this Agency has previously rejected similar arguments.

On July 10, 2008, the ALJ granted the Government's motion. ALJ at 6. The ALJ noted that no material facts were in dispute and that Respondent did not deny that he is currently not authorized under California law to handle controlled substances. *Id.* Noting that this Agency has consistently held that a practitioner may not maintain his registration if he lacks authority to handle controlled substances under the laws of the State in which he practices, the ALJ granted the motion and recommended that Respondent's registration be revoked and that any pending applications to renew or modify his registration be denied. *Id.* Thereafter, the ALJ forwarded the record to me for final agency action.

Having considered the entire record in this matter, I adopt the ALJ's decision in its entirety. I find that Respondent holds DEA Certificate of Registration, BS6026529, which authorizes him to dispense controlled substances in schedules II through V at the registered location of 17655 Harvard Place, Suite F, Irvine, California. I further find that while the expiration date of the registration was February 28, 2007, Respondent submitted a timely renewal application and therefore his registration has remained in effect pending the issuance of this Final Order. *See* 5 U.S.C. 554(e).

I further find, however, that on December 19, 2007, the Dental Board of California ordered that Respondent's State Dental Certificate be revoked with an effective date of January 21, 2008.[2] Moreover, while it has been more than seven months since Respondent's challenge to the Dental Board's proceeding was heard in State court, Respondent has submitted no evidence to the Agency that the Board's revocation order has been set aside or stayed, and according to the Board's Web site, Respondent's Dental Certificate remains revoked.

Under the Controlled Substances Act (CSA), a practitioner must be currently authorized to handle controlled substances in ''the jurisdiction in which he practices'' in order to maintain a DEA registration. *See* 21 U.S.C. 802(21) (''[t]he term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to distribute, dispense, [or] administer * * * a controlled substance in the course of professional practice''). *See also id.* § 823(f) (''The Attorney General shall register practitioners * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.''). As these provisions make plain, possessing authority under State law to handle controlled substances is an essential condition for holding a DEA registration.

Accordingly, DEA has held repeatedly that the CSA requires the revocation of a registration issued to a practitioner whose State license has been suspended or revoked. *David Wang*, 72 FR 54297, 54298 (2007); *Sheran Arden Yeates*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988). *See also* 21 U.S.C. 824(a)(3)(authorizing the revocation of a registration ''upon a finding that the registrant * * * has had his State license or registration suspended [or] revoked * * * and is no longer authorized by State law to engage in the * * * distribution [or] dispensing of controlled substances'').

Here, there is no dispute over the material fact that Respondent's California Dental Certificate has been revoked and that Respondent lacks authority under California law to dispense control substances. Respondent is therefore not entitled to maintain his DEA registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, BS6026529, issued to Scott Sandarg, D.D.S., be, and it hereby is, revoked. I further order that any pending application of Scott Sandarg, D.D.S., to renew or modify his registration, be, and it hereby is denied. This Order is effective May 15, 2009.

Dated: April 3, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–8613 Filed 4–14–09; 8:45 am]

BILLING CODE 4410–09–P

[2] The State ALJ's decision concluded that the State had proved nine different causes to discipline Respondent, several of which related to his abuse of controlled substances. *In re Sandarg*, Proposed Dec. at 44–46, No. DBC 2006–36 (2007).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–52]

George C. Aycock, M.D.; Revocation of Registration

On June 25, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to George C. Aycock, M.D. (Respondent), of Sumter, South Carolina. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, AA1071947, which authorizes him to dispense controlled substances as a practitioner, and the denial of any pending application to renew or modify the registration, on the grounds that: (1) Respondent's state controlled substance registrations had been suspended, and thus he no longer has authority to handle controlled substances under South Carolina law; and (2) Respondent had committed acts inconsistent with the public interest. ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

With respect to the second ground for the proceeding, the Show Cause Order alleged that Respondent had ''repeatedly failed to establish a proper physician-patient relationship, as required by state and federal law, and ha[d] authorized controlled substance[] prescriptions without a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a), 21 U.S.C. 841(a)(1), and S.C. Code Regs. 81–28.'' *Id.* More specifically, the Order alleged that Respondent issued controlled-substance prescriptions to persons he knew were exhibiting drug-seeking behavior, abusing controlled substances, or selling their drugs to others. *Id.* The Order further alleged that Respondent failed to obtain appropriate medical histories, perform appropriate physical examinations, discuss treatments options and create a therapeutic plan as required by state law.[1] *Id.* at 2.

Thereafter, the Government sought the Immediate Suspension of Respondent's registration based on information that on July 3, 2008, the State of South Carolina had reinstated Respondent's controlled-substance registration, and that on the same day, Respondent had issued to a person, who had traveled 250 miles to see him, prescriptions for sixty tablets of Oxycontin (80 mg.), 90 tablets of Lortab (10 mg.), and 90 tablets of Xanax (1 mg.). ALJ Ex. 2, at 1–2. The Order further alleged that this person had been receiving prescriptions from Respondent since July 2007, and that medical records which the Government had seized during the execution of a search warrant indicated that Respondent had not ''perform[ed] an appropriate physical examination, ma[de] appropriate diagnoses or

[1] On July 10, 2008, the Government served the Show Cause Order on Respondent. ALJ Ex. 3.

formulate[d] a therapeutic plan before prescribing high doses of opioids to this individual.'' *Id.* at 2.

Based on the above, I found that Respondent had authorized, and was ''continu[ing] to authorize, controlled substance[] prescriptions'' which lacked a ''legitimate medical purpose,'' and were issued ''outside the usual course of professional practice,'' and that there was a ''substantial likelihood that [he] will continue to allow the diversion of controlled substances.'' *Id.* I further concluded that Respondent's ''continued registration during the pendency of the[] proceedings would constitute an imminent danger to the public health or safety.'' *Id.* Accordingly, on July 22, 2008, I immediately suspended Respondent's registration.

On or about July 10, 2008, Respondent was served with the Show Cause Order, and on July 25, 2008, Respondent was served with the Immediate Suspension Order. ALJ Ex. 3. On July 25, 2008, Respondent requested a hearing on the allegations, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJ). ALJ Ex. 4.

On December 10, 2008, a hearing was held in Arlington, Virginia. At the hearing, the Government called witnesses to testify and introduced various documents into evidence; Respondent introduced various documents and testified on his own behalf. Thereafter, the Government submitted a post-hearing brief. While Respondent sought and was granted an extension of the filing deadline, he failed to file a post-hearing brief.

On January 21, 2009, the ALJ issued her recommended decision (ALJ). Therein, the ALJ generally ''found the Government's witnesses more credible than Respondent,'' that the former ''appeared to be straightforward and candid, but Respondent appeared to tailor his testimony to suit his version of [the] events.'' ALJ at 50.

The ALJ also found that the various patient files were consistent with hearsay evidence as to what the patients had told Investigators regarding Respondent's prescribing practices. *Id.* at 51. Moreover, the ALJ found credible the testimony of the Government's expert as to the appropriate treatment of pain patients and the use of methadone to treat pain. *Id.*

With respect to the public interest factors, the ALJ found that Respondent was authorized to handle controlled substances under South Carolina law and had not been convicted of any offense under either Federal or State law related to controlled substances. ALJ at 51 & 53. As for Respondent's experience in dispensing controlled substance, the ALJ specifically found that:

> Respondent saw patients in groups; that he did not conduct complete physical examinations of them or document complete medical histories; that he did not document the bases for his diagnoses, especially his diagnoses of anxiety; and that he did not document any treatment plans other than to list the medications he prescribed and note the date of the next visit. Respondent also failed to order any tests or refer patients to specialists for their underlying conditions.

Id. at 52.

The ALJ also found that Respondent inappropriately prescribed methadone to treat pain, and that ''he ignored indications that at least some of the persons to whom he issued controlled substance prescriptions were abusing those medications.'' *Id.* More specifically, the ALJ noted that ''some of Respondent's patients had obvious track marks * * * but Respondent's only response to this testimony was that he took blood pressure and listened to patient's lungs through their shirts, and thus did not see their arms.'' *Id.* Relatedly, the ALJ found that Respondent ''ignored obvious signs of drug-seeking behavior,'' and that he ''increased the strength and/or quantities of the drugs he prescribed without explaining the increases in the patient charts and, in some instances, [did so] while simultaneously recording that the patients were doing well.'' *Id.* at 52–53. Finally, the ALJ adopted the conclusion of the Government's expert ''that Respondent issued prescriptions for other than legitimate medical reasons.'' *Id.* at 53. The ALJ thus concluded that this factor supported ''a finding that Respondent's continued registration would be inconsistent with the public interest.'' *Id.*

Relatedly, the ALJ found that Respondent had failed to comply with the laws and regulations of South Carolina which require that a physician establish a valid doctor-patient relationship (and set forth various steps a physician must take) prior to prescribing a drug. *Id.* The ALJ thus concluded that Respondent violated both South Carolina law and the Controlled Substances Act's prescription requirement, 21 CFR 1306.04, and that this factor also supported ''a finding that the Respondent's continued registration would be inconsistent with the public interest.'' *Id.*

As for the fifth factor, the ALJ noted that while Respondent had introduced into evidence letters ''attesting to his good character and professional competence,'' the letters did not ''controvert the [Government's] evidence.'' *Id.* at 54. Finally, the ALJ found that Respondent had ''refus[ed] to acknowledge his wrongdoing,'' and that his refusal to do so ''offers little hope * * * that he will act more responsibly in the future.'' *Id.*

The ALJ thus apparently concluded that Respondent's continued registration ''would not be consistent with the public interest,'' and recommended that I revoke his registration and deny any pending application to renew or modify his registration. *Id.* Neither party filed exceptions to the ALJ's recommendation. Thereafter, the recorded was forwarded to me for final agency action.

Having considered the entire record in this matter, I adopt the ALJ's decision in its entirety with the exception of the first paragraph of footnote 82.[2] More specifically, I conclude that Respondent's experience in dispensing controlled substances and record of compliance with applicable laws amply demonstrate that he committed acts which render his registration ''inconsistent with the public interest.'' 21 U.S.C. § 824(a)(4). I further conclude that Respondent failed to rebut the Government's *prima facie* showing that his continued registration would be inconsistent with the public interest. Accordingly, I will order the revocation of Respondent's registration and the denial of any pending application to renew or modify the registration. I make the following findings.

Findings

Respondent is a Medical Doctor who is currently licensed in the State of South Carolina to both practice medicine and handle controlled substances. ALJ Ex. 4, at 1. Respondent is also the holder of DEA Certificate of Registration, AA1071947, which prior to my issuance of the immediate suspension order, authorized him to dispense controlled substances in schedules II through V as a practitioner.

[2] Therein, the ALJ noted that Respondent had violated 21 U.S.C. 844(a) ''by asking someone else to pick up a controlled substance from [his] home.'' ALJ at 53 n.82. This provision, however, renders it ''unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter.'' 21 U.S.C. 844(a). It is not clear how Respondent violated the statute when the Government produced no evidence that he lacked a lawful prescription for the drug. Nor did the Government cite to any authority holding that the act it relies on constitutes a violation of the statute where a person has a lawful prescription.

GX 1, at 1. Respondent's registration does not expire until June 30, 2009.[3] *Id.*

Respondent, who is board-certified in family practice, previously practiced medicine in Greeneville, Tennessee, in a practice which apparently was owned by another physician. Tr. 276. In his testimony, Respondent claimed that while he lived in Greeneville, he ''ticked off'' a prominent person in the town and thereafter, became the target of ''the vindictiveness of the town.'' *Id.* at 278–79. As an example, Respondent testified that one day he was stopped for speeding. *Id.* at 279–80. Respondent did not, however, have his license on him and was arrested for driving without a license. *Id.* at 280. Following the incident, Respondent was also charged with resisting arrest; Respondent claimed, however, that he had done nothing to warrant the charge. *Id.* A jury apparently felt differently and convicted him of all three charges. *Id.* at 134.

In November 2005, Respondent, who apparently was also having marital difficulties, was arrested a second time by the Greeneville police and charged with domestic assault on his then-wife and stepdaughter; Respondent was also charged with resisting arrest on this occasion. *Id.* at 133. At some point, Respondent, who was arrested a third time for missing a court appearance, pled guilty to the charges. *Id.* at 134.

According to Respondent, at some point following his trial and conviction on the first set of charges, ''rumors * * * were being started around town'' that he was ''selling drugs out of [his] office.'' *Id.* at 282. Moreover, the doctor who owned the office where Respondent practiced died suddenly and the former's son-in-law told Respondent to leave. *Id.* at 283. Respondent then moved to Sumter, South Carolina. *Id.* at 285.

