform a physical examination. *Id.* Mosley then completed the paperwork and handed the file to the TFO; the TFO took the file to the front desk and handed it to a clinic employee. *Id.* The employee opened the file and gave the TFO two prescriptions; the prescriptions were for 199 tablets of oxycodone 30mg, with the notation ''PRN Pain,'' and 60 tablets of alprazolam 2mg, with the notation ''PRN anxiety.'' *Id.;*[13] GX 25.

On August 25, 2011, the TFO went to the Brandon clinic and saw Respondent. Tr. 464. The TFO signed in, and after a short wait, was called by the receptionist who asked for his driver's license and current address, and collected payment for the visit; the receptionist then provided the TFO with an appointment card for a visit of September 22, 2011. RX 4, at 39. The TFO then took a seat in the waiting room. *Id.*

Thereafter, the TFO was called by a male nurse to an exam room where he had his vital signs taken. *Id.* The nurse then told the TFO to return to the waiting room. *Id.* A short while later, the nurse took the TFO to another exam room and placed his file in a tray near the door. *Id.*

Respondent removed the TFO's file, entered the room, and introduced himself. *Id.,* GX 27, at 1. Respondent and the TFO discussed the reason why he had come to the Brandon clinic (''I don't know if it was just they couldn't get me in'' and ''[m]aybe, I told them I was thinking about moving up here''), how many times the TFO had seen Dr. Mosley (''twice''), whether the TFO lived in Orlando (''that's an old address'') and where he now lived (''Bradenton''), and his employment status (''I don't work right now''), and what he formerly did for employment (''a lot of warehouse stuff'' and ''some heavy lifting''). GX 27, at 1–2.

Next, Respondent asked the TFO if he had insurance; the TFO said ''No.'' *Id.* at 2. Respondent remarked, ''[o]k, so, you're getting two hundred of these pills, that's probably about four hundred fifty dollars. How are you affording all these meds?'' *Id.* The TFO answered that he ''had some money saved up from before,'' and Respondent said ''ok.'' *Id.* Respondent and the TFO then discussed the problem of people not showing for their appointments and the clinic's policy for no shows. *Id.* at 2–3.

Respondent then discussed the TFO's MRI, stating:

> Alright, so I reviewed your MRI. I mean, it's, you got a few things here and there, but not a ton. You know, my honest opinion, I'm a straight shooter, I don't BS anybody. Uh, my honest opinion is that you're a little bit over-medicated. But I'm going to leave you on what you've been on.

Id. at 4. The TFO replied ''ok, thanks,'' and Respondent added: ''we'll, you know if it comes down to it later, down the road that we need to bring you down a bit, we'll do it. But (at which point the TFO interjected with ''ok'') I don't think we'll need to. The only reason why we would need to is because if the government makes me.'' *Id.*

The TFO replied, ''ok, gotcha, gotcha,'' Respondent stated ''So, um,'' and the TFO stated: ''Yeah, you guys get people in and out quick here. It's nice.'' *Id.* Respondent said ''yeah'' and that ''we try not to play around,'' and after the TFO said, ''Yeah,'' Respondent asked the TFO if he ''ha[d] any questions for me?'' *Id.* The TFO answered ''nope.''

Respondent then asked to feel the TFO's ''low back''; the TFO stood up, and Respondent pressed against the TFO's lower back in several locations, asking if it was painful. *Id.;* RX 4, at 39–40. The TFO replied, ''Yeah. It's a little sore,'' and then agreed with Respondent that it was ''more on the right.'' GX 27, at 4.

The TFO was instructed to sit in a chair, and raise each leg separately and then simultaneously. *Id.* Respondent then asked, ''How's your range of motion, pretty good?'' *Id.* The TFO replied ''yeah, it gets better when it loosens up throughout the day. Like in the mornings, the mornings always rough.'' *Id.* Respondent said ''[r]ight,'' and the TFO added: ''And if I sit down for a long time, it hurts.'' *Id.* Respondent stated: ''Alright. You're all set,'' the TFO expressed his thanks, and Respondent took the TFO and the file to a reception area. *Id.* at 5. *See also* Tr. 469 (When asked to describe how brief Respondent's physical examination was, TFO testified: ''He pressed on my lower back and had me raise both of my legs, and that was it.'').

[13] While Respondent introduced medical records for the undercover officers, the record for Mike Corleone does not contain a progress note for his second visit with Dr. Mosley. *See* RX 1, at 1–13. At several points in his recommended decision, including with respect to this undercover officer, the ALJ expressed that ''I have no confidence, based on the record evidence before me, that the Government produced all of the relevant portions of the patient files, particularly given various testimony at hearing that the Government has not 'had time' to review much of the seized material since October 28, 2011.'' ALJ at 84 n.111; *see also id.* 69 n.95 (noting absence of pharmacy profile in patient record for Anthony Thompson notwithstanding Agent's testimony that he had provided one at his initial visit). *See also id.* at 78 n.104 (reasoning that ''[it] is also worth noting that the Government bears the initial burden of proof in this matter, yet it is not entirely clear from any of the testimony whether the undercover patient charts produced at hearing are complete'').

The charts for the four undercover officers, however, were entered into evidence by Respondent and not the Government. Moreover, the custodian of records for the QCMG Brandon clinic testified that she had reviewed Respondent's Exhibit #1 (which comprised the records maintained by the clinic on the four undercover officers) prior to the day of her testimony, and when asked whether the records were ''a fair and accurate representation of the medical charts,'' answered ''yes.'' Tr. 893–94; *see also id.* at 887. Indeed, Respondent has not contended that any of the charts pertaining to the undercover officers were incomplete.

Nor does the testimony cited by the ALJs support his implication that the Government failed to turn over relevant evidence. While it is true that the TFO testified on the first day of the hearing, that she had not time to review the paper copy all of the records, she also testified that ''we don't have any of the UC files yet'' because ''[t]hey're all electronic.'' Tr. 140. The TFO was subsequently recalled to testify on the issue of when certain records were provided to the Government's Expert and testified that the Government had not obtained the electronic medical records until some point during or after February 2012, when it issued a subpoena to the entity which managed the EMR system. *Id.* at 1003. Moreover, both of Respondent's employees testified that various documents including patient IDs, MRIs, patient consents, and urinalysis results were scanned into the EMR, and that the clinic was not ''keeping papers anymore.'' Tr. 891, 908, & 952. To the extent there were any missing documents (such as a pharmacy profile for Anthony Thompson or a progress note for Mike Corleone's second visit with Dr. Mosley, assuming Mosley even prepared one), given that the clinic was using the EMR system and did not have hard copies of the files for the four UCs, it is unclear why the electronic files did not contain this information. What is clear, however, is that the ALJ's implication is nothing more than speculation.

In any event, for reasons explained in the discussion of the legality of the prescriptions issued to Bobby Payne, the existence of a pharmacy profile showing that a patient had obtained controlled substance from other physicians is not exculpatory evidence. As for the absence of a progress note for Mike Corleone's second visit with Dr. Mosley, there is no evidence that Mosley ever created one.

Respondent then gave the TFO prescriptions for 210 tablets of oxycodone 30mg and 60 tablets of alprazolam 2mg. RX 4, at 40; GX 28. On the oxycodone prescription, Respondent listed his diagnosis as ''[l]umbar lumbosacral disc degeneration'' and ''[l]umbar disc displacement.'' GX 28. On the Xanax prescription, Respondent listed his diagnosis as ''generalized anxiety disorder.'' *Id.*

With respect to his visit to the Brandon clinic, the TFO testified that he was not required to complete any paperwork. Tr. 464. In addition, with respect to the intake process at the Brandon clinic, the TFO testified that ''I met with the nurse and he took some information, as far as blood pressure and weight and that was really it. He also made some reference to my name,'' this being the same as that of one of the leading characters in the movie, ''The Godfather.'' *Id.* at 465. Based on the TFO's testimony and the report he filed for the visit, I conclude that the nurse did not ask the TFO any questions regarding his pain. *Id.; see also* RX 4, at 39.

In the medical record documenting this visit, Respondent noted that there was ''[n]o change'' in the status of the TFO's pain, that the severity was ''4 on pain scale,'' that the pain radiated into his ''shoulder blades and right arm,'' that the ''trend'' was ''tolerable'' and that the pain affected his ''sleep and physical activity.'' RX 1, at 9. Yet there is no evidence that any of these issues were raised by the Nurse or Respondent with the TFO.

Also, in the psychiatric portion of the review of systems, the record states: ''Patient denies problems with mood disturbance. No problems with anxiety.'' *Id.* Likewise, in the psychiatric portion of the physical examination findings, the record states: ''Oriented with normal memory. Mental status, judgment and affect are grossly intact and normal for age.'' *Id.* at 10.

Likewise, under the neurologic findings, Respondent noted that the TFO had ''[n]ormal and symmetrical deep tendon reflexes with no pathological reflexes.'' RX 1, at 10. Yet, the TFO testified that Respondent did not check his reflexes. Tr. 474. Moreover, for his range of motion findings with respect to the TFO's lumbar spine, Respondent noted that the he had ''[f]ull active ROM with rotation, [f]ull active ROM with bending, [f]ull active ROM with flexion and Full active ROM with extension.'' RX 1, at 11. Yet, the TFO testified that Respondent did not ask him to do any range of motion exercise ''other than just lifting up the legs.'' Tr. 474.

Respondent's Evidence

In addition to the testimony of Mr. Gomez, which was discussed above, Respondent elicited testimony from Stephanie Baez, who was an employee of the QCMG Brandon clinic from January 2011 until the end of October 2011.[14] Tr. 886–87. Ms. Baez testified that she was the clinic's custodian of records and handled ''all of the intake'' of patients. *Id.* at 887. She testified that as part of the intake process, she would collect a patient's photo ID, MRI, and pharmacy history, and that she would call the company that did the MRI and verify the patient's name, birth date, date of the MRI and the MRI's impressions. *Id.* at 888.