On November 21, 2006, Respondent was arrested in South Carolina and jailed in Sumter. *Id.* Respondent was eventually extradited back to Tennessee, and jailed in the Greene County Jail in Greeneville. *Id.* at 285–86. On or about February 13, 2007, Respondent was released from the jail. *Id.*

While in jail, Respondent met several individuals who eventually became his ''patients'' including W.G. and B.J.P.; both A.C. and B.C., who also became Respondent's patients, were incarcerated in the jail during some portion of the period of his residence therein. *Id.* at 156, 174, 243. In his testimony, Respondent admitted that while he was in jail, he had met ''three or four of'' his patients. *Id.* at 294.

While in jail, Respondent discussed with B.J.P. (who was his ''pod mate''), the latter's ''pain problems,'' and on one occasion, Respondent looked at B.J.P.'s back. *Id.* at 157–58. Respondent agreed to write controlled-substance prescriptions for B.J.P. after they were released from jail. *Id.* at 156. The day after he was released, Respondent wrote a controlled substance prescription for B.J.P., and called in another prescription a month later. *Id.* at 156–57; 184–85.

During an interview with investigators, Respondent initially denied writing prescriptions for B.J.P. Tr. 184. The Investigators then confronted Respondent with the prescription that he wrote for B.J.P. the day after his release from the jail. *Id.* Respondent then admitted he should not have written the prescription. *Id.*

Following his release from jail, Respondent returned to South Carolina. *Id.* at 157. While Respondent lived approximately four-and-a-half to five hours away (by driving) from Greeneville, Tennessee, B.J.P. began traveling to Respondent's home to obtain controlled-substance prescriptions from him. *Id.* According to the testimony of a DEA Investigator who interviewed B.J.P., B.J.P. would travel with a friend (M.H.), who also obtained controlled-substance prescriptions from Respondent. *Id.* at 158.

B.J.P. also related to the Investigator that during the visits, he and his friend would talk with Respondent but did not undergo a physical examination. *Id.* at 157–58. B.J.P. also told the Investigator that Lortab, a schedule III controlled substance which combines hydrocodone with acetaminophen, ''was his drug of choice'' and ''what he received from'' Respondent, *id.* at 159, but that Respondent had also given him prescriptions for Oxycontin, a schedule II controlled substance which contains oxycodone. *Id.* at 160. While Oxycontin was not B.J.P.'s ''drug of choice,'' he was able to sell it and pay for his trips to Respondent. *Id.* at 160.

An Investigator also interviewed M.H., who had accompanied B.J.P. on the latter's visits. *Id.* at 170–71. M.H. confirmed B.J.P.'s statement that when the two of them visited Respondent, they would talk with him in the latter's living room, and that Respondent did not take their blood pressure, require them to disrobe, or conduct any type of physical examination ''like [M.H.] had ever seen in a regular doctor's office.'' *Id.* at 171. After some discussion, Respondent would go upstairs and print out whatever prescriptions he was going to issue to them. *Id.* M.H. did not ''know what his diagnosis was,'' what his treatment plan was, and never ''receive[d] a referral for other treatment'' or tests. *Id.* at 172. M.H. told investigators that he initially received prescriptions for schedule III drugs containing 10 mg. of hydrocodone, ''after a short period,'' Respondent issued him prescriptions for Percocet or Oxycontin, both of which contain oxycodone. *Id.* at 171–72.

B.J.P. and M.H. were not, however, the only ''patients'' who jointly saw Respondent. H.R. and A.R., who were married to each other, told investigators that Respondent had been recommended to them by two other persons who were seeing him, M.C. and P.G. *Id.* at 234. These four individuals traveled together to see Respondent at his residence. *Id.*

Giving new meaning to the term ''group practice,'' the four persons jointly met with Respondent in his living room. *Id.* H.R. related to the investigators that he became ''rather embarrassed'' when during the meeting, Respondent ''asked him to unbutton his trousers so that [Respondent] could examine his back in front of the other three individuals in the same room.'' *Id.* at 234–35. Thereafter, Respondent ''went upstairs.'' *Id.* at 235. When Respondent returned he gave controlled-substance prescriptions to H.R. *Id.* Respondent charged H.R. $150 at the initial visit and $100 at subsequent visits. *Id.*

According to H.R.'s patient file, which was seized pursuant to a warrant, on July 24, 2007, Respondent diagnosed H.R. as having chronic lower back pain and anxiety, and issued him prescriptions for sixty tablets of Oxycontin (20 mg.), ninety tablets of Lortab (10 mg.), ninety tablets of Xanax (1 mg.), and ninety tablets of Soma (carisoprodol).[4] GX 51, at 5. At H.R.'s next visit (August 21, 2007), Respondent increased the strength of the Oxycontin to forty milligrams, and issued additional prescriptions for Lortab, Xanax, and Soma;[5] Respondent issued additional prescriptions for these four drugs on September 20 and October 19, 2007. *See id.* at 2 & 4.

The patient files of M.C. (GX 46) and A.R. (GX 59) reflect that both

[3] Respondent registration was issued to him at the address of 295 Lakewood Drive, Sumter, South Carolina. GX 1, at 2.

[4] Soma (carisoprodol) is not a controlled substance under federal law. It is, however, a highly abused drug which metabolizes into meprobamate, a schedule IV depressant. *See Paul Volkman,* 73 FR 30630, 30636 n.21 (2008). The drug is frequently taken by drug abusers as part of a cocktail which also includes an opiate and benzodiazepine. *See id.* at 30638.

[5] Respondent slightly reduced the number of tablets of the various drugs to reflect the fact that H.R. had returned after twenty-eight rather than thirty days. GX 51, at 4.

individuals obtained controlled-substance prescriptions from Respondent on both July 24 and August 21, 2007.[6] *See* GX 46, at 7; GX 59, at 2, 5–6. More specifically, at the July 24 visit, Respondent issued to A.R., prescriptions for sixty tablets of Oxycontin (20 mg.), ninety tablets of Lortab (10 mg.), ninety tablets of Xanax (1 mg.), and ninety tablets of Soma. GX 59, at 5. On the same date, Respondent issued to M.C. a refill of the prescriptions he had previously issued to him (on June 26) for Oxycontin (80 mg.), Lortab (10 mg.), Xanax (1 mg.) and Soma.[7] GX 46, at 7–8.

According to the note dated August 21, 2007, M.C. was ''working [and] unable to come.'' *Id.* at 7. The note nonetheless related that M.C. ''is doing well [and] pain is stable,'' and that Respondent issued him prescriptions for fifty-six tablets Oxycontin (80 mg.), eighty-four tablets of Lortab (10 mg.), eighty-four tablets of Xanax (1 mg.), and eighty-four tablets of Soma.[8] *Id.* M.C. received prescriptions for the same drugs from Respondent on September 15, October 8, November 5, and December 3, 2007. *Id.* at 2, 4–6.

As for A.R., at the August 21 visit, Respondent prescribed fifty-six tablets of a stronger version of Oxycontin (40 mg.), as well as eighty-four tablets of Lortab (10 mg.), Xanax (1 mg.), and Soma. GX 59, at 5. On September 20 and October 19, 2007, Respondent issued to A.R. prescriptions for the same four drugs. *Id.* at 2 & 4.

On or about October 1, 2007, Respondent opened an office in Sumter and started seeing patients there. Tr. 185. Prior to opening his office, Respondent sought to develop his patient base by placing ads in newspapers that were published in both Sumter and Greeneville, Tennessee. *Id.* at 229. Apparently, the ad placed in the Greeneville paper was far more successful than the one placed in the local paper as the overwhelming majority of the fifty-seven patients he had (as of the date the warrant was executed) were from Tennessee, and only three of them were from South Carolina. *See* Tr. 244–45 (testimony that Respondent told his nurse that ''the patients were his previous patients from Tennessee, who came when [he] ran the ad in the newspaper''); *id.* at 229, 180–81. Investigators were only able to identify two persons (J.C., and an unnamed woman), who he had previously treated when he practiced in Tennessee. *Id.* at 180–81.

K.C., M.B., and S.M. were also among the patients interviewed by DEA Investigators who drove from the Greeneville, Tennessee area, to obtain prescriptions from Respondent. M.B., an admitted drug dealer, told Investigators that H.R. and A.R. had told him that if he saw Respondent, he could ''get whatever you want from'' him.[9] *Id.* at 164. M.B. accordingly visited Respondent and obtained controlled-substance prescriptions from him. *Id.* During one of the visits, M.B. told Respondent that he had ''just tried a friend's [Oxycontin] and liked it.'' *Id.* M.B. asked for an Oxycontin prescription and Respondent obliged. *Id.* M.B. further told investigators that when he saw Respondent ''he didn't have a normal exam,'' and ''wasn't asked to disrobe.'' *Id.* at 166. ''Basically,'' M.B. ''just talked to'' Respondent. *Id.*

Various prescription records show that Respondent issued to M.B. the following prescriptions for Oxycontin (20 mg.): sixty tablets on October 1, fifty tablets on October 26, and ninety tablets on November 27, 2007. *See* GX 64, at 26, 56 & 130. Respondent also issued to M.B. the following prescriptions for Percocet (10/325): sixty tablets on both November 27 and December 28, 2007. *See id.* at 24 & 149. Finally, on January 28, 2008, Respondent issued M.B. a prescription for 90 Klonopin (clonazepam 2 mg.). *See id.* at 268.

S.M., who admitted to investigators that he was a lifelong drug abuser, had also purchased drugs from M.B., which the latter had obtained from Respondent. Tr. 138–39. According to both a DI and Lt. Crum, S.M. had visible track marks on his arms, which indicated that he was taking drugs intravenously (IV). *Id.* at 138 & 167. S.M. also told the DIs ''that he would use any drugs that he could get his hands on,'' and that he would shoot up every day but for the expense. *Id.* at 167. Moreover, S.M. had chronic obstructive pulmonary disorder and was being treated for this condition by a physician (Dr. R.L.) in Greene County. *Id.* at 190; GX 52, at 15. In April 2008, two DIs interviewed Dr. R.L. regarding S.M. *Id.*

Dr. R.L. told the DIs that S.M. had admitted to him that he was an IV drug abuser, and in any event, S.M.'s track marks and gaunt appearance made it obvious that he was a drug abuser, and that one did not have to be a physician to recognize as much. *Id.; see also id.* at 167 (Investigator testifying that S.M.'s track marks were ''very obvious,'' that his vein area was ''discolored,'' and there were ''open sores on his arms where he shot up''). Dr. R.L. stated that because of S.M.'s history of drug abuse, he would not prescribe controlled substances to him. *Id.* at 191. Moreover, Dr. R.L. had never been contacted by Respondent regarding S.M., and ''had no idea'' that S.M. was seeing Respondent. *Id.*

S.M.'s patient file contains several documents which indicated that he was being treated by Dr. R.L. See GX 52, at 15–16. Moreover, a report of a physical examination which was done on May 4, 2007 when S.M. sought disability, noted that he ''has used marijuana and IV drug[s], specifically cocaine.'' *Id.* at 8. While the report also indicated that S.M.'s ''last use of [illicit drugs] was about [three] years ago,'' *id.*, the report also noted that he had been in jail ''for the last 17 months and * * * has been out about 2 or 3 months.'' *Id.* at 7.

Respondent first saw S.M. on, or about October 1, 2007.[10] While S.M.'s file includes the report of a recent MRI of his right knee which indicated that he had tears of the lateral and medial menisci, chondromalacia, a ''probable tear of the anterior cruciate ligament,'' and a Baker's cyst, S.M. had not been treated with controlled substances. *Id.* at 5, 12–13. Respondent issued S.M. a prescription for sixty tablets of Oxycontin (20 mg.), with instructions to take one tablet twice a day, as well as for Motrin, a non-controlled drug. *Id.* at 6. Respondent's treatment plan was limited to prescribing these two drugs and a follow-up in thirty days. *Id.*

On October 26, S.M. again saw Respondent. *Id.* at 4. The progress note indicates that S.M. had only one tablet of the Oxycontin left, even though only twenty-five days had passed since the earlier visit. *Id.* Moreover, S.M. told Respondent ''[h]e also took someone else's Roxicodone 30 mg, & says it really helped his pain.'' *Id.* S.M. also complained of ''nerves'' and that he was ''not sleeping well.'' *Id.* On the note,

[6] The patient file for P.G. was not admitted into the record.

[7] The patient file for M.C. does not indicate the number of tablets he prescribed for the various drugs on June 26 and July 24, 2007; the file does, however, include the abbreviations for the dosing instructions on the progress note which is dated June 26. GX 46, at 7–8. The note indicates that M.C. was to take the Oxycontin b.i.d., or twice a day (thus suggesting that the prescription was for sixty tablets); the other drugs were to be taken t.i.d., or three times per day (thus suggesting that prescriptions were for ninety tablets).

[8] The record does not establish whether the prescriptions were mailed to M.C. or were provided to M.C.'s acquaintances.

[9] According to Lieutenant Crum of the Greeneville, Tennessee Police Department, during the execution of a search warrant at M.B.'s residence, the authorities found both ''several pounds of marijuana and several pill bottles from Respondent.'' Tr. 138.

[10] While the notes pertaining to the initial visit are cut off where the date is indicated, the note for the October 26, 2007 visit, indicates that Respondent had ''first seen [S.M.] 25 days ago.'' GX 52, at 4.

Respondent indicated that S.M. had the following conditions: 1) Chronic knee pain—menisci tears, 2) osteoarthritis, 3) chronic anxiety, 4) COPD, and 5) Hepatitis C. *Id.* Respondent then issued S.M. prescriptions for fifty tablets of Oxycontin (20 mg.), sixty tablets of Roxicodone (15 mg.), and sixty tablets of Klonopin, and indicated that there would be a follow-up in ''30 days.'' *Id.*[11]

S.M. returned to Respondent on November 27. S.M. complained of knee pain and lower back pain/hip pain, which radiated down his leg. *Id.* at 2. He also complained that the ''pain meds aren't lasting long enough.'' *Id.* At the visit, Respondent prescribed sixty tablets of Oxycontin (20 mg.), sixty tablets of Klonopin, increased the Roxicodone (15 mg.) prescription to ninety tablets ''temporarily due to'' the earlier car accident, and added a prescription for Soma. *Id.* Respondent also noted that there would be a follow-up in thirty days and if S.M.'s back was not better, he ''will get MRI.'' *Id.*[12]

On one occasion, S.M. had traveled to Respondent accompanied by M.B. and K.C. On the way to South Carolina, S.M. was having trouble breathing, and according to K.C. was exhibiting ''extreme respiratory distress.'' Tr. 162; *see also id.* at 165 (M.B. told DI that S.M. ''was having extreme difficulty breathing''). Respondent nonetheless gave S.M. a prescription for Oxycontin, and apparently after S.M. filled the prescription at a pharmacy in South Carolina, he proceeded to inject the Oxycontin intravenously.[13] *Id.* According to both K.C. and M.B., S.M. injected himself with Oxycontin three times on the trip back to Tennessee. *Id.* at 162–63, 165. After returning to Greeneville, S.M., who had a collapsed lung, was admitted to the intensive care unit of a local hospital. *Id.* at 165 & 168.

Regarding his visit with Respondent on the day of this incident, S.M. acknowledged that he ''was having great difficulty breathing.'' *Id.* at 168. Respondent did not, however, mention S.M.'s condition or question him about it. *Id.* Respondent did not recommend that S.M. seek treatment for the condition, and after S.M. paid him in cash, issued him controlled-substance prescriptions. Tr. 168.

DEA Investigators interviewed several other persons who had obtained prescriptions from Respondent and related similar information regarding his prescribing practices. W.G., who as found above, had met Respondent in the Greene County Jail, saw Respondent at his home on multiple occasions. Tr. 174; GX 7. W.G., who at the time of the interview had been re-incarcerated, told Investigators that Respondent did not perform a physical examination on him, and he could not recall what conditions he was diagnosed with. Tr. 174. W.G. also told the Investigators that Respondent did not refer him to any specialist, and that his treatment was limited to taking medication. *Id.*

W.G.'s patient file indicates that he first saw Respondent on May 21, 2007. GX 7, at 3. According to the file, W.G. had a history of lower back pain, and an MRI indicated that he had disc problems. *Id.* W.G.'s file did not, however, contain an MRI report.[14] *See* GX 7. Moreover, under the portion for the physical exam, the notation for ''Back'' is blank. *Id.* at 3. Respondent nonetheless diagnosed W.G. as having the following conditions: (1) Lumbar Disc Disease, (2) Hypertension, (3) Hyperlipidemia, and (4) Chronic Anxiety. *Id.* At this visit, Respondent prescribed to W.G. ninety tablets of Lortab (hydrocodone) (10 mg.), sixty tablets of Avinza (morphine sulfate)[15] (90 mg.), ninety tablets of Valium (1 mg.) and ninety tablets of Soma. *Id.* At W.G.'s second visit, which occurred on June 26, 2007, Respondent re-issued prescriptions for each of these four drugs in the same quantities and strengths. *Id.*

On July 24, 2007, W.G. again saw Respondent. *Id.* at 2. Respondent noted that W.G. ''still has [Lower back pain]. Meds are helping but he took one of daughters [sic] Oxycontin & it helped better than Avinza.'' *Id.* Respondent also noted that he observed ''mild tenderness @ lower paravertebral area of lumbar spine,'' and that ''muscle spasm [is] present.'' *Id.* Instead of renewing the Avinza prescription, Respondent prescribed sixty tablets of Oxycontin (80 mg.). *Id.; see also* GX 64, at 3. Respondent also issued refills of the Lortab, Valium and Soma prescriptions. *Id.*

W.G.'s fourth visit with Respondent occurred on August 21, 2007. *Id.* Respondent indicated that W.G. is ''doing well'', but that he had a ''muscle spasm lower back & mild tenderness @ paravertebral area.'' *Id.* Respondent re-issued prescriptions for Oxycontin (80 mg.), Lortab (10 mg.), Valium (1 mg.), and Soma, although he decreased the quantities because W.G. had showed up two days early.[16] *Id.*

R.B. received at least five prescriptions for controlled substances from Respondent including three for Opana ER (oxymorphone hydrochloride), a schedule II controlled substance (21 CFR 1308.12(b)(1)), hydrocodone/acetaminophen (10/500 mg.), and clonazepam (1 mg.). *See* GX 64, at 110; GX 65, at 1–3. Moreover, at his visit of October 20, 2007, Respondent issued R.B. prescriptions for Opana ER, hydrocodone, clonazepam, and carisoprodol. *See* GX 65, at 1–3. While R.B. told Investigators that he had ''some pain problems,'' he also stated that Respondent did not examine him, did not refer him to any specialists, and that he did not know ''how long he was going to be on the medications.'' Tr. 173. Rather, R.B.'s understanding was ''that if he paid, he got this many [drugs] for this month,'' and that he was to ''come back next month.'' *Id.*

The Expert Testimony

Y. Eugene Mironer, M.D., testified for the Government as an expert witness in pain management. Dr. Mironer is a 1980 graduate of the Moscow State Medical School, did a four-year residency in general surgery at Moscow Medical School Hospital, and practiced for five years as a general surgeon at the Municipal Hospital, Moscow, in the former Soviet Union. GX 5, at 1. Thereafter, Dr. Mironer emigrated to the United States, and has completed an internship in Internal Medicine at SUNY–St. John's Hospital, Queens, NY; a three-year residency in Anesthesiology at the University of Massachusetts, Worcester, MA; and a fellowship in Pain

[11] In this note, Respondent also indicated that S.M. had been in a motor vehicle accident when he fell asleep while driving. *Id.*

[12] According to prescriptions records, Respondent issued to S.M. additional prescriptions for ninety tablets of Roxicodone (15 mg.) on December 28, 2007, and January 28, 2008; on the latter date, he also issued to S.M. prescriptions for sixty Oxycontin (20 mg.) and sixty Klonopin. *See* GX 64, at 151 & 228.

[13] K.C. testified that on her first trip to see Respondent she obtained a prescription for Percocet. Tr. 163. Various records show that on January 28, 2008, S.M., K.C., and M.B. all filled prescriptions issued by Respondent at the same pharmacy which was located in Columbia, South Carolina. *See* GX 64, at 228–29 (Rx to S.M. for Oxycontin 20 mg.), 266–67 (Rx to S.M. for Klonopin), 246–47 (Rx to K.C. for Percocet 10/325 mg.), 268–69 (Rx to M.B. for Klonopin). According to the records, these four prescriptions were dispensed between 4:11 p.m. and 4:58 p.m. *See id.* Approximately one hour later, S.M. filled a prescription for Roxicodone at a CVS Pharmacy, which was also located in Columbia. *See* GX 64, at 308–09.

[14] W.G.'s file also indicated that he had a history of HTN (hypertension) and lipid problems. GX 7, at 3.

[15] Avinza (morphine sulfate), a schedule II controlled substance. *See* 21 CFR 1308.12(b)(1).

[16] It also appears that W.G. saw Respondent on January 11, 2008, after he was released from jail, at which time he obtained additional prescriptions for Lortab and Valium. *See* GX 64, at 248–49, 250–51.

Management at the Medical College of Virginia, Richmond,VA[17] *Id.*

Dr. Mironer is board certified in both Anesthesiology and Pain Management, and is the Managing Partner and Medical Director of the Carolinas Center for Advanced Management of Pain, which has numerous offices in South Carolina and North Carolina, where he has practiced since 1996.[18] Tr. 10, GX 5, at 1. Dr. Mironer is also a member of various medical organizations including the American Pain Society, the Southern Pain Society, the International Spinal Injection Society, the American Medical Association, and the North Carolina and South Carolina Medical Associations. *Id.* at 2. Dr. Mironer has published numerous articles, and written several chapters of a textbook, on pain management; he has also presented at several conferences. *Id.* at 2–5; Tr. 12–13. Moreover, Dr. Mironer has continued to keep himself informed as to developments in the practice of pain management. Tr. at 13.

Dr. Mironer was qualified as an expert and testified at length regarding the course of medical practice used to assess, diagnose and treat pain patients. Dr. Mironer testified that ninety-nine percent of his practice's patients have been referred by either their primary care physician or a specialist, and that the patients either have their records sent prior to their appointment or hand carry them. *Id.* at 14. Before seeing a doctor, new patients are required to register and complete various forms and disclose what drugs they are currently taking and what pharmacies they are using. *Id.*

Upon meeting the patient, the physician obtains a thorough medical history which includes questions about the pain's location, origin, frequency, intensity, length of time it has been present, what aggravates it or eases it, and whether there are any other sensations that are related to it. *Id.* at 15–16. The physician also asks the patient about tests that have been done; what treatments including medications have been previously, or are currently being, used; if the patient has allergies; and the patient's surgeries. *Id.* at 16. The final part of the patient's history including reviewing other medical problems that the patient may have including mental health conditions and treatments, past drug and alcohol abuse, and sleep disorders.[19] *Id.* at 16–17.

Next, the physician does ''a full physical examination.'' *Id.* at 17. In the case of a complaint of back pain (which was a common complaint among Respondent's patients), this involves observing the patient's gait, assessing his ability to walk on both his toes and heels, and checking the patient's range of motion in his back both forwards/backwards and from side to side. *Id.* at 17–18. The patient's back is then visually examined for abnormalities such as scoliosis and scars from surgery; this is followed by palpation of the back for tender spots or trigger points. *Id.* at 18.

The physician next examines the strength, sensory condition, and reflexes of the patient's lower extremities. *Id.* Finally, the physician tests for Wadell's non-organic signs; these tests are used to determine whether the patient's pain has a psychological component. *Id.* at 18–19.

Based on the above, the physician arrives at his findings, formulates a treatment plan, and discusses both the findings and treatment plan with the patient. *Id.* at 20. As part of this process, the physician provides a detailed explanation as to why he/she is prescribing a particular drug (or no longer prescribing a drug the patient was previously taking), what procedures or treatments may help, and whether consultations with other specialists would be beneficial. *Id.* According Dr. Mironer, at least three out of four patients have not undergone enough diagnostic testing to determine the exact ''source of the[ir] pain and how to treat it.'' *Id.* at 21.

Dr. Mironer also stated that if a patient appeared at the initial visit without his/her records, he would prescribe a controlled substance—and do so only in a limited amount and in a low dose—only if the physical ''examination reveal[ed] some significant abnormalities.'' *Id.* at 23. The patient would be told, however, to come back in a couple days with all of his records. *Id.*

While Dr. Mironer testified that he accepts a patient's word that he is ''in pain,'' he further stated that ''not every pain is the same, and not every pain requires prescribing controlled substances,'' some pain may not be so bad as to require ''any serious intervention,'' and that some pain may be of ''a psychological origin'' and ''should not be treated with medication.'' *Id.* at 23–24. Dr. Mironer further noted that there are a variety of treatment modalities available for treating pain including physical therapy, psychological counseling, various types of injections, nerve blocks, and referrals to a spinal surgeon if short-term treatments do not improve the patient's pain level. *Id.* at 27–28.