Ms. Baez also testified that if a patient transferred from the Bradenton to Brandon clinic, his records would be transferred and that if any form was missing, the patient would have to complete the form again. *Id.* at 890–91. Ms. Baez also testified that the clinic required the patients to complete an authorization for release of their medical information from previous providers. *Id.* 899–900. While there are such releases in the patient files of Mike Corleone and Eric McMillan, both of whom completed these forms during the initial visits to the Bradenton clinic, but neither of which was filled out by listing their previous doctors, *see* RX 1, at 2 & 53, there are no such forms in the patient files of Anthony Thompson and Bobby Payne, both of whom initially presented at the Brandon clinic. *See generally* RX 1. Moreover, none of the four undercover patient files contain any medical records from prior physicians or clinics, even though they presented that they had been treated by other physicians, or notes indicating that the clinic attempted to obtain such records but could not do so. *Id.* Also, when questioned on cross-examination as to whether Respondent had attempted to verify whether several of the undercovers had been treated by another doctor, Ms. Baez testified that she did not know. Tr. 912 (testimony regarding whether Respondent verified that patient Corleone was treated by Coast to Coast clinic with either Dr. Mosley or Coast to Coast), *id.* at 925 (testimony regarding whether Respondent verified that patient McMillan was treated by Dr. Foster).

Respondent was called to testify by the Government. However, he invoked his Fifth Amendment privilege and declined to answer any questions. Tr. 37–38. Nor, even after the Government presented its case in chief, did Respondent testify regarding any of the allegations.

Discussion

Before proceeding to analyze the evidence under the public interest factors, a review of the ALJ's discussion of the Agency's obligation to disclose what he deemed to be exculpatory evidence is warranted. Therein, the ALJ noted that the Government had resisted turning over investigative reports prepared by the undercover officers (which were relied upon by the Government's Expert) until after Respondent's counsel had completed the first day of his cross-examination of the Government's Expert. ALJ at 10. However, the Government did eventually turn over the investigative reports and Respondent was able to cross-examine the Expert with them. Notwithstanding his conclusion ''that denial of Respondent's motions for discovery were [sic] consistent with applicable legal precedent, and supported by other procedural deficiencies in Respondent's pleadings,'' and that, in fact, his discussion was entirely gratuitous because the Government did turn over the reports and Respondent raised no claim of prejudice in his post-hearing brief, the ALJ found ''that [the] existing Agency holdings and practice with regard to exculpatory evidence warrants further discussion.'' *Id.*

While noting that ''the term 'exculpatory' should be carefully defined in the context of an administrative proceeding,''—an admonition which, as explained below, the ALJ promptly proceeded to ignore—the ALJ reasoned that ''other Agencies have found it appropriate to establish by regulation a practice of reviewing and disclosing exculpatory evidence to litigants during administrative hearings, while recognizing such disclosure is not constitutionally mandated.'' *Id.* at 12. After noting that three federal agencies have provided for disclosure of exculpatory evidence in administrative proceedings,[15] the ALJ opined that ''[a]

[14] Respondent also called TFO Wendy Zarvis, who was involved in sending materials to the Expert for his review. Tr. 1013. Respondent called the Agent to impeach the testimony of the Expert regarding whether he had been provided certain documents at the time he produced his report, as well as to show what documents he had been provided and when he received them. *Id.* at 1017–18. Because for reasons explained later in this decision, the Expert's testimony is not necessary to decide this matter, I conclude that there is no need to make any findings regarding when she sent various documents to him.

[15] Most federal agencies do not, however, provide for the disclosure of exculpatory evidence in administrative proceedings, and several federal appeals courts have held that *Brady* v. *Maryland,* 373 U.S. 83 (1963), does not apply in this type of

Continued

disclosure practice that emphasizes only what is alleged in the [Order to Show Cause], along with only that evidence the Government chooses to disclose in its pre-hearing statement, supplements thereto, and related documentary evidence, by definition de-emphasizes any investigative interest in considering evidence favorable to a Respondent, which, by extension, permeates the entire record'' and that ''[s]uch a systemic practice *may* also contravene clear guidance from federal appellate courts.'' *Id.* at 13 (emphasis added).

The ALJ then quoted from the unpublished decision of the Eleventh Circuit in *Jayam Krishna-Iyer,* which vacated an agency order for failing ''to consider [Dr. Krishna-Iyer's] experience with twelve patients whose medical charts were seized by the DEA * * * [or] consider any of Petitioner's positive experience in dispensing controlled substances.'' *Id.* at 13–14 (quoting *Krishna-Iyer* v. *DEA,* 249 Fed. Appx. 159, 160 (11th Cir. 2007)). Notwithstanding that under the Eleventh Circuit's rules an unpublished opinion is not ''binding precedent,'' 11th Cir. R. 36–2, the ALJ then asserted that the ''impact of this [decision] as precedential authority in DEA decision-making, to include the interpretation of 'positive experience,' apparently remains a matter of some confusion.'' ALJ at 14. The confusion, however, rests entirely with 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.

On remand in *Krishna-Iyer,* I assumed that the respondent's prescribing to not only the twelve patients whose files were seized, but also to the thousands of other patients (other than the undercover operatives to whom she had unlawfully distributed controlled substances) constituted evidence of dispensing controlled substances in circumstances which did not constitute diversion. However, as I explained, Dr. Krishna-Iyer'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.''' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009). As I further explained:

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

Id. (citing *Paul J. Caragine, Jr.,* 63 FR 51592, 51600 (1998) (noting that ''even though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future'')); *Medicine Shoppe-Jonesborough,* 73 FR 364, 386 & n.56 (2008) (even though pharmacy ''had 17,000 patients,'' ''[n]o amount of legitimate dispensings'' could render the pharmacy's ''flagrant violations [acts which are] 'consistent with the public interest'''), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409 (6th Cir. 2008).

Accordingly, in *Krishna-Iyer,* I held that ''evidence that a practitioner has treated thousands of patients [without violating the CSA] does not negate a prima facie showing that a practitioner has committed acts inconsistent with the public interest.'' 74 FR at 463. 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.*

Subsequent to *Krishna-Iyer,* I adhered to this rule in *Dewey C. MacKay,* 75 FR 49956 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). To be clear, the ALJ entirely ignored both the decision of the Agency as well as that of the Tenth Circuit in *MacKay.*

In *MacKay,* I held that, based on the substantial evidence that the physician had knowingly diverted controlled substances to two patients who acted in an undercover capacity, the Government had satisfied its *prima facie* burden of showing that Respondent had committed acts which rendered his registration inconsistent with the public interest. 75 FR at 49977. Relying on the Agency's decision on remand in *Krishna-Iyer,* I rejected the physician's contention that ''[a] better assessment of [his] medical practice and habits can be ascertained from [his] numerous positive experiences in prescribing controlled substances, some of which were recounted by the patients themselves * * * at the hearing.'' *Id.* (quoting Resp. Br. at 3). I therefore held that ''even assuming, without deciding, that Respondent's prescribing practices to all of his other patients (including those whose medical records were reviewed by the Government's Expert but who did not perform undercover visits [16]) fully complied with the CSA and Utah law, these prescribings do not refute the evidence showing that he intentionally diverted to [the two undercovers] in violation of both the CSA and Utah law.'' 75 FR at 49977. Noting that Dr. MacKay had failed to testify and offer evidence that he recognized the extent of his misconduct and was prepared to remedy his prescribing, I revoked his registration.

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

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

proceeding. *See Mister Discount Stockbrokers, Inc.* v. *SEC,* 768 F.2d 875, 878 (7th Cir. 1985); *NLRB* v. *Nueva Eng. Inc.,* 761 F.2d 961, 969 (4th Cir. 1985). *Cf. Echostar Comm. Corp.* v. *FCC,* 292 F.3d 749, 755–56 (D.C. Cir. 2002) (rejecting litigant's claim that ''the Agency's decision to deny it discovery * * * denied it due process''); *Silverman* v. *CFTC,* 549 F.2d 28, 33 (7th Cir. 1977) (''There is no basic constitutional right to pretrial discovery in administrative proceedings.'') (citations omitted).

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

to the knowing diversion of drugs to these two patients.

664 F.3d at 819.

The Court of Appeals thus concluded that ''[a]lthough Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to K.D. and M.R. is sufficient to support her determination that his continued registration is inconsistent with the public interest.'' *Id.* Given that the Court of Appeals' decision in *MacKay* was circulated to the Office of Administrative Law Judges, and in any event, had been issued nearly five months prior to the ALJ's issuance of his recommended decision in this matter, it is inexplicable that the ALJ entirely ignored it.

More recently, I revoked the registration of a Florida-based physician for violations of the CSA's prescription requirement. *See Ronald Lynch, M.D.,* 75 FR 78745, 78750–54 (2010). The physician then filed a petition for review in the Eleventh Circuit. Before the court of appeals, the physician argued that the Agency's order was arbitrary and capricious because ''it limited its consideration of [his] experience to only ten prescriptions issued to out of state patients, the two undercover patients, and the use of a rubber stamp on nine prescriptions.'' Brief of Petitioner at 31, *Lynch* v. *DEA,* 2012 WL 1850092 (11th Cir. 2012) (No. 11–10207–EE). The physician further argued that the Agency had failed to ''consider the evidence that he had been dispensing controlled substances for over twenty years,'' that ''[e]ven with respect to the undercover patients, the DEA Order did not consider the fact that the two undercover patients did not get the medication they requested or that the consultation [between the physician and the patients] was thoughtful and thorough,'' and that the Order ''ignore[d] the fact that one of the undercover patients asked [him] for stronger schedule II drugs'' and that he declined the request. *Id.* The physician thus contended that the Agency's order was arbitrary and capricious because it ''fail[ed] to consider any of [his] positive experiences with dispensing controlled substances.'' *Id.* at 32 (citing *Krishna-Iyer,* 249 Fed. Appx. at 160).