Dr. Mironer also explained that he does not rely on a patient's recollection as to what drugs they are using because the patient may give mistaken information or mix up medications. *Id.* at 24. Moreover, in prescribing controlled substances, the amount of drug taken by the patient should be titrated. *Id.* at 34. Specifically, if treatment with a controlled substance is warranted and the patient is not currently taking a controlled substance, the patient is started on a lower strength drug such as hydrocodone of either 5 or 7.5 mg. strength, to be taken two to three times a day. *Id.* at 36. However, if the condition is severe, the dosing may be increased to ''every four to six hours.'' *Id.* at 37. Moreover, some patients may be started on oxycodone. *Id.* at 36 & 38.

Dr. Mironer further testified that he had reviewed the files Respondent maintained on fifty-seven of his patients, which were provided to him by Investigators with the DEA Columbia, S.C. Office. *Id.* at 40–41. The Government also introduced thirteen of the files into evidence and specifically questioned Dr. Mironer regarding what the records showed with respect to Respondent's prescribing practices.[20]

With respect to his review of all of the patient files, Dr. Mironer noted that ''practically all [of the] patients were self-referred and not from the local area,'' Tr. 44, and that fifty-four of the fifty-seven patients ''were coming from Tennessee,'' that this ''is usually not the case unless they are coming for some unique procedure,'' *id.* at 45, and that Respondent was not providing any unique procedures. *Id.* at 46. With respect to the out-of-state patients, Dr. Mironer observed that ''it is difficult to provide pain management for patients that live far away, because your ability to control what they take and what they receive and how they do it [is] significantly diminished with the distance'' they live from the practice. *Id.*

Dr. Mironer explained that when patients live out of state, ''there is much less communication [with] the pharmacist,'' a patient may be ''receiv[ing] the same medication from you and their family doctor,'' or even going to another pain clinic. *Id.* at 47. Dr. Mironer also noted that in his practice, at least ninety-nine percent of

[17] Dr. Mironer has also served as an Instructor in Anesthesia at the University of Massachusetts, and practiced as an anesthesiologist. GX 5, at 1.

[18] According to Dr. Mironer, the Carolinas Center has fifteen to twenty thousand patients. Tr. 10.

[19] Dr. Mironer also testified that it is not the ''usual or typical way of conducting [medical] practice'' to see multiple patients simultaneously, whether in one's living room or an examination room. Tr. 90.

[20] The contents of some of the files have been set forth above.

the patients are referred to it by another physician, whether a specialist or a family doctor. *Id.* at 47–48. According to Dr. Mironer, in dealing with self-referred patients, it is ''much more difficult to get the information from them and verify what kind of treatment they [have] received and are receiving currently.'' *Id.*; *see also id.* at 64 (discussing importance of communicating with a patient's other physicians to ensure that he/she is not receiving similar drugs from other physicians).

Relatedly, Dr. Mironer subsequently explained that he did not find ''any'' evidence that Respondent was attempting to control his patients' use of controlled substances through such standard practices as ''random urine toxicology screening to make sure that the patient is taking the medications that [are] prescribed, and not taking other controlled substances or street drugs,'' and/or calling the patients to come to the office for pill counts. *Id.* at 63–64. Dr. Mironer also noted that pill counts were not possible, because most of the patients lived out of state.[21] *Id.* at 64–65.

Dr. Mironer further opined that ''practically all of the patients [were] receiving an inadequate physical examination, as far as the areas of their pain is concerned,'' that ''practically all, if not all, receive[d] a prescription of controlled substances, but no specific treatment plan ha[d] been made.'' *Id.* at 48. Moreover, ''practically all the patients received opioids without any specific discernible plan,'' and a ''very significant number of the patients were receiving very high doses of opioids.''[22] *Id.* at 49.

Furthermore, the files contained ''no indications that there were any attempts to control or verify or check the use of controlled substances, such as urine toxicology screening or pharmacy check[s,] or check[ing] with the other treating physicians to see what kind of medication [the patients] have been prescribed, which is one of the typical steps that pain clinics * * * tak[e] to'' monitor their patients. *Id.* Dr. Mironer also explained that he found that ''very significant numbers [of patients] were diagnosed with anxiety without indication of how that diagnosis was made, and they were treated with the same medications for anxiety.'' *Id.* at 48–49.

Dr. Mironer further noted that in the ''vast majority of the cases'' in which Respondent prescribed controlled substances for lower back pain, the physical examination was limited to determining whether the patient had tenderness. Tr. 54. Moreover, ''most of the time'' Respondent's patient files lacked ''enough diagnostic or physical examination to confirm the severity of [the] disease,'' and ''[n]o additional tests were done or planned that [would] help[] with the determination.'' *Id.* at 122–23. Dr. Mironer also rejected the notion that additional tests should not be performed simply because a patient lacks insurance, noting that certain tests such as x-ray and CT scan are considerably cheaper than an MRI, and in any case, while a CT scan ''is still expensive,'' its cost is ''on par'' with the cost of filling multiple prescriptions. *Id.* at 126–27.

Accordingly to Dr. Mironer, Respondent's exam involved ''just basically press[ing] on the area, and if the patient says ouch, that is tenderness.'' *Id.* at 54. Dr. Mironer reiterated that to properly examine a patient's back, ''[t]here should be a range of motion examination of [the] musculoskeletal, nervous system, including the reflexes, strength of the muscles, sensitivity to touch, the possibility of abnormality in the sympathetic system which you check by examining the look of the skin, the possibility of what is called allodenia, or extremely painful response to a non-painful stimulus, and so on.'' *Id.*

With respect to Respondent's diagnosis of anxiety in various patients and prescribing of benzodiazepines, Dr. Mironer explained that ''there was nothing in the notes indicating as to why this diagnosis appears.'' *Id.* at 55. According to Dr. Mironer, there should be ''something in [the] description of [the] encounter with the patient [which] should tell us something. For example, the patient looks anxious and jittery, constantly shaking, sweating, complaining of constant feeling of anxiety running all the time, or panic attacks or what not. There was nothing like that described in any of the patients most of the time. * * * '' *Id.*

Dr. Mironer also stated that ''it is a common practice in pain clinics to do psychological testing * * * for a majority of the patients, because it is well known that a significant number of patients with chronic pain are suffering from psychological conditions,'' and the ''prevalence of psychological conditions among pain patients is higher than in general populations.'' *Id.* at 56. Moreover, among chronic pain patients, depression ''is more prevalent'' than anxiety. *Id.*

Dr. Mironer further observed that ''benzodiazepines were the medications that were prescribed in most of the cases I reviewed.'' *Id.* at 57. According to Dr. Mironer, they are ''usually not the first line of defense for anxiety,'' and are ''not the best medication to prescribe for patients who are on opioids as well.'' *Id.* Dr. Mironer explained that prescribing benzodiazepines with opioids increases the risk ''of opioid overdose or significant side effect[s] such as drowsiness.'' *Id.* at 58. Dr. Mironer also noted that most of his patients that are being treated for chronic anxiety ''are being treated without benzodiazepines or other controlled substances.'' *Id.* at 61.

Next, Dr. Mironer noted that in most of the files, after Respondent issued prescriptions, ''the only plan of care was to come back in one month.'' *Id.* at 62. Dr. Mironer opined ''[t]hat this is fairly unusual,'' because for ''the majority of the patients, prescribing medication'' is ''just a starting point to get them into other modalities of treatment, either testing or consulting and so on.'' *Id.* Dr. Mironer further explained that practically none of the files included ''a plan of treatment saying I will start the patient on hydrocodone and muscle relaxants, obtain nerve conduction studies, obtain new MRIs, consider doing this injection or sending him to physical therapy or neurosurgical consult. * * * [T]here were no plans for treatment other than a follow up report.'' *Id.*

Dr. Mironer also noted that there were ''quite a few patients'' whose ''dose of opioids was increased after the patient asked for an increase.'' *Id.* at 63. Dr. Mironer found that this was ''very significant'' because there was no ''specific plan of treatment,'' and the patients ''were just on this free flow regimen where they received controlled substances, and whenever they wanted an increase they were getting an increase most of the time.'' *Id.* According to Dr. Mironer, this is ''not the regular way of practicing pain medicine.'' *Id.* Dr. Mironer also noted that there were instances in which patients had told Respondent that they had obtained a controlled substances from others or patients had taken their drug ''more often'' than was prescribed. *Id.*

[21] Dr. Mironer also observed that while patients who engage in drug-seeking behavior may indeed have legitimate medical conditions that cause pain and require treatment, these patients must be more closely monitored through pill counts, urine tests, and pharmacy checks. *Id.* at 87.

[22] Dr. Mironer explained that giving high doses of opioids can cause constipation, depression, hormonal release and in the event of an overdose, respiratory depression and even death. Tr. 52–53. Moreover, because patients develop tolerance, ''one would try to increase the [dosing] from small amounts * * * very slowly, because after you reach a certain amount of medicine you are not getting much more benefit at all.'' *Id.* at 53.

Patient Specific Evidence

Next, Dr. Mironer testified regarding Respondent's prescribing to specific patients. With respect to W.G. (GX 7), who met with Respondent while they were both in jail, and to whom Respondent prescribed three controlled substances including morphine, hydrocodone, Valium, as well as carisoprodol at the first visit (as well as at three subsequent visits), Dr. Mironer opined that Respondent prescribed inappropriate amounts of opioids and that ''[t]here were no reasons obvious from the chart for prescribing benzodiazepines.'' [23] Tr. 67. Dr. Mironer further noted that the ''physical examination was incomplete,'' and that Respondent's diagnoses, which included both lumbar disc disease and chronic anxiety (*see* GX 7, at 2) ''had no support with tests or as a result of'' the physical examination. *Id.* at 67–68. Moreover, Respondent did not create a treatment plan. *Id.* at 68. Based on all of these findings, Dr. Mironer concluded that the prescriptions Respondent issued to W.G. ''were not issued for medical purposes.'' *Id.*

Respondent diagnosed D.F. (GX 13) with mild degenerative disc disease in the lumbar region, facet joint arthropathy, chronic muscle tension headaches, and chronic anxiety, and issued her prescriptions for sixty tablets of Oxycontin (80 mg), as well as ninety tablet prescriptions for Lortab (10 mg.), Xanax (1 mg.) and Soma. According to Dr. Mironer, a radiologist who reviewed a CT scan of D.F.'s lumbar spine had found that she had ''very mild degenerative changes'' of her lumbar spine, but that ''significant discomfort or radiculopathy would not be expected from these findings.'' Tr. 73, GX 13, at 9. Moreover, while D.F.'s file contained multiple radiology reports, it did not contain any records of prior treatments she had received. *See* GX 13; Tr. 73.

Dr. Mironer noted that ''there was again an inadequate examination of the back, and the patient was diagnosed with chronic anxiety without any'' findings to support the diagnosis. Tr. 73, *see also* GX 13, at 7–8.[24] Dr. Mironer also found that D.F. had ''received an extremely high dose of opioids together with Xanax and a muscle relaxant [Soma], and no treatment plan, and the same prescribing continue[d] for durations [sic] that was in the chart.'' Tr. 73. Dr. Mironer thus concluded that the prescriptions were ''not issued for legitimate medical purposes.'' *Id.*

On March 19, 2007, Respondent diagnosed D.M. as having five conditions: (1) Degenerative Lumbar Disc Disease with Radiculopathy, (2) Bilateral Lumbar Facet Joint Arthropathy, (3) S 1 Nerve Root Compression, (4) L Sciatica, and (5) Chronic Anxiety. GX 25, at 8. D.M.'s file contained the reports of two MRIs, which were done on May 12, 2001, and May 29, 2003. *Id.* at 9–10. At this visit, Respondent issued D.M. prescriptions for Avinza 90 mg (morphine sulfate), Lortab (10 mg), Xanax (1 mg.), and Soma. *Id.* at 8. Respondent issued to D.M. new prescriptions for these drugs on April 16, May 29, June 29; at the July 28 visit, Respondent noted that D.M. ''would like to [change] Avinza to Oxycontin due to expense,'' and issued her prescriptions for Oxycontin (40 mg.), as well as Lortab (10 mg.), Xanax (1 mg.), and Soma. *Id.* at 6–7. On August 25, September 20, October 18, and November 15, Respondent issued D. M. new prescriptions for the latter four drugs. *Id.* at 2, 4, 5, & 6.

According to Dr. Mironer, the findings of D.M.'s most recent MRI, which was then four years old, were not ''very significant.'' Tr. 74. Dr. Mironer opined that Respondent's ''examination of the back was again inadequate.'' *Id.* Relatedly, Dr. Mironer noted that Respondent had recorded the result of D.M.'s straight leg raise as negative, which suggested that ''a lack of radiculopathy, or nerve pinching of [the] sciatica,'' yet he had diagnosed D.M. with radiculopathy. *Id.* Moreover, Respondent had diagnosed D.M. as having chronic anxiety without noting any findings to support the diagnosis. *Id.*

Dr. Mironer observed that Respondent had prescribed a ''high dose of opioid, with benzodiazepine and no treatment plan.'' *Id.* Moreover, on the ''very next visit,'' Respondent increased ''the amount of opioids,'' and at a later visit, Respondent had ''changed from one medication to the other at [D.M's] request.'' *Id.* Finally, Respondent continued to prescribe ''for another five months without any treatment, testing or additional plans.'' *Id.* at 74–75. Dr. Mironer thus concluded that ''the prescription[s] of controlled substances were not issued for legitimate medical purpose in this case as well.'' *Id.* at 75.

With respect to F.M. (GX 26), Dr. Mironer noted that while he complained ''of low back pain,'' his patient file included records which indicated that he had been treated at a pain clinic and had been ''discharged just about ten days prior to'' his initial visit with Respondent. Tr. 75; *see also* GX 26, at 6–17. More specifically, F.M.'s file included a letter which indicated that during a September 6, 2007 office visit at the pain clinic, he had undergone a random urinalysis. GX 26, at 6. While F.M. had been prescribed Dilaudid (hydromorphone), a schedule II controlled substance, he tested negative for the drug when he ''should have been positive.'' *Id.* According to the letter, this was a breech of F.M.'s pain contract with the clinic; the clinic also recommended that F.M. go to a chemical dependency treatment center. *Id.*

At the initial visit (on October 18, 2007), Respondent noted that F.M. had been discharged based on the negative drug screen for Dilaudid; Respondent also diagnosed him as having approximately nine conditions including degenerative disk disease of the lumbar region, right SI joint pain, muscle spasm in his back, and chronic anxiety. GX 26, at 4–5. The progress note indicates, however, that Respondent performed a physical examination which included taking vitals signs, a neurological examination and various other findings. *Id.* at 4–5. Respondent issued him prescriptions for ninety tablets of Roxicodone 30 mg., sixty tablets of MS Contin 30 mg. (another schedule II drug), ninety tablets of Xanax (.5 mg), and sixty tablets of Soma. *Id.* Respondent also noted that he had discussed a narcotic contract with F.M. and told him that ''any breech will [result in] immediate dismissal,'' and that F.M. should consider injections of both his lower back and SI joint area. *Id.*

F.M. also saw Respondent on November 15, 2007. *Id.* at 2. At this visit, F.M. complained that he was ''still having pain'' and that ''the MS Contin causes some nausea.'' *Id.* F.M. reported, however, that ''the Roxicodone helps his pain the best.'' *Id.* Respondent noted he needed to make changes in F.M.'s medications; while Respondent renewed F.M.'s prescriptions for Roxicodone (30 mg.) and Xanax (.5 mg.), he also increased the strength of the MS Contin to 60 mg.[25]

Regarding Respondent's prescribing to F.M., Dr. Mironer observed that notwithstanding that ''a discharge letter * * * recommended treatment with

[23] W.G.'s patient file is discussed above.

[24] Dr. Mironer also found that Respondent had mistakenly diagnosed D.F. as having tension headaches, when her headaches were related to a brain cyst. Tr. 73. While this finding might be evidence of medical malpractice, it is not relevant to the issues in this proceeding.

Under the heading of ''Meds,'' a progress note dated June 26, 2007 contained in D.F.'s file indicates that she was taking Lortab (10 mg.), Xanax (1 mg.), Oxycontin (80 mg.) and Soma. GX 13, at 8. Yet, as Dr. Mironer testified, the patient file does not contain any records related to D.F.'s being prescribed these drugs by other physicians. Tr. 73.

[25] Respondent also changed F.M.'s muscle relaxant from Soma to Zanaflex. GX 26, at 2.

[an] addictionologist,'' F.M. ''was given a high dose prescription of benzodiazepine and a muscle relaxant with no plans for treatment or no plans for further strict control of his use of control substances, such as mediation check, pharmacy check, or urine toxicology screening.'' Tr. 75–76. Dr. Mironer further noted that while F.M. had complained that the MS Contin caused nausea, Respondent had issued him a new prescription which doubled the strength of the MS Contin. Tr. 76. Finally, Dr. Mironer noted that Respondent had not made a ''new plan.'' *Id.* Dr. Mironer thus concluded that the prescriptions were ''not issued for legitimate medical purposes.'' *Id.*

J.M.'s first visit with Respondent was April 16, 2007. GX 27, at 14. At the visit, J.M. complained of lower back pain, hip pain, and neck pain. *Id.* In the progress note, Respondent also indicated that J.M. had undergone an MRI on November 11, 2003, which showed that she had two herniated discs (L4–5 & L5–S1), and either an X-ray or an MRI (two years ago) of her cervical spine which showed that she had two ruptured discs (C1–2 & C2–3). *Id.* Moreover, Respondent noted that J.M. had seen another physician until October 2006. *Id.* J.M.'s file does not, however, contain reports for either radiological exam or any records from the physician who previously treated her. *See generally* GX 27.

Respondent's physical exam noted that J.M.'s lungs were clear and included a notation for a finding with respect to her cardiovascular system.[26] With respect to J.M.'s back, Respondent indicated ''nontender x over [right] buttocks,'' and with respect to her neck, Respondent indicated ''tender [with] spasm over [right] trapezius [and] periscapular area.'' *Id.* Respondent diagnosed J.M. with cervical disc disease, lumbar disc disease, and chronic anxiety, although there were no findings to support the latter. *Id.* Respondent's treatment plan for J.M. was to issue her prescriptions for sixty tablets of each of the following: Avinza (morphine sulfate 120 mg.), Roxicodone (30 mg.), and Xanax, as well as ninety tablets of Soma, with a follow-up in thirty days. *Id.* At J.M.'s next visit, Respondent issued her new prescriptions for each of the above drugs (although he reduced the number of pills by one day's worth). *Id.* at 13.

At J.M.'s third visit (June 6, 2007), Respondent noted that J.M. ''wants to [change] Avinza to MS Contin due to cost.'' Respondent obliged and issued J.M. a prescription for ninety tablets of MS Contin (60 mg.); Respondent also issued J.M. new prescriptions for sixty tablets of both Roxicodone (30 mg.) and Xanax (1 mg.), as well as ninety Soma. *Id.*

On the next visit (July 1, 2007), Respondent noted that the MS Contin was not helping her as well as the Avinza. *Id.* at 12. He also noted that J.M.'s hip pain was ''much worse internally [with] very limited movement'' and that she was ''still tender over [left] trapezius.'' *Id.* Respondent then issued new prescriptions for the same three controlled substances (as well as the Soma) and increased the quantity of MS Contin to 120 tablets. *Id.* Respondent re-issued the same four prescriptions on August 3, September 1 and 29, October 24, and November 20. *Id.* at 7, 9–11. Throughout the entire course of his treating J.M., her plan of care was limited to prescribing medication and follow-up visits. *See generally* GX 27.

Based on his review of J.M.'s record, Dr. Mironer concluded that Respondent's physical examination was ''inadequate,'' that she had ''received exceedingly high doses of opioids,'' as well as a ''benzodiazepine for anxiety'' with no findings to support the diagnosis. Tr. 76. Dr. Mironer further noted that ''no treatment plan was given,'' and that the ''prescribing was continued for more than half a year with no additional treatments, testing, or additional plans for the future.'' *Id.* Dr. Mironer thus opined that ''the prescriptions of controlled substances in [J.M's] case were * * * not issued for legitimate medical purposes.'' *Id.* at 77.

L.C.'s initially visited Respondent on March 19, 2007, and complained of lower back pain. GX 41, at 8. L.C.'s file includes a copy of a report for an MRI which had been done on November 29, 2006; the Radiologist's report indicates that the MRI had found ''only minimal disk disease'' of her lumbar spine, and that her disks ''are actually still within normal limits.'' *Id.* at 12. While the report also noted that there were ''degenerative changes * * * within the facet joints,'' it indicated that ''these should not be the cause of a radiculopathy.'' *Id.*

The note for L.C.'s first visit listed three doctors she had previously seen, yet her patient file did not contain any records from these doctors. *Id.* at 8. According to the history section, L.C. also had radiculopathy in her left leg to the back of her knee, and that her pain level was ''8.'' *Id.* According to the physical examination section, Respondent found tender the paravertebral area of L.C.'s lower back. *Id.* Respondent also apparently did a straight leg raise test on L.C; while findings appear to have been noted, the significance of the findings is not clear on the record.[27]

Respondent diagnosed L.C. as having four conditions: 1) Facet joint arthropathy, 2) mild lumbar disc disease, 3) chronic anxiety, and 4) chronic lower back pain with left radiculopathy. *Id.* Respondent then issued her prescriptions for Avinza (90 mg.), Lortab (10 mg.), Xanax (1 mg.), and Soma, with a follow-up in thirty days. *Id.* Respondent re-issued the prescriptions for the same drugs on April 16 (although he increased the dosing of the Avinza from twice to three times a day), and on May 29; on the latter date, Respondent did so without even requiring L.C. to appear. *Id.* at 7.

On June 29, L.C. returned to Respondent and requested that he prescribe Oxycontin instead of Avinza due to the latter's cost. *Id.* Respondent agreed and issued her a prescription for ninety tablets of Oxycontin (40 mg); Respondent also issued L.C. prescriptions for sixty tablets of Lortab (10 mg.), as well as ninety tablets of both Xanax and Soma. *Id.* Respondent issued new prescriptions for these drugs on or about July 28, August 25 (based on a telephone call), September 27, October 29, and November 30, 2007. *Id.* at 2, 4–6.

While L.C.'s patient file spans eight months of visits, it contains no indication that she was ever subjected to a urine drug screen or pill count. *See generally id.* at 2–8. Moreover, Respondent's plan of treatment for L.C. was invariably to prescribe controlled substances (and Soma); Respondent did not recommend any other treatment modalities to L.C. *Id.*

With respect to L.C., Dr. Mironer observed that ''[t]he only available record was an MRI, which was appropriate for [her] age,'' and that at the first visit, she had ''received a very high amount of opioids on this visit, with [a] benzodiazepine for anxiety that was again not documented.'' Tr. 77. Dr. Mironer further noted that at L.C.'s ''next visit,'' Respondent had increased her medications by ''[thirty] percent,'' that he ''later changed to a different pain medication,'' and that the prescribing ''continued for * * * seven, eight months with no control of intake of the medication and no plans for a future treatment.'' *Id.* Dr. Mironer thus concluded that the prescriptions Respondent issued to L.C. were ''not

[26] The record does not establish what the notation signified.

[27] Respondent also apparently checked L.C.'s lungs and cardiovascular system. GX 41, at 8.

issued for legitimate medical purposes.'' *Id.* at 77–78.

M.C., a patient who participated in Respondent's ''group practice,'' received prescriptions for Oxycontin (80 mg.), Lortab (10 mg.), Xanax (1 mg.) and Soma on June 26, July 24, August 21, September 15, October 8, November 5, and December 3, 2007. *See generally* GX 46. According to the progress note for his initial visit, M.C. reported that he was currently taking all four of the above drugs yet the file contains no records from other physicians. *Id.*

Respondent performed a physical examination of his lungs, cardiovascular, and back. *Id.* at 8. With respect to M.C.'s back, Respondent noted that it was tender at both the ''lower & upper paravertebral areas of [the] lumbar region,'' as well as ''at [the] lower [right] scapula area.'' *Id.* Respondent diagnosed M.C. as having degenerative disc disease in the lumbar region, facet joint arthropathy, and anxiety. *Id.* There is, however, no indication of any finding that would support a diagnosis of anxiety. *Id.*

Dr. Mironer noted with respect to M.C. that ''[n]o records [were] available at the time of the visit,'' and that Respondent's examination of his back ''was not adequate.'' Tr. 78. Dr. Mironer further observed that Respondent had prescribed ''an extremely high dose opioids * * * with benzodiazepines for anxiety that was not documented, and muscle relaxants,'' and that ''the pain prescribing continued for * * * half a year with again no'' plans for other treatment modalities. *Id.* Dr. Mironer thus concluded that Respondent's prescribing of controlled substances to M.C. ''was not for [a] legitimate medical purpose.'' *Id.* at 79.