In an unpublished decision, the Eleventh Circuit denied Lynch's petition for review. *See* 2012 WL 1850092, *2. The Court of Appeals noted that ''[a]fter reviewing the record, reading the parties' briefs and having the benefit of oral argument,'' it had concluded that the Agency's order was supported by substantial evidence and that the revocation of Lynch's registration ''was not arbitrary, capricious, an abuse of discretion, or contrary to law.'' *Id.* Significantly, the Court of Appeals did not deem Lynch's argument that the Agency had failed to consider his positive experience to warrant any discussion.

Ignoring both *MacKay* and *Lynch,* the ALJ opined ''that the evidence of record in this case is fully consistent with an administrative practice that only focused on evidence in support of revocation to the virtual exclusion of any 'positive experience' by Respondent, particularly relating to his prescribing practices and other conduct that may have evidenced compliance with applicable law and regulations.'' ALJ at 15. The ALJ then explained that:

> For purposes of this Recommended Decision, I have interpreted 'positive experience' in a common sense fashion, which appears to me to have been the intent of the Eleventh Circuit Court of Appeals in 2007 given their decision not to define it further. In other words, if there is investigative evidence that refutes the allegations in the [Order to Show Cause] or materially supports a finding that Respondent's prescribing practices are consistent with the public interest, such as that found in patient files, it must be made available to a respondent, and if found to be 'competent, relevant, material, and not unduly repetitious,' must be considered in any Agency decision.

Id. at n.16.

As support for his contention that the Agency's investigation had failed to consider evidence of Respondent's positive experience, the ALJ cited a TFO's purported testimony that although she was aware that Respondent had stated to an undercover officer that he ''had previously reported misconduct by a clinic employee to DEA,'' the TFO ''testified that she did not view such information as 'important' to the investigation and had not followed up on'' it. *Id.* (quoting Tr. 120–21). The ALJ then asserted that ''[t]he significance and relevance of such positive conduct by Respondent, if confirmed to be true, could demonstrate Respondent's compliance with various applicable DEA regulations, and materially refute to a degree the allegation in the [Order to Show Cause] that Respondent's conduct was contrary to the public interest.'' *Id.* (citing 21 CFR 1301.76, which requires a registrant to report the theft or loss of controlled substances; 21 CFR 1301.91, stating Agency's position that the employee of a registrant has an obligation to report diversion by another employee; and 21 CFR 1301.92, stating Agency's position that where an employee engages in unlawful activities with controlled substances, employer should immediately assess the need for disciplinary actions).

However, the Government did not allege that Respondent had failed to comply with any of the regulations cited by the ALJ. *See* ALJ Ex. 1, at 2–3 (Order to Show Cause); ALJ Ex. 5 (Gov. Pre-Hearing Statement). Rather, the Government's case was based entirely on the allegations that Respondent violated the CSA by ''issuing prescriptions to undercover law enforcement officers for other than a legitimate medical purpose or outside the usual course of professional practice.'' Order to Show Cause (ALJ Ex. 1), at 2.[17]

As set forth in countless cases brought under sections 303 and 304 of the CSA, violations of the prescription requirement strike at the core of the Act's purpose of preventing the diversion of controlled substances. *See United States* v. *Moore,* 423 U.S. 122, 135 (1975) (''Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.'') (citations omitted). Accordingly, the Agency has held that proof of a single act of intentional or knowing diversion is sufficient to satisfy the Government's *prima facie* burden of showing that a practitioner's continued registration is inconsistent with the public interest, and if unrebutted by a showing that the practitioner accepts responsibility for his misconduct and will not engage in future misconduct, warrants the revocation of a registration. *See MacKay,* 75 FR at 49977; *see also*

[17] Even if such conduct was relevant, Respondent's statement is hearsay, which was uncorroborated by any other evidence, and because he invoked his Fifth Amendment privilege, could not be tested by examining him. *See J.A.M. Builders, Inc.,* v. *Herman,* 233 F.3d 1350 (11th Cir. 2000).

It is further noted that during the colloquy cited by the ALJ, the TFO was not questioned as to whether she found it significant that Respondent had stated to one of the undercovers that he had reported a clinic employee to the Agency. *See* Tr. 120–21. Rather, the question asked if she found it significant that Respondent had said to an undercover ''that he was cleaning up the clinic and had made reports of patients to the DEA.'' *Id.* at 120. In response, the TFO stated that she did not consider it significant ''because it was just constantly mentioned and it just doesn't seem the norm for a doctor to talk about DEA and law enforcement, during a patient visit, unless that's something that's a constant problem with a medical office.'' Tr. 120. This is just one of many instances in which the ALJ misstated the evidence.

Alan H. Olefsky, 57 FR 928, 928–29 (1992) (revoking registration based on physician's presentation of two fraudulent prescriptions to pharmacist in single act where physician failed to acknowledge his misconduct). Contrary to the ALJ's understanding, whether Respondent complied with other provisions of the Agency's regulations does not ''materially refute'' to any degree whether he violated the CSA's prescription requirement.

The ALJ further faulted the Government for not having reviewed the patient charts, other than those for the four undercover officers, which had been seized pursuant to the search warrants which were executed at the Brandon and Bradenton locations. ALJ at 15–16. Noting the testimony of a TFO that she had reviewed only a part of those records, as well as the Expert's testimony that while he had received an additional fifteen patient charts approximately one week before the hearing but had not had time to review them, the ALJ reasoned that ''[t]he lack of investigative effort or 'time' to develop any evidence that might enlighten the administrative record of positive prescribing practices by Respondent, or permit access to such information by Respondent or the fact-finder, underscores the due process limitations of DEA's existing 'discovery' practice.'' *Id.* at 15–16.

Contrary to the ALJ's ludicrous suggestion, the Government was not required to go through all of Respondent's patient charts looking for evidence of his so-called ''positive prescribing practices'' and ''develop evidence to enlighten the administrative record.'' *See MacKay,* 664 F.3d at 819. Having garnered evidence of what it believed to be unlawful prescriptions issued to the four undercover officers, the Government was entitled to go to hearing with that evidence. Whether the Government's evidence was sufficiently ''reliable, probative, and substantial'' to satisfy its burden of proof—after considering relevant and material evidence which might refute the allegations—is one thing. But as the Tenth Circuit recognized in *MacKay,* even if Respondent prescribed controlled substances to numerous other persons in circumstances which did not involve diversion, such evidence is not material to the allegations that he unlawfully prescribed to any of the four undercover officers and thus is not exculpatory.

In short, the ALJ did not identify any undisclosed material evidence that would tend to exculpate Respondent from the allegations that, in prescribing to the undercover officers, he lacked a legitimate medical purpose and acted outside of the usual course of professional practice. Indeed, no such claim is even raised by Respondent in his brief. And given that the Government fully disclosed the evidence it intended to rely on in proving the allegations, and Respondent has raised no contention that it was prejudiced by the lateness of the disclosure, the Government has satisfied due process. *See Goldberg* v. *Kelly,* 397 U.S. 254, 270 (1970) (''where governmental action seriously injures an individual, and the reasonableness of the action depends on fact findings, the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue''); *see also Bowman Transp., Inc.,* v. *Arkansas-Best Freight System, Inc.,* 419 U.S. 281, 288 n.4 (1974) (''A party is entitled * * * to know the issues on which [the] decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it.'').[18] Indeed, given that the Agency's procedures comply with the Supreme Court's (and various court of appeals') teachings as to the scope of due process, it is absurd to suggest, as the ALJ did, that the procedures are ''fundamentally at odds with basic concepts of fairness.'' ALJ at 17.

In short, neither the Supreme Court, nor any federal appeals court—who, unlike the ALJ, are the ultimate arbiters of whether an Agency's procedures satisfy the fundamental fairness that the Due Process Clause requires—has ever held that the Clause imposes on any federal agency the far-reaching obligation proposed by the ALJ. I thus reject it.

The Public Interest Factors

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * *has committed such acts* as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4) (emphasis added). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

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

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. 823(f).

''[T]hese factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.'' *Id.; see also MacKay,* 664 F.3d at 816; *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222 (quoting *Hoxie,* 419 F.3d at 482)).[19]

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. 824(a) are met. 21 CFR 1301.44(e). However, ''once the [G]overnment establishes a prima facie case showing a practitioner has committed acts which render his registration inconsistent with the public interest, the burden shifts to the practitioner to show why his continued registration would be consistent with the public interest. *MacKay,* 664 F.3d at 817 (citing *Medicine Shopper-*

[18] In any event, DEA precedent has already made clear that where an expert relies on data or documents in forming his opinions, the failure of the sponsoring party to produce the data or documents denies the other party a meaningful opportunity to cross-examine the expert and show that his opinions are unfounded, and that where challenged by the other party, this also ''precludes a finding that the expert's conclusions are supported by substantial and reliable evidence.'' *See CBS Wholesale Distributors,* 74 FR 36746, 36749 (2009); *see also Bowman,* 419 U.S. at 288 n.4 (''[T]he Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation.''). In short, if the Government fails to disclose underlying data or documents that its expert relied, it runs the very substantial risk that the expert's conclusions will be rejected. It is, however, for the Government to assess this risk.

[19] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

Jonesborough, 73 FR 364, 387 (2008) (citing cases)).

In this matter, while I adopt the ALJ's findings of fact and legal conclusions that neither factor one (the recommendation of the state licensing board), nor factor three (Respondent's conviction record under laws related to the manufacture, distribution or dispensing of controlled substances), supports the revocation of Respondent's registration, it has long been settled that neither factor is dispositive. *See MacKay,* 664 F.3d at 817; s*ee also Krishna-Iyer,* 74 FR at 461; *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007), *pet. for rev. denied* 533 F.3d 828 (DC Cir. 2008); *Mortimer B. Levin,* 55 FR 8209, 8210 (1990). Rather, the primary focus of this proceeding is whether, as alleged by the Government, Respondent violated the CSA's prescription requirement, 21 CFR 1306.04(a), when he prescribed to the undercover officers. Whether this conduct is considered under factor two—Respondent's Experience in Dispensing Controlled Substances—or factor four—Respondent's Compliance with Applicable Laws Related to Controlled Substances, or both factors, is of no legal consequence, because, if proven, the conduct would be sufficient to support a finding that Respondent ''has committed such acts as would render his registration * * * inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). *See Krishna-Iyer,* 74 FR at 462. Accordingly, I turn to whether the record as a whole supports the allegations.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act ''in the usual course of * * * professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *See United States* v. *Moore,* 423 U.S. 122, 142–43 (1975); *United States* v. *Lovern,* 590 F.3d 1095, 1100–01 (10th Cir. 2009); *United States* v. *Smith,* 573 F.3d 639, 657 (8th Cir. 2009); *see also* 21 CFR 1306.04(a) (''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances'').

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

The ALJ rejected each of the Government's allegations, explaining that he did ''not find Respondent's prescribing practices with regard to the undercover patient visits to be remotely close to 'outright drug deals.''' ALJ at 50 (quoting *Cynthia M. Cadet,* 76 FR 19450, 19450 n.3 (2011)). The ALJ also reasoned that ''the undercover patient visits objectively reflect that Respondent's prescribing practices included, to a degree, a documented medical history, physical examination, documented urinalysis testing, medical record release forms, and pharmacy prescribing profiles, among other information, consistent with applicable Florida law.'' *Id.* (citations omitted). The ALJ thus reasoned that ''any finding that Respondent's prescribing conduct in this case was not for a legitimate medical purpose and outside the usual course of professional practice * * * will significantly depend on the evidentiary weight to be given to the opinion testimony of the Government's sole expert witness,'' whom the ALJ did not find credible. *Id.*

However, with respect to the first undercover visit of Bobby Payne, the ALJ's conclusion that the evidence does not establish that Respondent's prescribing practices with respect to the undercover officers were ''remotely close to 'outright drug deals,''' ignores nearly all of the evidence of the actual conversation which occurred between Payne and Respondent. *See* ALJ at 61–67. Nor, contrary to the ALJ's understanding, does the Agency's decision in *Cadet* stand for the proposition that the only circumstance in which expert testimony is not required to prove violations by a physician of 21 CFR 1306.04(a) is where a physician manifests his knowledge that he is engaging in an outright drug deal. Rather, as *Cadet* makes clear it, it simply cited a single example of where expert testimony is not required to prove a violation of 21 CFR 1306.04(a).

Indeed, the ALJ ignored numerous decisions of both federal and state courts in criminal cases (which require proof beyond a reasonable doubt rather than simply a preponderance of the evidence) which have found violations of 21 CFR 1306.04(a) or 21 U.S.C. 841, or similar state laws, without requiring expert testimony. *See United States* v. *Pellman,* 668 F.3d 918, 924 (7th Cir. 2012) (quoting *United States* v. *Armstrong,* 550 F.3d 382, 388–89 (5th Cir. 2008) (''While expert testimony may be both permissible and useful, a jury can reasonably find that a doctor prescribed controlled substances not in the usual course of professional practice or for other than a legitimate medical purpose from adequate lay witness evidence surrounding the facts and circumstances of the prescriptions.'')); *Armstrong,* 550 F.3d at 389 (''Jurors have had a wide variety of their own experiences in doctors' care over their lives, thus and expert testimony is not necessarily required for jurors to rationally conclude that seeing patients for as little as two or three minutes before prescribing powerful narcotics is not in the usual course of professional conduct.''). *See also United States* v. *Word,* 806 F.2d 658, 663 (6th Cir. 1986); *United States* v. *Larson,* 507 F.2d 385, 387 (9th Cir. 1974); *United States* v. *Bartee,* 479 F.2d 484, 488–89 (10th Cir. 1973); *State* v. *Moody,* 393 So.2d 1212, 1215 (La. 1981).

The ALJ also ignored several decisions of this Agency which have found violations of the prescription requirement notwithstanding the absence of expert testimony. *See Morris W. Cochran,* 77 FR 17505, 17519–20 (2011) (holding, without expert testimony, that prescriptions lacked a legitimate medical purpose where physician noted in patient medical records that patients had no pain, did not document any findings to support a diagnosis, and yet diagnosed patients as having chronic pain); *Robert F. Hunt,* 75 FR 49995, 50003 (2010) (holding, without expert testimony, that physician lacked a legitimate medical purpose based on statements made during undercover visits and falsification of chart). *See also Jack A. Danton,* 76 FR 60900, 60904 (2011).

Thus, while it true that ''where a physician ma[kes] some attempt to comply with various state medical practice standards and the adequacy of those efforts is at issue,'' expert testimony is typically necessary to establish that a physician violated 21 CFR 1306.04(a), *see id.* & n.13, the facts and circumstances surrounding the issuance of the prescription may nonetheless establish a violation even

without expert testimony. Here, while the ALJ noted that Respondent's prescribing practices included ''a medical history, a physical examination, documented urinalysis testing, medical record release forms, and pharmacy prescribing profiles,'' ALJ at 50, a fact-finder can nonetheless consider the totality of the facts and circumstances of the visit and conclude that a registrant did not prescribe in the course of legitimate medical treatment but rather was creating a sham justification to support an unlawful prescription.

The Prescriptions for Bobby Payne

As found above, at Payne's first visit (July 28, 2011), he presented a prescription profile showing that he had filled prescriptions for 210 tablets of oxycodone 30mg, 90 tablets of oxycodone 15mg, and 90 tablets of alprazolam 2mg, on a monthly basis from December 10, 2010, but had last filled the prescriptions on April 10, 2011, more than three and a half months before his visit. Moreover, Respondent's assistant falsified Payne's urine drug screen to show that he was positive for oxycodone. While the ALJ observed that there was no evidence to show that ''Respondent had any knowledge of the false entry,'' ALJ at 63, Respondent, notwithstanding the lengthy gap since Payne had last filled prescriptions for oxycodone, did not question him about why he had tested positive for the drug.

Indeed, the evidence is clear and convincing that Respondent knew that Payne was not seeking treatment for a legitimate medical condition but was either engaged in self-abuse or diversion. Notably, without even discussing whether Payne had any symptoms or his pain levels, Respondent noted that Payne's MRI showed two mild disc bulges, that the reason Payne's prior clinic was out of business was because they were ''prescribing inappropriately,'' and that based on the MRI and without even doing a physical exam, he could not give Payne ''near the pills that you were getting. Not even remotely close.''

Moreover, even after Payne said that the amounts of his previous prescriptions were ''just what they prescribed, and ''that's not what I actually took,'' thus suggesting that he diverted some of his prescriptions to others, Respondent did not question him regarding what he did with the drugs he did not take. Thereafter, Respondent put to rest any doubt as to whether he knew Payne was not a legitimate patient, stating that Payne's MRI did not show any ''pushing on any nerve roots or anything like that'' and was ''as close to a normal MRI as you can get without it being actually normal,'' and adding: ''I mean the most I can do for you would * * * And I'm telling you this in case you don't want to come here. Okay? Cause I hate for you to spend all of your money, coming here and not get what you need.''

This was followed by Respondent telling Payne that what he needed and what he should get ''sometimes is two different things,'' because if ''you've been on a certain number of pills, for a long time, if you don't get those number of pills, you're going to be sick.'' Respondent then stated that ''just by looking at this [the MRI] without even doing the physical exam,'' he was looking at prescribing ''maybe a hundred and fifty,'' the amount of oxycodone 30mg which he subsequently prescribed to Payne. Notably absent from Respondent's interaction with Payne was a discussion of the causes of his pain, its nature and intensity, and how it affected his ability to function. *See* Fla. Admin Code r. 64B8–9.013(3)(a). In short, Respondent's comments manifest that he knew that Payne was an abuser of controlled substances; his negotiation with Payne over the amount of oxycodone he could prescribe based on his MRI and without even having performed a physical examination likewise manifests that this was not a legitimate medical evaluation but rather a drug deal.

It is true that Respondent subsequently performed a physical exam. Yet throughout the exam, Payne generally denied that the various tests caused pain or gave vague responses such as ''uh-hum,'' and never complained that the tests caused anything more than ''a little bit'' of pain. Indeed, given Respondent's comments prior to the exam, it is manifest that the exam was done to go through the motions and not to engage in a legitimate clinical evaluation. Moreover, Respondent documented in the medical record that he palpated Payne's cervical spine area even though the video recording shows that he did not do so. He also documented having performed various range of motion tests on each portion of Payne's spine (including his lumbar region) even though the video shows that he did not do so.

Furthermore, subsequent to the exam, Respondent made additional comments which demonstrate that he had knowledge that Payne was a self-abuser. For example, during his ''new patient talk,'' Respondent stated: ''I don't want you taking medication, the way you want to take them, because that will put you in jeopardy of overdose,'' and that the UC's doing so, would place his license at risk. Respondent then added that while ''we're pretty strict here * * * we do have fun also,'' a point which he reiterated.