H.R., another of Respondent's group practice patients, first saw Respondent on July 24, 2007, complaining of lower back pain, but ''no radiation.'' GX 51, at 5. H.R.'s file included two radiology reports, one for an MRI of his hips (dated June 19, 2006), and another for an apparent X-ray examination of his lumbar spine (dated March 28, 2006). *Id.* at 6–7. With respect to the latter exam, the Radiologist found that ''degenerative disc disease is present at the lumbar spine with mild degenerative levoscoliosis.'' *Id.* at 7.

In the physical exam section of the progress note, Respondent indicated that H.R.'s back was ''tender [bilateral] paravertebral areas of lumbar spine,'' and that he was ''able to bend to 90'' degrees. *Id.* at 5. Respondent further noted that H.R.'s straight leg raise was negative. *Id.*

According to the progress note, Respondent diagnosed H.R. as having chronic lower back pain caused by degenerative disc disease, and chronic anxiety. *Id.* Here again, the progress note contains no findings that support a diagnosis for anxiety. *Id.* As found above, Respondent issued H.R. prescriptions for sixty tablets of Oxycontin (20 mg.), ninety tablets of both Lortab (10 mg.) and Xanax (1 mg.), and ninety tablets of Soma. *Id.*

At the next visit (Aug. 21, 2007), H.R. reported that he was still having lower back pain. *Id.* at 4. Respondent doubled the strength of the Oxycontin he prescribed to 40 mg. and issued new prescriptions for Lortab, Xanax and Soma. *Id.* Respondent re-issued the same four prescriptions on two additional occasions. *Id.* at 2 & 4. Moreover, there is no indication in H.R.'s file that Respondent ever recommended alternative treatment modalities.

H.R.'s file also contained a Tennessee Board of Pharmacy Patient Rx History Report (dated November 26, 2007), which showed that H.R. had been receiving prescriptions for alprazolam (Xanax) and hydrocodone from multiple doctors and had obtained several of the prescriptions during the same period in which he was obtaining prescriptions from Respondent. *Id.* at 8–9. There is, however, no evidence that Respondent prescribed to H.R. after he received the report.

Dr. Mironer observed that ''the only available record at the time of [H.R.'s] visit was [an] age-appropriate X-ray of the spine with some mild to moderate degenerative changes, and [a] normal X-ray of the hip.'' Tr. 79. Dr. Mironer also noted that Respondent's initial prescribing was for ''a fairly high dose of opioid,'' and that the benzodiazepine prescriptions ''for anxiety * * * was undocumented.'' *Id.* Dr. Mironer further noted that ''[d]uring [the] next visit the amount of opioids that was fairly high already was increased more than fifty percent, and that [the] prescribing continued for a couple more months.'' *Id.* Here again, Dr. Mironer concluded that Respondent's prescribing of controlled substance lacked a ''legitimate medical purpose.'' *Id.* at 79–80.

A.R., who was H.R's wife, also visited Respondent on July 24, 2004, and complained of lower back pain and pain radiating down her left leg to her ankle. GX 59. A.R.'s file included the reports of two radiological examinations (one of her cervical spine and one of her lumbar spine), which were then more than three and a half years old. *Id.* at 7–9. While the report on A.R.'s cervical spine noted the presence of a paravertebral muscle spasm, it was otherwise ''unremarkable''; similarly, while the report on A.R.'s lumbar spine found ''disc desiccation at the level of L5/S1, with mild posterior and left paracentral disc bulging * * * the remaining portions of the exam are unremarkable.'' *Id.* at 7 & 9.

According to the progress note, Respondent examined A.R. and found tenderness at the bilateral paravertebral region of her lower back and a muscle spasm. *Id.* at 6. Respondent also found tenderness over A.R.'s left buttocks in the region of the sciatic nerve, that A.R. was able to bend over to ninety degrees, and that the straight leg raise was negative bilateral. *Id.* Respondent thus diagnosed A.R. as having chronic lower back pain caused by degenerative disc disease, chronic anxiety, and chronic left sciatica, and issued her prescriptions for sixty Oxycontin (20 mg.), ninety Lortab (10 mg.), ninety Xanax (1mg.), ninety Soma, with a follow-up in thirty days. *Id.* at 5–6.

At the next visit (August 21), A.R complained that she still had lower back pain despite her taking Oxycontin (20 mg.). *Id.* at 5. Respondent thus doubled the strength of the Oxycontin to 40 mg. and also re-issued the prescriptions for Lortab (10 mg), Xanax, and Soma. *Id.* Respondent also issued prescriptions for the same four drugs on September 20 and October 19. *Id.* at 2 & 4. At no point in his treatment of A.R. did Respondent recommend alternative treatment modalities.

At each of her four visits, Respondent issued the exact same prescriptions to A.R.—including drug, drug strength, and dosing—as he did for her husband, H.R. Moreover, at their August 21 visit, Respondent doubled the strength of the Oxycontin he prescribed to both H.R. and A.R. *Compare id.* at 5, *with* GX 51, at 4.

As Dr. Mironer observed, ''the treatment of both Mr. and Mrs. [R] was exactly the same as far as medication and increases and the dates.'' Tr. 80. Dr. Mironer further noted that while an MRI indicated that A.R. had a bulging disk, it ''may be a very benign condition.'' *Id.* Moreover, A.R. had ''received a fairly high amount of opioids on her first visit with [a] benzodiazepine for anxiety that was not documented.'' *Id.* Dr. Mironer also observed that Respondent had increased the amount of opiates at the second visit, and that A.R. continued to receive the medication for two more months thereafter. *Id.* Dr. Mironer thus concluded that the prescriptions Respondent issued to A.R. lacked a legitimate medical purpose. *Id.*

C.H. first saw Respondent on November 8, 2007, and apparently complained of back and shoulder pain.

GX 19, at 3. According to the progress note, C.H. had been undergoing treatment by a clinic for opiate dependence for the last ten months and was taking a ''maintenance dose of methadone hcl 80 mg daily.'' *Id.* at 3. C.H. further reported to Respondent that methadone ''controls his pain better than hydrocodone,'' which he had become addicted to. *Id.*

C.H. patient's file included numerous records from the methadone clinic including a printout of C.H.'s ''Patient Drug Screen Results,'' which indicated that it was printed out on the morning of his first visit with Respondent. *Id.* at 16. This document showed that C.H. had been given a urine drug screen the day before; the document also contained a handwritten notation stating that ''[C.H.] is currently medicating @ 80 mg. daily.'' [28] *Id.* There is no indication in C.H.'s file that Respondent contacted the clinic to determine whether C.H. was still being treated by it.

Dr. Mironer did not take issue with the physical exam that Respondent performed on C.H. or his diagnosis of pain. Tr. 81–82. He noted, however, that Respondent had prescribed to C.H. an eighty milligram dose of methadone to be taken once a day. *Id.* at 81. More specifically, Dr. Mironer explained that ''methadone is prescribed once a day for treatment of addiction because of the length of methadone being in the body makes it different'' as the drug remains in the body ''exceed[ing] two days.'' *Id.* 50. In contrast, the analgesic effect of methadone ''is only six to eight hours,'' and thus the ''prescribing [of] methadone for pain should be in the form of [a] low dose for three, four, five times a day, rather than a high dose once a day.'' *Id.*

According to Dr. Mironer, ''[w]hen you prescribe a high dose once a day, you are not providing pain relief, but you are providing a certain amount of opioid in the body for a long duration that is usually what is needed for [the] treatment of addiction.'' *Id.* Moreover, if methadone is used to treat pain, the dosing ''should be started at 5 to 10 milligrams three or four times a day,'' and titrated to a total dosage of sixty milligrams a day. *Id.* Finally, because methadone is ''so long acting,'' a patient ''may eventually accumulate [a] significant amount of the drug,'' thus risking ''respiratory depression and the possibility of death.'' *Id.* at 52. Dr. Mironer therefore concluded that Respondent's prescribing of methadone to C.H. was not issued for ''appropriate medical purposes.'' [29] *Id.* at 81.

Finally, with respect to S.M. (GX 52), whose history of medical problems and substance abuse, as well as his road trip (accompanied by K.C. and M.B.) to visit Respondent was discussed above, Dr. Mironer acknowledged that the records ''showed significant disease of the knee joint.'' Tr. 83. Dr. Mironer further noted, however, that the available records showed that S.M had a ''history of street drug use'' including marijuana and IV cocaine use, and ''long term incarceration.'' *Id.*

Dr. Mironer noted that Respondent issued S.M. a prescription for Oxycontin (20 mg.) at the initial visit, that he did not create any treatment plan other than to prescribe drugs, and that he did not attempt control S.M.'s use of his medication. *Id.* at 83–84. Dr. Mironer also noted that S.M. had run ''out of his medication early,'' and had ''received additional controlled substance [Roxicodone 30 mg.] from a third person.'' *Id.* at 84. Dr. Mironer then observed that ''[d]espite all that, [S.M.] received [a] renewal of his prescription for Oxycontin, and actually received an additional prescription for the same medicine [Roxicodone] that he received from the third person.'' *Id.* Finally, Dr. Mironer again explained that while Respondent had increased the amount of controlled substances he prescribed, no plan was made for alternative treatments or to control S.M.'s ''intake of medication.'' *Id.* Dr. Mironer thus concluded that Respondent's prescribing of controlled substances lacked a legitimate medical purpose. *Id.*

Respondent's Cross-Examination of Dr. Mironer

On cross-examination, Respondent did not challenge Dr. Mironer's testimony with respect to a specific patient. Respondent did, however, inquire into the basis for Dr. Mironer's more general observations about both Respondent's patient pool and the practice of pain management.

For example, with regard to the ''large number'' of patients who were traveling from Greeneville, Tennessee to see Respondent, Dr. Mironer testified that while patients may go out of state ''to obtain a consult or to have a procedure done,'' it is ''fairly unusual'' for patients ''to go a long distance on a monthly basis just to see a family doctor or * * * a pain doctor who is prescribing their medication.'' *Id.* at 96. Moreover, when asked by Respondent whether he would still require studies and MRIs for a chronic pain patient who has been treated with medications for a five to ten-year period, Dr. Mironer testified that he ''would absolutely do'' the test ''unless [he had] a clear understanding of what is the pathology and * * * that there is nothing [that] can be done to improve the condition, which is extremely rare.'' *Id.* at 98. Dr. Mironer further stated that the ''majority'' of chronic pain patients can be helped with alternative treatments such as injections, nerve destruction or surgery, even if they ''cannot be cured completely,'' and that in his experience, the majority of chronic pain patients have ''never received proper medical treatment.'' *Id.* at 99–100.

Moreover, while acknowledging that ''[p]ain is subjective,'' Dr. Mironer explained that the cause of chronic pain can only be assessed through ''objective findings.'' *Id.* at 100. If the patient's findings through physical examination and diagnostic tests are normal, and the ''patient has severe pain,'' the pain is ''probably psychological in origin,'' and should be treated accordingly. *Id.*

Respondent's Evidence

Respondent testified on his own behalf. Respondent generally did not address Dr. Mironer's testimony regarding the specific patients and his opinion testimony regarding the legality

[28] While the notation gives a date of ''1/8/07,'' the date appears to be cut off and obviously could not have been written ten months before the document was printed out and a month before C.H. commenced treatment with the clinic. *See* GX 19, at 10. I thus find that the notation was made on November 8, 2007, the date the document was printed out.

[29] Dr. Mironer further noted that ''[i]f a patient finishes his treatment at a methadone clinic, we require usually a psychiatric or psychological evaluation * * * to make sure * * * that the patient * * * is a good candidate to try to treat * * * with chronic opioids. We will try to avoid it as much as we can. However, if we will prescribe for this patient medication, it probably won't be methadone, and it for sure won't be a high dose of methadone once a day.'' *Id.* at 81–82. Dr. Mironer also explained that ''it is a well documented knowledge, and even the PDR [Physicians' Desk Reference] refers to the duration of pain action and advises to not prescribe methadone for pain.'' *Id.* at 83. *See also id.* at 111 (''If the patient is treated for addiction and cured, then he shouldn't be on methadone any more. If he still required daily doses of methadone, it means that he is still in treatment for addiction'' and the prescribing should ''be done only by the methadone clinic'').