As for the alprazolam prescription, while Respondent listed a diagnosis of ''generalized anxiety disorder,'' which he deemed to be ''chronic'' and ''active,'' the medical record contains the findings that ''patient denies problems with mood disturbance. No problems with anxiety.'' In addition, Respondent documented that Payne's ''[m]ental status, judgment and affect are grossly intact and normal for age.''

While Respondent offered the testimony of his medical assistant to the effect that the EMR provided certain default entries when information was not entered into the patient's record, he could not identify what any of the specific entries were. Moreover, if a patient had actually complained of anxiety and a discussion of his symptoms had occurred, one would expect that the complaint and the nature of the symptoms would be documented in the patient's record. Indeed, the rules of the Florida Board of Medicine require such. *See* Fla. Admin. Code r.64B8–9.003(3) (''The medical record shall contain sufficient information to identify the patient, support the diagnosis, [and] justify the treatment * * * .''); Fla. Admin. Code r. 64B8–9.013(3)(f) (''The physician is required to keep accurate and complete records * * * .''). Finally, other than his single question to the TFO of whether he was getting Xanax ''for anxiety,'' with Payne saying he was getting it for sleep, there is no evidence that Respondent (or Gomez for that matter) discussed with Payne any problems he had with anxiety or with sleeping.

In rejecting the Government's evidence, the ALJ noted that at the time of Respondent's initial evaluation, he ''had evidence of [Payne's] prior treatment for pain from December 2010 until April 10, 2011, by two different physicians.'' ALJ at 67. This is a gross mischaracterization of the evidence, as Respondent did not have any medical records from the two physicians showing that they treated Payne for pain, but rather only a prescription profile showing that the two physicians had prescribed drugs to Payne. That profile, however, establishes only the dates and drugs that various doctors prescribed and says nothing about the legitimacy of the prescriptions. Moreover, given the date of the profile (June 14, 2011) and the absence of any prescriptions since April 10, one might reasonably ask whether the patient had been discharged by his prior doctor and attempt to contact that doctor. Beyond this, as Respondent's own comments

manifest, he surmised that Respondent's prior clinic had been shut down for prescribing inappropriately.

The ALJ also noted that Respondent had a ''verified MRI report, correlating, to a limited extent, [the TFO's] statement of pain and reported history of 'low back pain.' '' *Id.* The ALJ ignored, however, that Payne testified that one of the forms he filled out had a picture of a human body and that he deliberately circled a part of his body different than his MRI, to, in his words, ''disprove basically the MRI.'' Tr. 180; *see also* ALJ at 20 (ALJ finding that ''[w]ith regard to his stated pain complaint, [the] TFO * * * recalled one of the forms had a picture of a human body and he believed he circled part of the body that was different than his MRI, 'just to disprove basically the MRI.'''). Notably, the ALJ did not reconcile his finding that the MRI correlated with Payne's ''reported history of 'low back pain''' and his earlier finding that the TFO had circled a different part of the body as the area in which he had pain. *See* ALJ at 67. In addition, it should be noted that Respondent's own witness testified that the clinic shredded the patient questionnaires.

The ALJ then noted that ''at the outset of the patient visit, [Respondent] made clear that he intended to decrease the amount of controlled substances [Payne] had previously been provided, particularly given the limited correlation of reported pain in the MRI report.'' *Id.* Contrary to the ALJ's understanding, that a practitioner prescribes a lesser quantity of a controlled substance than what a patient had previously received does not establish that the prescription was lawfully issued. Rather, what determines whether a prescription complies with Federal law is whether the physician had a legitimate medical purpose and acted within the usual course of professional practice. 21 CFR 1306.04(a)

The ALJ also reasoned that Respondent's statement that ''[w]hat you should get and what you need, oftentimes is two different things cause if you've been on a certain number of pills, for a long time, if you don't get those number of pills, you're going to be sick,'' ''reflect[s] positively on his prescribing conduct or intent in this case.'' ALJ 66. However, when considered in the context of the entire conversation which occurred between Respondent and the TFO, and as demonstrated by Respondent's subsequent statement that ''I don't want you taking medication, the way you want to take them, because that will put you in jeopardy of overdose,'' it is clear that Respondent believed that Payne was a drug abuser.

The ALJ's reasoning likewise reflects a stunning disregard for Federal law, which, however, does not permit a practitioner to prescribe schedule II controlled substances such as oxycodone to a narcotic dependent person for the purpose of maintaining him on narcotics and preventing withdrawal symptoms.[20] *See* 21 CFR 1306.04(c). Rather, when a patient presents as narcotic dependent, a practitioner may only administer (and not prescribe) narcotic drugs ''for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment,'' may not administer more than ''one day's medication at a time,'' and may not do so ''for more than three days.'' 21 CFR 1306.07. Thus, contrary to the ALJ's understanding, there is nothing positive in Respondent's decision to prescribe 150 tablets of oxycodone 30mg (as well as Xanax) to a person he knew was a drug abuser.[21]

I therefore conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing oxycodone and Xanax (alprazolam) to Payne. Moreover, by themselves, Respondent's issuance of these two prescriptions is enough to establish a *prima facie* showing that he has committed such acts as to render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4). *See Dewey C. MacKay,* 75 FR at 49977; *Jayam Krishna-Iyer,* 74 FR at 463; *Olefsky,* 57 FR at 928–29 (revoking registration based on physician's presentation of two fraudulent prescriptions to pharmacy).

Likewise, with respect to the TFO's second visit, the ALJ did not find the evidence sufficient to support the conclusion that Respondent violated federal law. According to the ALJ, the evidence showed that ''Respondent did review the course of treatment with the patient, to include an inquiry about how the medication was working and a physical examination, albeit short.'' ALJ at 68. Indeed, the entire interaction between Respondent and Payne lasted two minutes. *See Armstrong,* 550 F.3d at 389.

Respondent is, of course, charged with the knowledge he obtained at Payne's first visit that he was a substance abuser, none of which is documented in the medical record. *See* Fla Admin Code r. 64B8–9.013(3)(a) & (f) (requiring documentation of history of substance abuse). Moreover, while Respondent asked Payne if the medication was treating his ''pain well,'' neither Respondent nor Gomez asked Payne if there was any change in the status of his pain, whether it still radiated into his upper back, nor any questions about the timing and quality of the pain, and whether it still affected his sleep and physical activity. *See id.* r.64B8–9.013(3)(d). Yet such findings were documented in the medical record for the visit.

Moreover, as found above, the medical record documented that Respondent had performed a neurologic exam, that he had palpated Payne's cervical spine and surrounding areas, and that he had required Payne to perform range of motion tests for various portions of his spine. However, Respondent did not perform a neurologic exam, nor any range of motion tests of any portions of Payne's spine, and the only area that he palpated was Payne's lower back. Once again, the evidence shows that Respondent falsified the medical record.[22] Respondent also falsified the

[20] A practitioner may prescribe narcotic drugs for the purpose of maintenance or detoxification treatment only if ''the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in 1301.28 of this chapter.'' 21 CFR 1306.04(c). Oxycodone is a Schedule II drug and cannot be prescribed for this purpose. Moreover, Respondent is not authorized to dispense narcotic drugs for maintenance or detoxification treatment under either 21 U.S.C. 823(g)(1) or 823(g)(2).

[21] So too, that Respondent explained various clinic policies in his new patient speech, *see* ALJ at 67, does nothing to refute the conclusion that he knowingly prescribed oxycodone to a drug abuser. Rather, it is simply a case of Respondent's going through the motions.

[22] While the ALJ opined that there was no evidence that Respondent knowingly falsified the medical records, each of the visit notes (for all four UCs) prepared by Respondent includes the statement:

I declare that I have read and verified the document.

T.J. McNichol, MD.

See RX 1, at 29; *id.* at 33. *See also id.* at 12(8/25/11 visit note for Mike Corleone); *id.* at 18 & 22 (7/28/11 and 8/25/11 visit notes for Anthony Thompson); *id.* at 44 (8/25/11 visit note for Eric McMillen).

The ALJ also noted that ''[t]here are also various entries in the relevant patient chart for the[UCs] that do not correlate to other objective evidence and testimony of what transpired during the examination.'' ALJ at 70. As an example, the ALJ cited a statement in the chart for Anthony Thompson that ''there were 'no external hemorrhoids or rectal masses. Stool Hemoccult was negative[,]' '' and that the Agent testified that ''no examination was performed consistent with such findings in the patient chart.'' *Id.* (quoting RX 1, at 17; and citing Tr. 253). The ALJ then reasoned that there was no evidence that ''the forgoing errors, such as gastrointestinal findings as to hemorrhoids, had any rational relationship to Respondent's

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record by documenting that Payne had ''active'' and ''chronic'' ''generalized anxiety disorder.''

Here again, the evidence shows that Respondent's evaluation of Payne was simply a case of going through the motions. Moreover, notwithstanding the substantial probative evidence of irregularities in his prescribing practices, Respondent failed to testify regarding them. Under these circumstances, an adverse inference is warranted that Respondent knowingly diverted oxycodone and alprazolam to Payne on his second visit as well.[23] *See Baxter* v. *Palmigiano,* 425 U.S. 308, 318 (1976) (''[T]he Fifth Amendment does not forbid adverse inference against parties to civil actions when they refuse to testify in response *to probative evidence* offered against them'') (emphasis added); *MacKay,* 664 F.3d *at* 820 (quoting *Keating* v. *Office of Thrift Supervision,* 45 F.3d 322, 326 (9th Cir. 1995) (''Not only is it permissible to conduct a civil [administrative] proceeding at the same time as a related criminal proceeding, even if that necessitates invocation of the Fifth Amendment privilege, but it is even permissible for the trier of fact to draw adverse inferences from the invocation of the Fifth Amendment in a civil [administrative] proceeding.''); *Hoxie,* 419 F.3d at 483. *See also* 21 CFR 1306.04(a). Respondent's issuance of these prescriptions provides further support for the conclusion that he has committed acts which render his registration inconsistent with the public interest. 21 U.S.C. 824(a)(4).

The Prescriptions Issued To Anthony Thompson

With respect to Thompson's first visit, the ALJ noted that there were ''various entries in the relevant patient charts for [this undercover], * * * that do not correlate to other objective evidence and testimony of what transpired during the examination,'' ALJ at 70, that Respondent's medical assistant had falsified the urine drug screen report to show that Thompson tested positive for benzodiazepines and oxycodone, *id.* at 71, and that Respondent's physical examination at the initial visit lasted all of two minutes. *Id.* at 72. The ALJ nonetheless concluded that these ''irregularities'' do not ''support a finding by a preponderance of the evidence that Respondent's prescribing conduct on July 28 * * * 2011, was not for a legitimate medical purpose or outside the usual course of professional practice.'' ALJ at 75.

However, even if expert testimony was required to demonstrate that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing the oxycodone prescription, there is nonetheless substantial evidence to support the conclusion that Respondent's prescribing of alprazolam to Thompson lacked a legitimate medical purpose. Here, Respondent's discussion of Thompson's need for Xanax was limited to Respondent's asking: ''I take it you have some anxiety as well[,] is that what's going on with you?,'' with Thompson using the street term for Xanax to reply, ''Yeah, that's the Zanny's help out.'' While Respondent then advised Thompson that ''we don't call them Zanny's or bars or any of the street terms, here, ok?'' Respondent engaged in no further inquiry as to whether Thompson actually had symptoms consistent with generalized anxiety disorder, let alone symptoms which warranted the prescribing of alprazolam. Moreover, while Respondent then stated that under state law if a pain patient had a psychiatric problem, he had to be referred to psychiatry, he then added that Thompson did not necessarily have to go. Nor did Respondent provide the name of any psychiatrists to see.

Most significantly, in the medical record for this visit, Respondent noted in the psychiatric portion of the review of systems that ''Patient denies problems with mood disturbance. No problems with anxiety.'' And in the physical examination findings, Respondent documented that Thompson's ''[m]ental status, judgment and affect are grossly intact and normal for age.'' Notwithstanding these findings, Respondent documented a diagnosis of generalized anxiety disorder which was ''active'' and ''chronic'' and prescribed 60 Xanax 1mg to Thompson.[24]

In his discussion of Thompson's visits, the ALJ completely ignored the evidence showing that: (1) Respondent's discussion of Thompson's use of Xanax was limited to a single question with Thompson using the street name for the drug and involved no discussion of the nature and duration of any symptoms which might support a diagnosis of ''chronic'' and ''active'' generalized anxiety disorder; (2) the evidence that Respondent documented that Thompson had ''[n]o problems with anxiety''; and (3) Respondent's finding that Thompson's ''mental status, judgment and affect are grossly intact and normal for age.'' See ALJ at 69–74. And while it is true that the Florida standards of practice do not mandate a referral for psychiatric treatment, *see id.* at 74 & n.98 (characterizing Respondent's referral as ''half-hearted''), this does nothing to refute the

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prescribing of controlled substances[,]'' and that ''[t]here is also no evidence that any of the discrepancies in the patient chart were * * * related in any material way to his prescribing of controlled substances in this case.'' *Id.*

Even if gastrointestinal findings are not materially related to a complaint of lower back pain, as found above, there was evidence with respect to several of the undercovers (including the TFO who posed as Bobbie Payne) that Respondent documented various findings including having performed various range of motion tests on the TFO's lumbar spine, which was the area of his purported pain complaint. *See* RX 1, at 21. However, the ALJ entirely ignored this evidence. As for the ALJ's reasoning that there is no evidence these discrepancies were materially related to Respondent's prescribing, if findings related to the area of the body which a patient complains is causing him pain are not materially related to the making of the diagnosis and decision to prescribe controlled substances, then nothing in a medical record is material. The Florida standards, however, suggest otherwise. *See* Fla. Admin Code r.64B8–9.003(3) (''The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum, * * * examination results. * * *'').

[23] I reject the ALJ's reasoning that ''in light of the fact that the Government's evidence was insufficient to establish a prima facie case * * * Respondent's silence in and of itself does not appreciably tip the balance of evidence in favor of the Government'' as contrary to settled law. *See Baxter,* 425 U.S. at 318. Here, the Government did not rely solely on Respondent's failure to testify to prove its case. Rather, it introduced independent and probative evidence as to the illegality of the prescriptions through the testimony of the undercovers officers and the recordings (and transcripts) of their visits. Moreover, Respondent's own evidence, which included the patient charts and the undercover officers' reports of investigation, also provides independent and probative evidence of Respondent's illegal conduct, which he failed to address. Accordingly, as ultimate factfinder, I conclude that an adverse inference is warranted with respect to the prescriptions issued to Payne, as well as the alprazolam prescriptions issued to the other three undercover officers.

[24] The progress note for the visits of the Agent include the following statement under the caption of ''History of Present Illness'' and ''Low Back Pain'':

Associated Conditions: None. Aggravated by standing, walking, and exercise. Denies None with pertinent positives of stiffness and anxiety and [sic] relieved by rest and pain medications.

RX 1, at 15, 19. Similar statements are found in the progress notes for two of the other UCs. *See* RX 1, at 9 (Corleone; ''Associated conditions: None. Aggravated by sitting, climbing stairs, cold, lifting, exercise, and driving. Denies None with pertinent positives of anxiety and [sic] relieved by ice, rest, and pain medications''); *id.* at 26 (Payne; ''Associated Conditions: None. Aggravated by movement, climbing stairs, and lifting. Denies None with pertinent positives of stiffness and anxiety and [sic] relieved by lying down, rest, and pain medications'').

No explanation was offered as to how either Respondent or Gomez could have documented that the UCs had no history of associated conditions but nonetheless had ''pertinent positives'' of anxiety, and given that each of the charts contains the finding that the ''Patient denies problems with mood disturbance. No problem with anxiety[,]'' *see, e.g.,* RX 1, at 16, the statements are obvious gibberish.

conclusion that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax to Thompson.

In short, where a medical record contains no findings that support a diagnosis, or, as in this case, those findings contradict a diagnosis, in the absence of credible testimony from Respondent explaining the reason for the inconsistency, expert testimony is not necessary to conclude that a prescription lacked a legitimate medical purpose. 21 CFR 1306.04(a); *see also Baxter,* 425 U.S. at 318; *Cochrane,* 76 FR at 17519–20. I thus hold that there is substantial evidence to support the conclusion that the Respondent lacked a legitimate medical purpose and acted outside the course of professional practice when he prescribed Xanax to the Agent at the July 28 visit.

Likewise, on Thompson's second visit, neither Respondent's assistant, nor Respondent, discussed with Thompson whether he had any symptoms consistent with an anxiety diagnosis and which warranted a prescription for Xanax. Moreover, here again, the medical record contains the same findings as on the previous visit that ''Patient denies problems with mood disturbance. No problems with anxiety'' and that Thompson's ''[m]ental status, judgment and affect are grossly intact and normal for age.'' Yet, once again, Respondent prescribed Xanax to Thompson.

Here again, the ALJ failed to even consider any of the evidence regarding Respondent's prescribing of Xanax to Thompson. ALJ at 74–75. For the same reasons as discussed above, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax to Thompson at the latter's second visit. *See* 21 CFR 1306.04(a).

The Prescriptions Issued to Michael Corleone

As found above, a TFO, using the name of Michael Corleone, saw Respondent on August 25, 2011, after having seen Dr. Mosley at the Brandon clinic on two prior occasions. With respect to Respondent's prescribing of controlled substance to Corleone, the ALJ noted Respondent's statements to the TFO that he believed that the TFO ''was 'a little bit over-medicated,'' but that he was ''going to leave [him] on what [he had] been on,'' as well as his statement that '''you know if it comes down to it later, down the road that we need to bring you down a bit, we'll do it * * * I don't think we'll need to. The only reason why we would need to is because the government makes me.'' '' ALJ at 87.

The ALJ further noted that Respondent ''conducted a brief physical examination * * * which in context appears to be somewhat perfunctory since Respondent had also communicated his intent to leave [the TFO] on his current medications prior to initiating the examination.'' *Id.* As the ALJ noted, the exam was limited to Respondent pressing against the TFO's lower back in several locations and asking if it was painful, with the TFO responding that his back was ''a little sore,'' as well as Respondent directing the TFO to sit in a chair and raise each leg both separately and simultaneously, with the TFO expressing ''no discomfort.'' *Id.*

The ALJ then noted that ''[t]he forgoing evidence is certainly suggestive of questionable prescribing by Respondent in this instance, particularly given Respondent's comments about dosing and future reductions based on government action, rather than his medical judgment,'' and that ''Respondent's physical examination appears perfunctory since his decision to prescribe was made moments after his review of the patient file, apparently in reliance on the medical judgment of Dr. Mosley.'' *Id.* at 88. However, the ALJ explained that notwithstanding this evidence, ''Respondent's deference to another physician's medical judgment appears to be a relevant factor since a comparison of the limited patient files made available by the Government in this case reflects that Respondent initially prescribed lower doses of oxycodone and alprazolam to similarly situated patients than his colleague, Dr. Mosley.'' *Id.* The ALJ further noted the testimony of the Government's Expert that ''physicians can and do ascribe some deference to the prior prescriber's approach, assuming that the physician has either spoken with the prior prescriber or has the records from the prior prescriber's intervention.'' *Id.* (citing Tr. 591).[25]

It is true that Respondent had available to him the TFO's medical records which were maintained by Dr. Mosley. However, in the absence of testimony by Respondent that he deferred to Dr. Moseley's medical judgment when he prescribed to the TFO, the ALJ's suggestion is unsupported by substantial evidence and is pure speculation. As the ALJ was want to explain, ''[s]peculation is, of course, no substitute for evidence.'' ALJ at 90 (internal quotations and citations omitted).