The Government also introduced the patient file of K.M., who complained of chronic lower back pain. GX 24, at 2. K.M.'s chart contains but a single progress note, which appears to be incomplete as indicated by the notation ''OVER'' at the bottom of the page, but the continuation page is not in the record. *Id.* Nor does the note appear to document the full scope of the physical examination as it makes no mention of Respondent's findings with respect to K.M.'s back, even though with respect to every other patient, Respondent made some finding with respect to a patient's back even if his exams were inadequate. *Id.* Moreover, the file is missing Respondent's assessment and does not clearly indicate what drugs he may have prescribed and the plan of treatment; while the file contains a document which lists various medications, the record does not establish the significance of this document. Nor did the Government submit other records which show the prescriptions Respondent issued to K.M.

of the prescribings. Rather, Respondent testified as to the circumstances surrounding his starting his South Carolina practice, the results of the patient interviews conducted by the Investigators, his reasons for not requiring his patients to undergo diagnostic testing and alternative treatments, his prescribing for anxiety, and his prescribing to a person with track marks.

The ALJ found that ''Respondent appeared to tailor his testimony to suit his version of the events.'' ALJ at 50. This was for good reason as beyond her personal observation of Respondent's demeanor, as much of his testimony was patently self-serving, and frequently, absurd.

According to Respondent, he opened up his pain management practice notwithstanding his lack of board certification in pain management and that he had not attended any conferences on pain management, based on what he had learned in his seven years as a family practitioner in Tennessee and while being treated by a board-certified pain specialist. *Id.* at 322 & 324. Respondent maintained that he opened a pain management practice rather than a family practice, because it ''would be simple,'' ''[i]t wouldn't require a lot of employees'' or ''a lot of the things that family practice requires,'' and he ''wouldn't have to mess with insurance companies taking [forty to sixty] percent of the money.'' *Id.* at 290. Respondent subsequently testified that he ''needed money for retirement'' and to pay bills for his old office in Tennessee because his office manager had ''stolen between forty and two hundred thousand dollars.'' *Id.* at 304. Respondent maintained, however, that his need for money was not the only reason he resumed practicing as he missed caring for patients. *Id.*

Respondent also maintained ''that it made sense that probably patients would come down'' from Greeneville, Tennessee to see him, because ''the pain clinics'' near Greenville ''were mostly full,'' and the patients are ''not going to go to a pain clinic that they don't know something about the doctor.'' *Id.* at 291. Respondent did not, however, establish that he had surveyed any pain clinics to determine whether they were still accepting patients. According to Respondent, patients would not simply go to a pain management center of a university-hospital (such as Duke or the University of Tennessee, which might also be a shorter drive) to be treated because they want a doctor that ''they know something about.'' *Id.* at 324–25.

With respect to the evidence pertaining to his prescribing practices, Respondent admitted that ''I could have done blood pressures and all at the house, but it is a little more cumbersome to do blood pressures.'' *Id.* at 292. Respondent further acknowledged that ''[i]f there were families there or whatever, they're on the couch and we're talking and I'm getting a history from them and all.'' *Id.* Respondent maintained, however, that ''I did examine patients that were there,'' that ''I don't [sic] people's pants down in front of other people,'' that ''I didn't discuss anything that was * * * confidential'' without taking the person to another room. *Id.* at 292–93.

Moreover, Respondent asserted that he was ''just floor[ed]'' by the evidence that the patients had told investigators that ''they weren't examined.'' *Id.* at 293. Relatedly, Respondent stated that ''[i]t's nothing to listen to somebody's heart[ ], lungs, check their back and neck,'' and that he could ''do a complete physical on somebody in three or four minutes.'' *Id.* Respondent, however, then implicitly acknowledged that he had not performed physical examinations on at least some of the persons, testifying that ''[B.J.P.] and a number of these patients say that they were not examined at my house, but they were at the office.'' *Id.*

Respondent also testified that ''this is probably some of the worse documentation I've probably ever done.'' *Id.* at 301. Respondent further asserted that those patients who told investigators that they didn't know ''what their diagnosis is or what the [treatment] plans are for them [were] lying, plain and simple * * * because I go over the same routine with every patient.'' *Id.* Respondent also maintained that he was ''eminently qualified to treat anxiety and depression,'' and that he would ''always ask the basic questions'' that are needed to diagnose ''anxiety and depression.'' *Id.* at 303. I conclude, however, that the records speak for themselves and because they do not set forth the findings required to support the numerous diagnoses Respondent made for both pain and chronic anxiety, or that he created plans that recommended treatments (other than taking drugs), I reject Respondent's testimony.

Relatedly, Respondent testified that ''he was probably at fault'' for not seeing track marks on several of his patients' arms was ''because it was easier [to] listen to somebody's heart and lungs, just underneath their shirt, [to] lift up their shirt, because they would wear long-sleeved shirts * * * and I didn't remove their shirts usually.'' *Id.* at 294. On cross-examination, Respondent acknowledged that if a patient's medical records indicated that he had a history of IV drug use (as in the case of S.M., GX 52, at 8), it would ''[t]o some degree'' raise a red flag to examine his arms for current use. Tr. 329. Respondent insisted, however, that ''I * * * make my own decisions about patients I treat.'' [30] *Id.*

Respondent also maintained that that he was willing to accept that a patient has not ''had an MRI in four or five years * * * for a while,'' but ''there was going to be a time within a year, year and a half, that [he] was going to come up with something'' because he was ''not going to jeopardize a patient.'' *Id.* at 296.

Relatedly, Respondent maintained that he did not ''immediately'' ask his patients to get MRIs because of the costs involved. *Id.* Finally, Respondent maintained that if his patients continued to put off obtaining trigger point injections, ''the medication was going to stop.'' *Id.* at 297. Respondent admitted, however, that he had never actually stopped prescribing to a patient even though he acknowledged that there were a few patients who he had been prescribing to for that long a period (a year and a half). *Id.* at 319. Finally, when asked whether he was aware of what was required under South Carolina law to establish a doctor-patient relationship, Respondent testified that he did not ''know the details of it,'' but that ''you make contact and do basic things.'' *Id.* at 335.

Respondent also introduced into evidence various statements which were prepared by family members, professional acquaintances, and friends. *See* RXs 1–10. Of these statements, most are not remotely probative of the issues in this case. Among the statements, however, is one from a physician who ''assisted him at his clinic during the summer of 2008,'' RX 1, as well as one from a nurse who worked for him ''from approximately May 2002–May 2006,'' when he was practicing in Greeneville, Tennessee. RX 3.

[30] Respondent further maintained that S.M., who was hospitalized with a collapsed lung after obtaining prescriptions for Oxycontin which he proceeded to inject intravenously, was not in respiratory distress on ''that day.'' *Id.* at 299. While Respondent acknowledged that ''respiratory depression will come from the narcotics,'' he maintained that narcotics would not cause a lung to collapse. *Id.* at 300.

Regardless of whether narcotics would cause a collapsed lung, respiratory depression is a known side effect of taking opiates, and it seems unusual to prescribe narcotics to a patient who has been diagnosed with C.O.P.D. The Government did not, however, ask its expert regarding the propriety of Respondent's prescribing of Oxycontin and Roxicodone to S.M. in light of this condition. I thus do not rely on this conduct in determining whether the prescriptions were for a legitimate medical purpose.

Notably, neither of these persons worked with Respondent during the period when he issued the prescriptions which are at issue here. Moreover, the unsworn statement of Dr. Koon (RX 1), reflects his observations of Respondent at a time when the latter was aware that he was under investigation and had ample reason to portray himself as responsible and law abiding. *See* GXs 2 & 3 (Respondent's letters to DEA Investigators regarding pending investigation).

Nor does the statement from his former nurse support him. According to the nurse, Respondent ''was very strict when it came to pain medicine and always attempted to control a patient's pain first with a non-controlled substance and/or alternative medicine[,]'' and ''required all his patients to have supporting MRI/x-rays etc. * * * before ever giving any narcotic pain medication.'' RX 3. Respondent's former nurse also stated that he ''always did thorough examines on his patients with each office visit,'' that he requires his patents ''to bring in their narcotic prescription bottles with each monthly visit,'' and would do pill counts, and that he would request that his patients ''come in for a drug screen'' and give them 24 hours to come to the office and provide the specimen. *Id.* Indeed, the statement is remarkably consistent with Dr. Mironer's testimony as to the appropriate and usual course of professional practice in prescribing controlled substances to patients and monitoring them to ensure that they are neither abusing the drugs nor diverting them, and buttresses Dr. Mironer's opinion testimony that Respondent issued numerous prescriptions which lacked a legitimate medical purpose.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. § 824(a)(4). 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). 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.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

In this matter, it is undisputed that Respondent holds a valid medical license and a controlled substance registration from the State of South Carolina (factor one). It is also undisputed that Respondent had not been convicted of an offense related to controlled substances under either federal or state law (factor three).[31] This proceeding focused, however, on Respondent's experience in dispensing controlled substances (factor two) and his record of compliance with applicable federal and state laws (factor four). Having considered the record as a whole, I conclude that the Government has proved by a preponderance of the evidence that Respondent issued numerous controlled substance prescriptions which were unlawful under federal law and that he has therefore committed acts which render his continued registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). As the ALJ did, I also conclude that Respondent has failed to accept responsibility for his misconduct and therefore cannot be entrusted with a registration.

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

The principal issue in this case is whether the controlled-substance prescriptions Respondent issued complied with federal law. 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). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. § 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.'' *Id. See also* 21 U.S.C. § 802(10) (defining the term ''dispense'' as meaning ''to deliver a controlled substance to an ultimate user by, or pursuant to *the lawful order of, a practitioner*, including the prescribing and administering of a controlled substance'') (emphasis added).

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 *United States* v. *Moore*, 423 U.S. 122, 135, 143 (1975)).

Under the CSA, it is fundamental that a practitioner must establish and maintain 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.'' *Laurence T. McKinney*, 73 FR 43260, 43265 n.22 (2008); *see also Moore*, 423 U.S. at 142–43 (noting that evidence established that physician ''exceeded the bounds of 'professional practice,''' when ''he gave inadequate physical examinations or none at all,'' ''ignored the results of the tests he did make,'' and ''took no precautions against * * * misuse and diversion''). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. *See Kamir Garces-Mejias*, 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.*, 72 FR 50397, 50407 (2007).

Under South Carolina law, ''[i]t is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship.'' S.C. Code Ann. § 40–47–113(A). The statute further provides that:

[a] proper relationship, at a minimum, required that the licensee make an informed medical judgment based on the circumstances of the situation and on the licensee's training and experience and that the licensee:

[31] Under Agency precedent, neither of these findings is dispositive. *See Edmund Chein*, 72 FR 6580, 6590 n.22 (2007); *Mortimer B. Levin*, 55 FR 8209, 8210 (1990).

(1) personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan;

(2) discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options;

(3) ensure the availability of the licensee or coverage for the patient for appropriate follow-up care.

Id.

Relatedly, the South Carolina Board of Medical Examiners had adopted *Pain Management Guidelines*, which represent ''what the Board considers to be within the boundaries of professional practice.'' GX 67, at 2. The Guidelines advise that the prescribing of ''controlled substances for pain [will be considered] to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds.'' *Id.*

However, ''[a]ll such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.'' *Id.* Moreover, ''[a] complete medical history and physical examination must be conducted and documented in the medical record.'' *Id.* at 2. The Guidelines further state that ''[t]he medical records should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or condition, the effect of the pain on physical and psychological function, and history of substance abuse,'' as well as ''the presence of one or more recognized medical indications for use of a controlled substance.'' *Id.*

Moreover, ''[t]he written treatment plan * * * should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.'' *Id.* at 3. Continuing, the Guidelines advise that ''[o]ther treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.'' *Id.* The Guidelines also advise that the physician should periodically review the patient's progress toward treatment goals, ''monitor patient compliance in medication usage,'' and ''refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives.'' *Id.*

The Guidelines further state that ''special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion.'' *Id.* Finally, the Guidelines advise that ''[t]he management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.'' *Id.*

The record clearly establishes that Respondent repeatedly exceeded the bounds of professional practice and issued controlled-substance prescriptions which lacked a legitimate medical purpose as required by Federal law. 21 CFR 1306.04. Even putting aside the scandalous evidence obtained by the Investigators in their interviews with the patients, Dr. Mironer, who reviewed the patient files, testified that Respondent invariably prescribed narcotic controlled substances for pain based on inadequate physical examinations, as well as benzodiazepines for anxiety without any findings to support his diagnosis. Moreover, Respondent's treatment plans were typically limited to prescribing multiple controlled substances; he rarely recommended that a patient undergo further testing, obtain a consultation from specialists, or try alternative treatment modalities, and failed to do so even when the prescribing went on and on.