Moreover, even assuming, that under the Florida standards of medical practice, a physician can appropriately prescribe a controlled substance based on his review of the records from the patient's prior physician, the evidence still establishes that Respondent lacked a legitimate medical purpose when he prescribed alprazolam to the TFO. As the record for the TFO's first visit with Dr. Mosley shows, Mosley did not make any findings which support a diagnosis of anxiety.

More specifically, in the section of the progress note for documenting Corleone's primary complaint, Mosley did not document a complaint of anxiety. Moreover, in the section for documenting Corleone's psychiatric history, Mosley did not check the blank for anxiety or any other mental illness. And in the section for documenting whether Corleone had a family history of mental health (as well as other conditions), Mosley wrote ''none.'' Finally, Mosley did not document a diagnosis of any type of anxiety disorder. Indeed, in the record for the visit, the only mention of anxiety is where Mosley listed the medications he was prescribing and wrote: ''Xanax 2mg, q12hrs, PRN anxiety # 60.''

Thus, there were no findings, let alone a diagnosis, to support the prescribing of Xanax for anxiety, in the record maintained by Dr. Mosley on the TFO. The ALJ did not, however, explain why it would be reasonable to defer to the medical judgment of a prior physician when that prior physician did not make any findings which would support a diagnosis, let alone a make a diagnosis of anxiety. Indeed, notwithstanding his surmise that Respondent had deferred ''to another physician's medical judgment'' when he prescribed controlled substances to Corleone, ALJ at 88, the ALJ completely ignored the evidence showing a total lack of documentation of findings to

[25] It is strange, given the ALJ's finding that the Government's Expert was so biased as to ''preclude[] *any reliance* on his opinion testimony,'' ALJ at 89 n.118 (emphasis added), that the ALJ then disregarded his own finding and relied on this testimony. However, the Expert's entire testimony was that ''it still is an absolute expectation of a physician, even if you've inherited a patient on certain medications, it's certainly—it's an expectation that a physician evaluate the database and form their own opinion.'' Tr. 591. Continuing, the expert testified that while the new physician's opinion ''can be influenced. It can be, in some ways, deferential to the prior prescriber, but it still is the individual physician[']s opinion and decision, when it comes to prescribing to that patient, when that physician has taken over the care of that patient.'' *Id.* at 591–92. No explanation was provided by the ALJ for disregarding the rest of the Expert's testimony on this issue.

support an anxiety diagnosis in the medical record created by Dr. Mosley.[26]

It is true that in the medical record for the TFO's August 25 visit with Respondent, there is a notation that his pain affected his sleep and physical activity. Yet there is no evidence that any of these issues were raised by the nurse or Respondent with the TFO. Nor is there any evidence that Respondent discussed with the TFO whether he had anxiety.

There is also evidence in the psychiatric portion of the record's review of systems section that ''[p]atient denies problems with mood disturbance. No problems with anxiety.'' Likewise, in the findings for the physical examination, Respondent wrote: ''Oriented with normal memory. Mental status, judgment and affect are grossly intact and normal for age.'' Yet Respondent diagnosed Corleone as having chronic and active generalized anxiety disorder and prescribed to him 60 alprazolam 2mg.[27]

Just as he ignored the evidence showing that Mosley had failed to make any findings to support a diagnosis of anxiety, the ALJ entirely ignored the evidence showing that the findings Respondent made during the TFO's August 25 visit were inconsistent with his diagnosis of generalized anxiety disorder and did not support his prescription for alprazolam. *See* ALJ at 83–91. Here again, Respondent failed to testify and offer an explanation for the inconsistency between his findings and his diagnosis. I therefore conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he prescribed 60 tablets of alprazolam 2mg to the TFO.

The Prescriptions Issued To Eric McMillen

As with the previous undercover officer, a DEA Special Agent, who used the name of Eric McMillen, initially saw Dr. Mosley at the Bradenton clinic prior to seeing Respondent. The Agent acknowledged that he had seen Mosley for at least thirty minutes and performed a physical exam, and on cross-examination, agreed that the exam was ''pretty thorough.'' He also testified that it was ''possible'' that he noted on paperwork he completed that he had ''some trouble sleeping.'' At the conclusion of the visit, Dr. Mosley prescribed 180 tablets of oxycodone 30mg and 30 tablets of Xanax 2mg.

Regarding the Agent's visit with Respondent, the ALJ found that Respondent had available to him the Agent's file including the progress note from the previous visit, as well as the information obtained during the triage procedures. ALJ at 79. The ALJ also noted that the Agent had filled out a medical questionnaire during his second visit. *Id.* However, the ALJ credited the Agent's testimony that during the triage procedures Mr. Gomez did not ask him about anxiety or sleeplessness. ALJ at 80 (citing Tr. 366–67). Moreover, at no point during the Agent's visit with Respondent did the latter ask the Agent whether he had problems with anxiety or sleeplessness.

Regarding the alprazolam prescription Respondent issued to the Agent, the ALJ noted that ''[t]he evidence * * * reflect[sic] some irregularities,'' noting that ''the final diagnosis of generalized anxiety disorder facially conflicts with the patient chart entry stating '' '[p]atient denies problems with mood disturbance. No problems with anxiety.' '' ALJ at 81–82. The ALJ also noted that the Agent's ''testimony also reflects no questioning by Mr. Gomez or Respondent about ongoing issues with anxiety or sleeplessness'' and that ''[t]he absence of any inquiry by Respondent about the medical basis for continuing the prescription for Xanax arguably supports a finding that such a prescription lacks a legitimate medical purpose, or is outside the usual course of professional practice.'' *Id.* at 82.

However, the ALJ then concluded that the Government had failed to established by preponderance of the evidence that the prescription lacked a legitimate medical purpose or was issued outside the usual course of professional practice, reasoning that ''there is other credible evidence of record that Respondent had information available to him as of August 25, 2011 that would support the continued prescription for Xanax.'' *Id.* According to the ALJ, this information included ''Dr. Mosley's initial diagnosis of anxiety and corresponding prescription for two milligram Xanax over a thirty day time period,'' as well as a pharmacy printout showing that similar prescriptions had been issued by ''another physician * * * covering the time period from March 14, 2011 to June 10, 2011.'' ALJ at 82. In addition, the ALJ noted that the Agent testified that he had filled out a medical questionnaire on August 25, 2011, but that ''[t]he record is unclear on exactly what information [the Agent] provided in answering the medical questionnaire * * * on the issue of anxiety, sleep disturbance, or pain.'' *Id.* However, the ALJ noted that the August 25 patient file stated that the patient's affected daily activities included ''sleep, work, and physical activity.'' *Id.*

Here again, Respondent did not testify and explain what he relied on in concluding that a prescription for Xanax was medically warranted,[28] and thus the ALJ's conclusion is nothing more than speculation. Moreover, even assuming that Respondent relied on the evidence cited by the ALJ, contrary to the ALJ's understanding, none of it refutes the conclusion that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax to the Agent.

As for Dr. Mosley's purported ''initial diagnosis,'' once again the ALJ misstated the evidence. As found above, in the medical record Dr. Mosley prepared for the Agent's July 21 visit, Mosley did not document that the Agent had a psychiatric history even though the form included a place for indicating that the Agent had anxiety, nor document that there was a family history of mental health conditions, or make any other findings consistent with an anxiety diagnosis. Indeed, Dr. Mosley did not list anxiety as among his various diagnoses. Thus, Mosley's record did not support the prescription he issued and Respondent could not have reasonably relied on it as a basis for concluding that the Agent had generalized anxiety disorder.[29]

As for the prescription profile which the Agent provided, as explained previously, that profile establishes only that another doctor had prescribed alprazolam (and oxycodone) to the Agent on various occasions. The profile, however, says nothing about whether

[26] As found above, the patient file for Corleone does not contain a progress note for the TFO's second visit with Dr. Mosley, which was of an extremely short duration. Respondent produced no evidence that Mosley ever prepared a note for the visit, and in any event, Respondent did not testify and thus cannot claim to have relied on any findings contained in such a note when he decided to prescribe to the TFO.

[27] As found above, on the alprazolam prescription, Respondent listed his diagnosis as ''Generalized Anxiety Disorder.'' GX 28.

[28] It is acknowledged that during the visit, Respondent told the Agent had he had ''just left [him] on everything that you were on down there.'' GX 22, at 9. This does not, however, establish anything more than that he reviewed the prescription issued by Dr. Mosley. As explained previously, that another physician has issued a prescription does not establish that that physician issued the prescription for a legitimate medical purpose and acted within the usual course of professional practice.

[29] The ALJ also stated that there is no ''evidence to support a finding that Respondent's reliance on records of Dr. Mosley's prescribing in this instance was unreasonable or unlawful.'' ALJ at 79. However, absent from the ALJ's discussion of the note for the Agent's visit with Dr. Mosley is any acknowledgement that Mosley made no findings that the Agent had anxiety and did not include anxiety among his diagnoses. *See id.* at 78.

the prescriptions issued by the previous doctor were for a legitimate medical purpose and issued within the usual course of professional practice.