For these reasons, Dr. Mironer specifically testified that Respondent lacked a legitimate medical purpose in issuing controlled substance prescriptions to W.G., D.F., D.M., J.M., L.C., M.C., H.R. and A.R. (the latter two being married to each other and who received the same exact prescriptions on the same dates). *See* Tr. 68, 73, 75, 77, 77–78, 79, 79–80. I agree and adopt Dr. Mironer's conclusion that these prescriptions lacked a legitimate medical purpose and were therefore unlawful under federal law. 21 CFR 1306.04(a).

With respect to F.M., who was discharged by his previous physician only a short while before his first visit with Respondent when a drug screen was negative for a drug (Dilaudid) which had been prescribed to him, Dr. Mironer did not find that Respondent's physical exam was inadequate. Tr. 75–76. Dr. Mironer did, however, note that notwithstanding F.M.'s having been discharged for noncompliance, Respondent issued controlled-substance prescriptions without any plan to monitor his use of the drugs through pill counts, pharmacy checks or urine testing; Dr. Mironer also noted that Respondent did not recommend any alternative treatments or consultations. *Id.* Notably, Respondent issued F.M. prescriptions for two schedule II opiates (MS Contin and Roxicodone), as well as benzodiazepines.

Based on Respondent's failure to properly monitor F.M.'s use of medications, his doubling of the strength of the MS Contin even though F.M. complained that the drug made him nauseous, and failure to create a treatment plan, Dr. Mironer concluded that the prescriptions were not issued for a legitimate medical purpose. Tr. 76. As the Supreme Court has explained, one of the purposes of the prescription requirement is to ensure that ''patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' 546 U.S. at 274. As Dr. Mironer's testimony establishes, Respondent did not properly supervise F.M.'s use of controlled substances, notwithstanding the evidence which suggests that he was either diverting or taking excessive amounts of Dilaudid. I thus adopt Dr. Mironer's conclusion that the prescriptions Respondent issued lacked a legitimate medical purpose as required by federal law. 21 CFR 1306.04(a).

Similarly, while S.M.'s medical history indicated that he had significant knee problems, it also established that he had abused street drugs including marijuana and cocaine, which he took intravenously. Moreover, at the second visit (which occurred twenty-five days after his initial visit), S.M. had only one tablet left of Oxycontin (out of the originally sixty tablets—a thirty day supply—which had been prescribed to him), and told Respondent that he had used Roxicodone (another schedule II drug) which he had obtained from a third person. Respondent nonetheless issued him a new prescription for Oxycontin and added a prescription for Roxicodone. As Dr. Mironer observed, notwithstanding the information Respondent had obtained as to S.M.'s history of drug abuse, he recommended no alternative treatment modalities and made no plan to control S.M.'s use of medications. Tr. 84. Dr. Mironer again concluded that Respondent's prescribing to S.M. lacked a legitimate medical purpose. *Id.* So do I.

Finally, with respect to C.H., Dr. Mironer did not take issue with Respondent's physical examination or his diagnosis of pain. Dr. Mironer did, however, note that Respondent had prescribed methadone to C.H., and used the same dosing regime (a large dose once a day) which the drug treatment clinic had used and which is used to treat addiction. *Id.* at 81, 50. Dr. Mironer's testimony established that

Respondent's prescribing to C.H. was fundamentally dangerous because the analgesic effect of methadone is only six to eight hours, the proper dosing for pain involves much smaller amounts of the drug such as five or ten milligrams which are taken three to four times a day, and a patient may accumulate significant amounts of the drug and risk respiratory depression and possibly death. *Id.* at 52.

Moreover, Dr. Mironer explained that when a patient has finished treatment for addiction, a psychiatric or psychological evaluation is required to ensure that the patient ''is a good candidate'' to treat with chronic opioids, that if the patient has been successfully treated for addiction he should no longer be on methadone, and if the patient still requires methadone, he is still addicted and should be treated by a methadone clinic. *Id.* at 81–82, 111.[32] Dr. Mironer also observed that the Physicians' Desk Reference advises against prescribing methadone for pain. *Id.* at 83.

Furthermore, given that C.H. had been subjected to a drug screen the day before his first visit with Respondent, and that the printout of C.H.'s drug screen results stated that he ''is currently medicating'' with 80 mg. of methadone, Respondent had ample reason to question why it was necessary to prescribe to C.H. C.H.'s patient file contains, however, no indication that Respondent contacted the methadone clinic to determine whether C.H. was still being treated by, and receiving methadone from, it. I therefore agree with Dr. Mironer that Respondent's prescribing of methadone to C.H. lacked a legitimate medical purpose.

As the forgoing demonstrates, Respondent repeatedly issued controlled substance prescriptions without a legitimate medical purpose and therefore violated the CSA's prescription requirement. *See* 21 CFR 1306.04(a). Moreover, substantial evidence supports the conclusion that Respondent was knowingly diverting controlled substances.

For example, Respondent initially denied writing prescriptions for B.J.P., his ''pod mate'' in the Greene County Jail, but then acknowledged that he had done so when confronted with the prescription he issued the day after his release from the jail. Moreover, the statements of various persons to Investigators regarding their road trips to see Respondent and the group sessions that occurred in his living room were to some degree corroborated by progress notes and prescription records indicating that the patients had seen Respondent on the same date. Relatedly, in his testimony Respondent did not deny that the group sessions occurred, but rather insisted that the patients were ''on the couch and we're talking and I'm getting a history from them and all.'' Tr. 292.

Furthermore, there was extensive evidence that nearly all of Respondent's patients were driving from the Greeneville, Tennessee area (a nine to ten-hour round trip), when they could have obtained treatment much closer to home. It is absurd to suggest—as Respondent does—that his patients were legitimate but could not obtain treatment much closer to home. Finally, not only did H.R. and A.R., who were married to each other, jointly visit Respondent; at each visit, they received the exact same controlled substance prescriptions and did so even when Respondent doubled the strength of the Oxycontin he was prescribing.

In sum, Respondent's experience in dispensing controlled substances and record of compliance with applicable laws is characterized by his knowing diversion of controlled substances. I thus conclude that the Government has made out its *prima facie* case that Respondent has committed acts which render his registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

Sanction

Under Agency precedent, where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present[] sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'" *Medicine Shoppe-Jonesborough,* 73 FR 363, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)). Moreover, because ''past performance is the best predictor of future performance, *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his]s actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

In her discussion of factor five, the ALJ specifically found that Respondent had ''refus[ed] to acknowledge his wrongdoing,'' and that there was ''little hope'' that ''he will act more responsibly in the future.'' ALJ at 54. The ALJ thus ''conclude[d] that Respondent is unwilling * * * to accept the responsibilities inherent in a DEA registration,'' and recommended that his registration be revoked and any pending applications be denied. *Id.* I agree.

On balance, Respondent's testimony does not establish that he has accepted responsibility for his misconduct. For example, while it was an ancillary issue in the proceeding, Respondent insisted that he had done nothing to warrant the charge of resisting arrest even though he was convicted by a jury of the charge. Moreover, he insisted that his patients had lied when they told Investigators that he had not performed physical exams on them or told them what their treatment plan was. Indeed, with respect to the latter, he maintained that his patients had lied notwithstanding that his records rarely listed any plan other than to prescribe drugs and return in thirty days.

Furthermore, Respondent maintained that he could do a complete physical examination ''in three or four minutes,'' and insisted that ''he always ask[ed] the basic questions'' needed to diagnose anxiety and depression even though the progress notes repeatedly lacked the findings necessary to support such a diagnosis. And while Respondent initially acknowledged that he was ''probably at fault'' for not examining his patients' arms for track marks indicative of current intravenous drug abuse, when asked whether he should have done so when a patient's medical records established a history of drug abuse, he insisted that he ''makes [his] own decisions about patients that [he] treat[s].'' Tr. 329.

As forgoing demonstrates, Respondent has not accepted responsibility for his misconduct. Moreover, while Respondent produced a letter from a physician, who had worked with him ''[f]or a short period of time'' during the summer of 2008, which suggests that Respondent has reformed his practices, it is significant that at the time, Respondent was well aware that he was under investigation and had ample incentive to behave. Finally, Respondent's misconduct was egregious

[32] Under federal law, a practitioner must meet extensive requirements and be separately registered to lawfully dispense narcotic drugs for maintenance or detoxification treatment. 21 U.S.C. 823(g).

and caused extraordinary harm to public health and safety.[33]

I thus conclude that the revocation of Respondent's registration is necessary to protect the public interest. For the same reasons that led me to order the immediate suspension of his registration, I conclude that public interest requires that this Order be effective immediately.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, AA1071947, issued to George C. Aycock, M.D., be, and it hereby is, revoked. I further order that any pending application to renew or modify the registration be, and it hereby is, denied. This Order is effective immediately.

Dated: April 3, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–8624 Filed 4–14–09; 8:45 am]

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[33] According to the National Center on Addiction and Drug Abuse, ''[t]he number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003.'' National Center on Addiction and Substance Abuse, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* 3 (2005). The above figure is ''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.* Moreover, ''between 1992 and 2003, there has been a * * * 140.5 percent increase in the self-reported abuse of prescription opioids,'' and during this 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.* at 4.

DEPARTMENT OF LABOR

Employment Standards Administration

Proposed Extension of the Approval of Information Collection Requirements

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment Standards Administration is soliciting comments concerning its proposal to extend the Office of Management and Budget (OMB) approval of the Information Collection: Application for Certificate to Employ Homeworkers (WH–46); Piece Rate Measurements; and Homeworker Handbook (WH–75). A copy of the proposed information collection request can be obtained by contacting the office listed below in the **ADDRESSES** section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before June 15, 2009.

ADDRESSES: Mr. Steven D. Lawrence, U.S. Department of Labor, 200 Constitution Ave., NW., Room S–3201, Washington, DC 20210, telephone (202) 693–0292, fax (202) 693–1451, E-mail *Lawrence.Steven@dol.gov.* Please use only one method of transmission for comments (mail, fax, or E-mail).

SUPPLEMENTARY INFORMATION:

I. Background

Fair Labor Standards Act (FLSA) section 11(d), 29 U.S.C 211(d), authorizes the Secretary of Labor to regulate, restrict, or prohibit industrial homework as necessary or appropriate to prevent the circumvention or evasion of the minimum wage requirements of the Act. The Department of Labor (DOL) restricts homework in seven industries (*i.e.,* knitted outerwear, women's apparel, jewelry manufacturing, gloves and mittens, button and buckle manufacturing, handkerchief manufacturing, and embroideries) to those employers who obtain certificates. *See* 29 CFR 530.1–.2. The DOL now allows employers to obtain general (employer) certificates to employ homeworkers in all restricted industries except women's apparel and hazardous jewelry manufacturing operations. *See* 29 CFR 530.101. In order to obtain general certificates to employ workers in the restricted industries under the certification program, an employer must apply to the Wage and Hour Division (WHD) of the DOL. *See Id.* Form WH–46 is the application form used to obtain a certificate to employ homeworkers in restricted industries, and it must contain information required by Regulations 29 CFR 530.102—including names, addresses, and languages (other than English) spoken by the homeworker—and the written assurances set forth in Regulations 29 CFR 530.103. If approved, the WHD issues a certificate that is valid for two-year periods unless suspended or revoked. 29 CFR 530.101(b). Employers in the restricted industries under the certification program who pay workers based on piece-rates must record and retain documentation of the method used to establish piece-rates in order to verify that rates were properly determined and resulted in wage payments to homeworkers at a rate at least equal to the FLSA minimum wage for all hours worked in the workweek. 29 CFR 530.202. To ensure employers fulfill their obligation to obtain and record accurate hours worked information whenever they distribute homework to employees and collect it from them, homeworkers record the information in Homeworker Handbooks (WH–75) as they perform the work and provide the Handbooks to their employer for transcription at the end of each pay period. *See* 29 CFR 516.31(c), 530.103(d)–(e). This information collection is currently approved for use through October 31, 2009.

II. Review Focus

The DOL is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions 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; and
- 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, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

The DOL seeks the approval of the extension of this information collection in order to ensure employees working as homeworkers are paid in compliance with the FLSA and to allow the agency to carry out its responsibilities under the Act.

Type of Review: Extension.

Agency: Employment Standards Administration.