As for the Respondent's purported reliance on the information in the August 25 progress note that the Agent's pain affected his sleep, the ALJ noted that the record is unclear as to what information the Agent provided in answering the medical questionnaire on the issues of anxiety [and] sleep disturbance,'' thus suggesting the possibility that the information the Agent provided was not consistent with what Mr. Gomez (who falsified two urine drug screen reports and admitted that he shredded the medical questionnaires pursuant to clinic policy) entered into the EMR. However, even if Gomez's destruction of the questionnaire does not support an adverse inference, the ALJ's conclusion is not supported by substantial evidence.

As explained above, Respondent did not testify that he relied on this notation. Moreover, if Respondent was engaged in legitimate medical practice, one would expect that at some point he (or Gomez) would have inquired of the Agent as to how the pain was affecting his sleep. Yet there was no such inquiry of the Agent. Also, while it may be that a patient's sleep problems may be a symptom of generalized anxiety disorder, there is no evidence establishing that this alone is sufficient to diagnose a patient as having generalized anxiety disorder, especially when the doctor finds that the patient ''denies any problems with anxiety'' and that the patient's ''[m]ental status, judgment and affect are grossly intact and normal for age.'' Again, because Respondent failed to testify and address the basis for his diagnosis and offer a credible explanation for why he diagnosed the Agent with general anxiety disorder while finding that he ''denies any problems with anxiety,'' I conclude that an adverse inference is warranted and hold that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he prescribed Xanax to the Agent.[30]

[30] With respect to the oxycodone prescription issued by Respondent, the ALJ wrote: ''Notably, Dr. Parran's report and testimony neglect to make any reference to [the Agent's] report of mild pain on the right side during the August 25, 2011 physical examination, or discuss whether such a report of mild pain would be consistent with a patient taking pain medication in the quantities and strengths prescribed to SA Rice by Dr. Mosely [sic].'' ALJ at 81. Contrary to the ALJ's statement, the Expert testified at length as to the appropriateness of prescribing schedule II narcotics to a patient who complains of only mild pain.

Summary of Evidence as to Factors Two and Four

As explained above, even assuming, without deciding, that the ALJ properly failed to give weight to the Expert's testimony, there is still substantial evidence that Respondent violated 21 CFR 1306.04(a) when he prescribed oxycodone and alprazolam to the undercover officer who presented as Robbie Payne. Moreover, the record contains substantial evidence that Respondent violated 21 CFR 1306.04(a) when he prescribed alprazolam to the undercover officers who presented as Anthony Thompson, Michael Corleone, and Eric McMillen.

I therefore conclude that the Government has satisfied its *prima facie* burden of showing that Respondent ''has committed such acts as would render his registration * * * inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). *See also MacKay,* 664 F.3d at 819 (Upholding Agency determination, noting that ''[i]n 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. 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 [two patients] is sufficient to support her determination that his continued registration is inconsistent with the public interest.'').

Sanction

Under Agency precedent, where, as here, the Government has made out a *prima facie* case that a registrant has committed acts which render his ''registration inconsistent with the public interest,'' he must '''present[] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.''' *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe-Jonesborough,* 73 FR at 387. As the Sixth Circuit has recognized, this Agency also ''properly considers'' a registrant's admission of fault and his candor during the investigation and hearing to be ''important factors'' in the public interest determination. *See Hoxie,* 419 F.3d at 483.

More recently, the Tenth Circuit upheld the Agency's rule, explaining that:

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

MacKay, 664 F.3d at 820.

So too, here, Respondent failed to testify and acknowledge his wrongdoing and provide evidence that he will not engage in future misconduct. In short, Respondent put on no evidence to rebut the Government's showing that his registration is inconsistent with the

For example, after the Expert noted that the UCs had generally complained of pain levels which ''were four or less,'' the Government asked if a ''reported pain level of four or less'' was significant in his review. Tr. 628. The Expert answered: ''A pain level of a four or less indicates mild pain, and a pain which is typically not treated with opiate analgesics, certainly not treated with around the clock opiate analgesics that are Schedule II.'' *Id.* at 629. Subsequently, the expert explained that ''typically, reports that are certainly below four are considered mild pain and pain which is, you know, not impactful or very impactful on patient function, and typically not prescribed certainly * * * high potency Schedule II opiate analgesics.'' *Id.* at 630–31. The Expert then explained that there are risks and benefits to prescribing opiate analgesics and that while the drugs can help patients improve their function, there is ''[t]he risk * * * that patients can and will develop physical dependence,'' as well as other problems such as endocrine changes and sedation, and that ''if a person's impairment of function and/or pain level is in the mild range, then the risk of putting a person on these kinds of medications are [sic] typically considered to outweigh the potential benefit.'' *Id.* at 631–32. Notably, none of this testimony was refuted or shown to be inconsistent through other evidence.

Subsequently, the Expert was asked (albeit with respect to his review of the visit of another UC), whether Respondent's prescribing of alprazolam was problematic. After noting that based upon the information contained on the recordings there did not seem ''to be a diagnosis established [to] prescribe the alprazolam,'' the Expert further testified:

> And my concern goes beyond that, that prescribing Alprazolam on top of Schedule II opiate medication increases the risk of the Schedule II opiate medications, because Alprazolam potentiates the problematic side of opiate medications. It potentiates the sedation, the respiratory depression and the euphoria of opiate medications.

Id. at 636. Notably, the ALJ did not offer any explanation for why he rejected this testimony other than his view that the Expert was so biased as to ''preclude[] any reliance on his opinion testimony,'' ALJ at 89 n. 118, except for when he did rely on it.

public interest.[31] And here, too, it is appropriate to draw an adverse inference from Respondent's failure to testify. *See MacKay,* 664 F.3d at 820.

Contrary to the ALJ's understanding, the existence of a pending criminal prosecution does not preclude the Agency from drawing an adverse inference from Respondent's failure to testify. *See id.* Indeed, as the Tenth Circuit recognized in *MacKay,* '''[n]ot only is it permissible to conduct a civil [administrative] proceeding at the same time as a related criminal proceeding, even if that necessitates invocation of the Fifth Amendment privilege, but it is even permissible for the trier of fact to draw adverse inferences from the invocation of the Fifth Amendment in a civil [administrative] proceeding.''' *Id.* (quoting *Keating,* 45 F.3d at 326). *See also Baxter,* 425 U.S. at 318 (''[T]he Fifth Amendment does not forbid adverse inferences against parties to civil actions when they refuse to testify in response to probative evidence offered against them * * * .''); *Hoxie,* 419 F.3d at 483. Moreover, ''the Fifth Amendment privilege is not 'a sword whereby a claimant asserting the privilege [is] freed from adducing proof in support of a burden which would otherwise have been his.''' *Grider Drug #1 & Grider Drug #2,* 77 FR 44069, 44104 (2012) (quoting *United States* v. *Rylander,* 460 U.S. 752, 758 (1983)).

I therefore hold that Respondent has failed to rebut the Government's *prima facie* case. Moreover, as the Supreme Court explained in *Gonzales,* the core purpose of the Act's prescription requirement is to prevent the diversion of controlled substances to those who seek the drugs for the purpose of engaging in self-abuse or selling them to others. *See* 546 U.S. at 274 (''the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'') (citing *Moore,* 423 U.S. at 135 & 143).[32]

As I have previously explained, the Agency has revoked other practitioners' registrations for committing as few as two acts of diversion, *see Krishna-Iyer,* 74 FR at 463 (citing *Alan H. Olefsky,* 57 FR at 928–29), and the Agency can revoke based on a single act of intentional or knowing diversion. *See MacKay,* 75 FR at 49977. Because Respondent's misconduct in diverting controlled substances is egregious and he has failed to accept responsibility for his misconduct and demonstrate why he can be entrusted with a registration, I conclude that his continued registration is inconsistent with the public interest. 21 U.S.C. 824(a)(4). Accordingly, I will order that Respondent's registration be revoked and that any pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FM0624139, issued to T.J. McNichol, M.D., be, and it hereby is, revoked. I further order that any application of T.J. McNichol, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effectively immediately.[33]

Dated: August 29, 2012.

Michele M. Leonhart,

Administrator.

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BILLING CODE 4410–09–P

[31] Respondent did not even put on evidence that Mr. Gomez, who clearly falsified the urine drug screens of two of the undercovers to show they were taking drugs when they were not, had been fired.

[32] *See Jayam Krishna-Iyer,* 74 FR at 463 (quoting National Center on Addiction and Substance Abuse, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* 3 (2005) [hereinafter, *Under the Counter*]). As noted in *Krishna-Iyer,* ''[t]he diversion of controlled substances has become an increasingly grave threat to this nation's public health and safety. According to The National Center on Addiction and Substance Abuse (CASA), '[t]he number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003.''' 74 FR at 463 (quoting *Under the Counter,* at 3). CASA also found that '''[a]pproximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000).''' *Id.* (quoting *Under the Counter,* at 3). Finally, CASA found that '''[b]etween 1992 and 2003, there has been a * * * 140.5 percent increase in the self-reported abuse of prescription opioids,'' and in the same period, the ''abuse of controlled prescription drugs has been growing at a rate twice that of marijuana abuse, five times greater than cocaine abuse and 60 times greater than heroin abuse.'' *Id.* (quoting *Under the Counter,* at 4).

[33] For the same reasons which led me to order the immediate suspension of Respondent's registration, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0224]

Agency Information Collection Activities: Proposed Collection; Comment Request; National Youth Gang Survey

ACTION: 60-Day notice of information collection under review.

The U.S. Department of Justice, Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''60 days'' until November 16, 2012. This process is conducted in accordance with 5 CFR 1320.10.

If you have additional comments, especially on the estimated public burden or associated reponse time, or suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Mr. Dennis Mondoro, (202) 514–3913, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street NW., Washington, DC 20531. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology;