DEPARTMENT OF JUSTICE

Notice of Lodging of First Addendum to Consent Decree Under the Emergency Planning and Community Right-To-Know Act, the Clean Water Act, the Resource Conservation and Recovery Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Comprehensive Environmental Response, Compensation, and Liability Act, the Safe Drinking Water Act, and the Clean Air Act

Under 28 CFR 50.7, notice is hereby given that on August 25, 2011, a proposed First Addendum to Consent Decree in *United States, et, al.* v. *INVISTA, S.à r.l,* Civil Action Number 1:2009-cv-00244, was lodged with the United States District Court for the District of Delaware.

The Consent Decree in this matter was entered on July 28, 2009. The Consent Decree resolves claims against INVISTA S.à r.l. (''INVISTA'') brought by the United States on behalf of the U.S. Environmental Protection Agency (''EPA'') under the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. 11001 to 11050; the Clean Water Act (CWA), 42 U.S.C. 1251 to 1387; the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 to 6992k; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 to 136y; Section 103(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601 to 9675; the Safe Drinking Water Act (SDWA), 42 U.S.C. 300f to 300j–26; and the Clean Air Act (CAA), 42 U.S.C. 7401 to 7671q (hereinafter ''Environmental Requirements''). The Consent Decree also resolves the claims against INVISTA brought by the State of Delaware Department of Natural Resources and Environmental Control, the State of South Carolina Department of Health and Environmental Control, and the Chattanooga-Hamilton County Air Pollution Control Board.

The First Addendum to Consent Decree modifies deadlines for benzene waste NESHAP program enhancements at two INVISTA facilities in Orange and Victoria, Texas. The First Addendum extends the time for INVISTA to elect between two options for further benzene emission reductions and extends the time to implement the selected option. INVISTA will continue to comply with the benzene NESHAP throughout this period.

The Department of Justice will receive, for a period of 30 days from the date of this publication, comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States et al.* v. *INVISTA, S.a.r.l,* DOJ Ref. No. 90–5–2–1–08892.

The proposed First Addendum to Consent Decree may be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed Consent Decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax number (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy of the Consent Decree from the Consent Decree Library, please enclose a check in the amount of $2.00 (.25 cents per page reproduction costs), payable to the U.S. Treasury.

Robert D. Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–33]

Richard A. Herbert, M.D.; Decision and Order

On June 15, 2010, Administrative Law Judge (ALJ) Mary Ellen Bittner issued the attached recommended decision. Thereafter, Respondent filed Exceptions to the ALJ's decision.

Having reviewed the entire record including Respondent's Exceptions, I have decided to adopt the ALJ's rulings, findings of fact, conclusions of law, and recommended Order except as expressly set forth below.[1]

In his Exceptions, Respondent raises several issues. First, Respondent argues that he ''was irreparably harmed'' because he was forced to represent himself ''pro se'' after the ALJ granted his previous attorney's motion to withdraw but did not grant his motion for a continuance of the hearing to allow him to obtain new counsel.[2] Exc. at 6–7. Respondent argues that his previous attorney had requested that he ''be given leave of 21 days to obtain new counsel,'' and that ''[t]he ALJ mistakenly assumed that the attorney and Respondent were not asking for a delay of the hearing'' and did not grant a continuance in her October 13, 2009 order. *Id.* at 7. Respondent further asserts that the ALJ ''unfairly denied a continuance'' and that he ''must be given a fair hearing with representation for a proper outcome in this matter.'' *Id.* at 10.

The record establishes that on October 9, 2009, Respondent's prior counsel filed a motion for leave to withdraw; in his motion, Respondent's prior counsel ''further requested that Respondent be given leave of twenty-one (21) days to secure new counsel.'' ALJ Ex. 5. On October 13, 2009, the ALJ granted the motion to withdraw. *Id.* However, the ALJ found ''it unnecessary to provide leave of twenty-one (21) days for Respondent to secure new counsel * * * as Respondent is free to retain counsel at any time.'' *Id.* The ALJ further ordered that ''the hearing in this matter, scheduled to begin on November 3, 2009, shall proceed as scheduled.'' *Id.* A copy of this ruling was served on Respondent by Federal Express. *Id.* In addition, the following day, the ALJ's law clerk wrote Respondent noting that it appeared that he was no longer represented by counsel and calling his attention to his ''right to be represented by an attorney''; the letter also included verbatim the language of 21 CFR 1316.50, which addresses a party's right to representation. ALJ Ex. 6. The letter further advised Respondent that he could contact the ALJ's law clerk if he had any questions. *Id.*

At the hearing, Respondent argued that his prior counsel had sought a continuance of twenty-one days. Tr. 11. However, the ALJ noted that Respondent's prior attorney ''did not ask for a postponement of the hearing'' and that he had simply requested that Respondent ''be given leave of 21 days to secure new counsel.'' *Id.* at 12–13. Respondent replied that his prior lawyer's intent was ''to get [him] time'' because ''we have blocked out four days'' for the hearing, and no ''major league attorney is going to have four days [open] on his calendar,'' having been notified approximately three weeks before the hearing date. *Id.* at 13. The ALJ responded that she did not

[1] Pursuant to 5 U.S.C. 552(a)(2), the ALJ's recommended decision has been edited to eliminate the names of various persons who were either witnesses or were referred to in the proceeding. All citations to the ALJ's decision are to the slip opinion attached to this Decision and Order.

[2] Respondent does not, however, contend that the ALJ erred in granting the motion to withdraw. *See* Resp. Exc. at 6–10.

know what Respondent's prior lawyer had ''intended,'' but only ''what he asked for.'' *Id.* Respondent then stated that he understood, and that ALJ ''ha[d] made [her] ruling.'' *Id.* The ALJ then proceeded to conduct the hearing.

I conclude that the ALJ did not abuse her discretion in proceeding to conduct the hearing. Whatever the intent of Respondent's counsel was in asking for ''leave * * * to secure new counsel,'' Respondent had at least three weeks between his prior attorney's moving to withdraw and the commencement of the hearing to find new counsel. While it may be the case that most capable attorneys would not have four days clear on their calendar on three weeks' notice, it is not as if Respondent had secured new counsel who, because his calendar was not clear, sought a continuance, which was denied. Indeed, it is notable that at the hearing, Respondent made no claim that he had actually contacted any attorney, let alone that an attorney had declined to represent him because the attorney had a scheduling conflict. I therefore reject Respondent's exception and conclude that he is not entitled to a new hearing.

Respondent takes further exception to the ALJ's conclusion that the OxyContin prescriptions he issued to E.M. lacked ''a legitimate medical purpose'' and that he ''was at least reckless or negligent in ignoring the warning signs of diversion.'' Exc. at 10–16. Respondent raises a number of contentions regarding the weight the ALJ gave to the testimony of various witnesses and exhibits; Respondent also notes that after the Agency's hearing, the Illinois Department of Financial and Professional Regulation (IDFPR) held a hearing on the same allegations and ''found that the State did not prove that any diversion occurred.'' *Id.* at 15.

Having reviewed each of these contentions, I concluded that a preponderance of the evidence supports the ALJ's conclusions that the OxyContin prescriptions which Respondent issued in the name of E.M. were issued outside of the ''usual course of * * * professional practice'' and lacked ''a legitimate medical purpose'' and therefore violated the CSA. 21 CFR 1306.04(a). The evidence shows that beginning in September 2003, Respondent prescribed 60 tablets of Oxycontin 80 mg. (BID, twice a day), to E.M., who was then 93 years old, on a monthly basis through May 2009, one month before her death. RX 16. Yet on various occasions throughout this period, E.M. was an in-patient in either a hospital or nursing home. *See* GX 42. Moreover, E.M. was under hospice care from June 9 through October 11, 2006; December 8, 2006 through June 1, 2007; and from July 11, 2007 through the date of her death.

According to the testimony of a hospice nurse who treated E.M. for between eight months to a year, under the hospice agreement, E.M.'s family was required to disclose whether any other physicians were treating her. Tr. 35, 38. In addition, the testimony established that the hospice was required to know what medications E.M. was taking. *Id.* at 35. As the hospice nurse explained, a doctor would need to communicate with hospice what drugs he was prescribing so that contraindicated drugs were not prescribed by another doctor. *Id.* at 65.

Yet E.M.'s family, including her son I.S., who was a long-standing friend of Respondent and who also received the same monthly prescriptions for 60 tablets of OxyContin 80 mg (*see id.* at 686) and filled his mother's prescriptions (*id.* at 690), did not disclose to the hospice either that E.M. was being treated by Respondent or that she was taking OxyContin 80 mg. *Id.* at 66. According to the hospice nurse, the only controlled substance she was aware of being prescribed to E.M. was Valium. *Id.* at 35. Moreover, on those occasions when the hospice nurse determined that E.M. needed some medicine for her arm or knee pain, I.S. told the hospice nurse that Tylenol (acetaminophen, a non-controlled drug) worked for his mother and that his mother could not handle stronger medicine. *Id.* at 65.

The Government also called as a witness Dr. S.D., a specialist in internal medicine who was E.M.'s primary care physician for the last four years of her life, including when she was in hospice. *Id.* at 72, 76. According to Dr. S.D., E.M. had lower back pain, shoulder and knee pain, for which he prescribed Tylenol or Darvocet. *Id.* at 89–90. However, she did not require constant medication, and he never prescribed OxyContin 80 mg, which he considered to be ''too strong for her.'' *Id.* at 91–92. While Dr. S.D. once prescribed Vicodin to E.M. upon her discharge from the hospital, GX 21, at 31; he did not prescribe Vicodin to her on a monthly basis. Tr. 143.

While Dr. S.D. talked with I.S.'s live-in girlfriend regarding E.M.'s condition, he further testified that he was never told that Respondent was prescribing OxyContin to her. *Id.* at 92, 95, 109, 141–42. Moreover, the hospice nurse never told him that E.M. was seeing another doctor and never listed OxyContin as one of her medications. *Id.* at 96, 102. Dr. S.D. further testified that if E.M. had, in fact, been taking two OxyContin 80 mg each day and had stopped (as when she was in the hospital), she would have undergone ''severe withdrawal,'' including such symptoms as abdominal pain, diarrhea, and vomiting. *Id.* at 105–06. Dr. S.D. also testified that when a patient is hospitalized, a family member is not allowed to give the patient medication. *Id.* at 107. There was, however, no evidence that E.M. underwent withdrawal during any of the various occasions when she was hospitalized. *Id.* at 106, 143–44.

Dr. S.D. further testified that because he was E.M.'s primary care physician, Respondent had ''the legal responsibility to send [him] a consult that [Respondent was] treating her for pain and prescribing'' OxyContin 80 mg to her. *Id.* at 140. Dr. S.D. testified that if doctors do not coordinate their prescribing to a patient, the patient could overdose. *Id.* at 144. Dr. S.D. then testified that it is outside of the normal course of medical practice for a physician, who is aware that a patient is being treated by another physician, to prescribe drugs and fail to consult with the other physician.[3] *Id.*

As noted above, during the period in which Respondent issued the OxyContin prescriptions in E.M.'s name, E.M. was admitted as an in-patient to a hospital on approximately twenty occasions.[4] *See* GX 42. Yet there is no evidence that she ever underwent withdrawal. Moreover, in the voluminous medical records entered into evidence, Respondent points to only a single instance (involving a January 18, 2006 emergency room visit for a potential stroke (CVA)), in which the medical records listed her medications as including OxyContin. GX 21, at 29. If E.M. was actually taking the OxyContin, this begs the question of why her family was so reluctant to disclose this information (as well as Respondent's) name to the hospitals where she was treated.

There is further evidence establishing that Respondent's prescriptions were unlawful. The evidence shows that on November 10, 2004, E.M. was discharged from the hospital to the

[3] Respondent acknowledged that he was aware that E.M. was being treated by other doctors, and the chart he maintained on her shows that he was aware at various points that she was a patient in a rehab facility and a nursing home. RX 16, at 5–6. Yet he never notified either her physicians or these facilities that he was prescribing OxyContin to her. While Respondent maintained he did not notify E.M.'s physicians and the facilities regarding the OxyContin prescriptions because E.M's family did not want him to, Respondent offered no credible explanation for why he continued to prescribe to E.M. when he knew she was under the care of other physicians.

[4] She was also taken to the Emergency Room approximately ten times.

Heritage Village Nursing Home, and that at 9:30 a.m., she was admitted to the latter. GX 11, at 1; GX 25, at 3; GX 27A, at 70. Yet Respondent noted in her chart that on the same day, he performed a physical exam at which he took her blood pressure, palpated her deformities and found that they were ''not as painful,'' and found that her ''hand grip good,'' RX 16, at 4; the same day, he also issued her a prescription for sixty OxyContin 80 mg. *See* GX 28, at 10. Respondent did not, however, offer any testimony explaining how he could have performed a physical exam on E.M. on this day.

Likewise, Respondent noted in E.M.'s chart that on November 17, 2006, her blood pressure was 138/94, she was ''[d]oing surprisingly well today,'' she ''spoke my 1st name,'' and was ''oriented,'' RX 16, at 5; he also issued a prescription in her name for sixty OxyContin 80 mg. *See* GX 14, at 5. However, between October 12 and December 8, 2006, E.M. was a patient in the Manor Care Nursing Home. GX 21, at 203; GX 27B, at 17, 956. Yet the record (including Respondent's testimony) establishes that Respondent did not travel to the facilities E.M. was in. Tr. 547.

The ALJ found that there were ''numerous inconsistencies between the testimonies of [I.S.] and Respondent'' and that this led her ''to believe that neither is a credible witness with regard to [E.M.'s] medication and treatment.'' ALJ at 54. The ALJ further noted the extensive amount of time that E.M. was in either a hospital or nursing home/rehab facility (approximately 290 days during the course of Respondent's prescribing to her) and found ''it difficult to believe that [E.M.'s] family was able to administer [80 mgs of] OxyContin twice a day for such an expansive time without ever arousing the suspicion of the facility staff.[5]'' *Id.* I agree and find Respondent's and I.S.'s testimony implausible. I also agree with the ALJ's conclusion that the record supports the conclusion that the OxyContin prescriptions Respondent issued in the name of E.M. lacked a legitimate medical purpose and were issued outside of the usual course of professional practice and thus violated Federal law.[6] 21 CFR 1306.04(a).

Respondent further points to an IDFPR Inspector's Report of an interview he conducted with E.M. and her son on August 9, 2005. During this interview, E.M. identified two green tablets, which were reportedly OxyContin, and stated that they ''were to combat pain.'' RX 10. However, earlier in the interview the Inspector had asked E.M. if she had pain when she initially went to see Respondent and she answered ''no.'' *Id.* I.S. had objected that ''the question was unfair as he felt she did not recall.'' *Id.* Moreover, Respondent had previously diagnosed E.M. as having ''senile dementia'' nearly two years earlier, RX 16, at 1; and Dr. P. (Dr. S.D.'s partner) had diagnosed E.M. as having Alzheimer's disease and dementia in June 2005, two months prior to the interview. Thus, there is ample reason to discount E.M.'s statement regarding the use of the OxyContin.

Respondent also argues that after the instant hearing, the IDFPR held a hearing on the ''same underlying allegations,'' at which much of the same evidence was presented; however, at the state hearing, Respondent was also able to procure the testimony of C.S. (I.S.'s wife). Exceptions at 15. Respondent argues that the State ALJ ''found that the State did not prove that any diversion occurred.'' *Id.*

Respondent does not, however, argue that C.S. was unavailable to testify in the DEA proceeding and her testimony does not constitute newly discovered evidence. *Cf. ICC* v. *Brotherhood of Locomotive Engineers,* 482 U.S. 270, 286 (1987). As for the state ALJ's findings, DEA was not a party to that proceeding. Moreover, this Agency has long held that it ''maintains a separate oversight responsibility [apart from that which exists in a state board] with respect to the handling of controlled substances and has a statutory obligation to make its independent determination as to whether the granting of [a registration] would be in the public interest.'' *Mortimer B. Levin, D.O.,* 55 FR 8209, 8210 (1990). Accordingly, even if Respondent had submitted the state ALJ's decision, the state ALJ's finding would not be entitled to collateral estoppel effect in this proceeding.[7] *Cf. United States* v. *Mendoza,* 464 U.S. 154 (1984). I therefore reject Respondent's exception that the evidence in the record of this proceeding does not demonstrate that he engaged in the diversion of controlled substances and agree with the ALJ's conclusion that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued OxyContin prescriptions in E.M.'s name. 21 CFR 1306.04(a). *See also George Mathew, M.D.,* 75 FR 66138, 66146 (2010) (under Federal law, where a physician issues a prescription in violation of 21 CFR 1306.04(a), the drug is deemed diverted).

Finally, Respondent argues that the proven allegations do not support the revocation of his registration. Resp. Exc. at 16. Contrary to Respondent's understanding, DEA has held that proof of a single act of diversion is sufficient to support the revocation of a registration and the denial of an application. *See Dewey C. MacKay,* 75 FR 49956, 49977 (2010); *Alan H. Olefsky,* 57 FR 928, 928–29 (1992) (revoking registration based on physician's act of presenting two fraudulent prescriptions to pharmacy for filling). The ALJ's finding that Respondent issued prescriptions which lacked a legitimate medical purpose is sufficient by itself to support the revocation of Respondent's registration, especially, where, as here, the ALJ

[5] Among the implausible testimony I.S. gave was that he or a family member would take the OxyContin to his mother when she was institutionalized and give her the drug, which was prescribed to be taken twice a day. Tr. 685. I.S. also asserted that when he went to his mother's various institutions, and told them that he had ''supplements [and] medications that I give my mother at home, and I would like you to administer them, * * * they said we won't do that * * * unless the doctor orders it. But if you want to come in yourself, or have somebody come in and give it to your mother, we haven't got a problem with that, and that's what I did.'' *Id.* at 692–93. However, I.S. testified that he did not tell the facilities that he would be administering OxyContin. *Id.* Indeed, it seems strange that the facilities did not ask I.S. what medications he intended to bring into the facility, and as the ALJ found, this testimony is patently disingenuous.

[6] Respondent argues that DEA Investigators ''could have easily secured a blood test of [E.M.] to discern whether she was receiving OxyContin,'' and that ''[b]y the time Respondent realized the focus of the investigation centered around this patient and the severity of the charges against him, it was too late because the patient had passed away.'' Exceptions at 12. Respondent further argues that ''even though OxyContin was listed as a home medication and there was evidence that she was taking the medicine s[u]rreptitiously, Dr. [S.D., her primary care physician,] never ordered a blood test for opioid levels.'' *Id.* at 13. As for DEA's obligation to secure a blood test, this is beside the point. Moreover, in his testimony, Respondent acknowledged that ''[i]n retrospect'' he should have done a blood test on E.M. to see if she was actually taking the OxyContin. Tr. 835. However, he then attempted to shift the blame to Dr. S.D., asking ''[w]hat is [his] excuse?'' *Id.*

Respondent ignores that he was one who prescribed 60 tablets of OxyContin 80 mg to E.M.—which is the second strongest formulation available and which just happened to be the same prescription that he was giving her son—each month, and did this for a period of more than five and a half years and did so even when he knew she was being treated by other doctors. At a minimum, this evidence establishes that Respondent acted with deliberate ignorance as to the likelihood the drugs were being diverted. *See Jeri Hassman, M.D.,* 75 FR 8194, 8228 (2010) (citing *United States* v. *Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006)).

[7] The Government also notes that in the IDFPR proceeding, the State's burden of proof was ''clear and convincing evidence,'' but in this proceeding the ''preponderance of the evidence'' standard applies. Gov. Resp. to Resp. Motion for Rehearing and Exceptions, at 13 (citing Tit. 68, Cp. VII, Subchapter a, Admin. Rule, Part 1110.190).

found that ''Respondent has repeatedly failed to accept responsibility for his misconduct.'' ALJ at 44. *See also Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe—Jonesborough,* 73 FR 364, 387 (2008) (DEA ''has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'')); *see also Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).[8]

Moreover, the ALJ found that Respondent had committed additional acts which support the revocation of his registration, including that he materially falsified his 2006 renewal application when he failed to disclose the 1998 probation imposed on his state medical license by the Illinois Department of Professional Regulation. ALJ at 43. As the ALJ found, this was a material falsification because the underlying conduct which gave rise to the State's order was Respondent's prescribing of Dilaudid, a schedule II controlled substance, to four patients ''under questionable circumstances, i.e., for pain related to old injuries or for pain in which surgery may have provided relief and that two (2) of the patients may have sold some of the Dilaudid back to Respondent.'' GX 7. This falsification was material because under the public interest standard, DEA is required to assess an applicant's experience in dispensing controlled substances and his record of compliance with state and federal laws related to controlled substances. 21 U.S.C. 823(f)(2) & (4). Accordingly, Respondent's failure to disclose the 1998 probation was capable of influencing the Agency's decision as to whether to grant his application and was a material falsification.[9] *See The Lawsons, Inc.,* 72 FR 74334, 74338–39 (2007) (other citations omitted). Under the CSA, material falsification provides a separate and independent ground for denying an application. 21 U.S.C. 824(a)(1).

Substantial evidence also supports the ALJ's findings that Respondent committed other acts of misconduct. These included his: (1) Obtaining Marinol, a schedule III controlled substance, from a patient, who had been dispensed the drug by another doctor, in violation of 21 U.S.C. 844(a); and his (2) failing to document his receipt of the Marinol in violation of 21 U.S.C. 827(a)(3). ALJ at 48–49. In addition, Respondent prescribed controlled substances from a new location at which he did not hold a registration and did so even after he was told by DEA personnel to stop doing so. ALJ at 30–31, 52–53 (citing GXs 9, 33, and 34). As the ALJ noted, ''Respondent's act of continuing to handle controlled substances after numerous warnings shows a flagrant disregard for the requirements of the law governing the handling of controlled substances.'' *Id.* at 53.

Finally, based on a 2003 state proceeding, the ALJ found that Respondent failed to properly supervise an unlicensed person who distributed phentermine, a schedule IV controlled substance, to patients of a weight loss clinic where Respondent worked and which was owned by the unlicensed person who was a personal friend. ALJ at 46. According to the record, this occurred when Respondent left his medical bag (which contained the drugs) at the clinic and the clinic owner distributed the phentermine to its patients. Notably, five years earlier—as part of the 1998 Consent Order, which resolved the allegations pertaining to his handling of Dilaudid—Respondent was required to take a course in controlled substance management. GX 7, at 3. Yet Respondent then committed additional violations of the CSA.

The numerous acts of misconduct proved on this record, along with Respondent's unwillingness to accept responsibility for much of it, and his demonstrated inability to take heed of the laws and regulations pertaining to controlled substances even after being required to undergo remedial instruction, make clear that his continued registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). I therefore reject Respondent's exception that the evidence does not support the revocation of his registration. Accordingly, I will adopt the ALJ's recommendation that his registration be revoked and that his applications to renew and modify his registration be denied.

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), I order that DEA Certificate of Registration, BH8738063, issued to Richard A. Herbert, M.D., be, and it hereby is, revoked. I further order that the applications of Richard A. Herbert, M.D., to renew and modify his registration be, and they hereby are, denied. This order is effective September 29, 2011.

Dated: August 12, 2011.

Michele M. Leonhart,

Administrator.

Bryan Bayly, Esq., for the Government.
Richard A. Herbert, M.D., Pro Se, for the Respondent.

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

Mary Ellen Bittner, Administrative Law Judge. This proceeding is an adjudication pursuant to the Administrative Procedure Act, 5 U.S.C. 551 *et seq.,* to determine whether the Drug Enforcement Administration (DEA) should revoke a physician's Certificate of Registration as a practitioner and deny any pending applications for renewal or modification of that registration. Without this registration the physician, Respondent Richard A. Herbert, M.D., of Riverside, Illinois, will be unable to lawfully handle controlled substances in the course of his practice.

On March 11, 2009, the Deputy Assistant Administrator, Office of Diversion Control, of the DEA issued an Order to Show Cause to Respondent, giving Respondent notice to show cause why the DEA should not revoke his

[8] In concluding that Respondent has not accepted responsibility for his misconduct, the ALJ noted that ''despite my previous rulings to the contrary, Respondent continues to assert that most of the evidence and testimony admitted in the instant hearing is inadmissible and should not be considered'' and that he ''continues to assert that he was 'not afforded a capable attorney' although he was at any time free to procure the assistance of counsel [and] was notified of such.'' ALJ at 44 (citing Resp. Closing Argument Br. at 10).

To make clear, that Respondent continues to object to the admission of certain evidence and argues that he was not afforded a capable attorney is of no relevance in determining whether he accepts responsibility for his misconduct. I thus reject the ALJ's reliance on Respondent's legal arguments as a basis for concluding that he does not accept responsibility. However, the record contains an ample evidentiary basis for concluding that Respondent does not accept responsibility for most of his misconduct, and his explanation of his prescribing to E.M. is utterly implausible. Thus, I conclude that Respondent has not rebutted the Government's *prima facie* case. *See Hoxie,* 419 F.3d at 483 (upholding Agency's reliance on registrant's lack of candor in determining whether registration is consistent with the public interest).

[9] In his Exceptions, Respondent also contends that the Agency's consideration of the 1998 Consent Order violates his right to due process because due process ''requires protection from a never-ending time limit for the DEA to bring an action.'' Exceptions at 3. Respondent, however, makes only a conclusory assertion of prejudice. *Cf. United States* v. *Brockman,* 183 F.3d 891, 895 (8th Cir. 1999). He likewise ignores that in making the public interest determination, Congress directed the Agency to consider his experience in dispensing controlled substances, an inquiry which necessarily entails review of prior incidents of misconduct.

DEA Certificate of Registration pursuant to 21 U.S.C. 824(a)(l) and (a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f), on grounds that he materially falsified an application for renewal of his registration and that his continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

In substance, the Order to Show Cause alleges that Respondent holds a DEA Certificate of Registration that expired on October 31, 2006, and for which Respondent submitted a timely renewal application on September 26, 2006; that on that renewal application, Respondent was required to answer whether a state medical board had taken action against his state license; that on February 26, 1998, the Illinois then-Department of Professional Regulation had placed Respondent's medical license on probation for one year because Respondent issued unlawful prescriptions for Dilaudid, a brand name product containing the Schedule II narcotic controlled substance hydromorphone hydrochloride; that Respondent failed to disclose the 1998 probation on his September 2006 renewal application; that Respondent obtained dronabinol, a Schedule III hallucinogenic controlled substance, from a patient who had acquired it pursuant to a prescription from another physician but had no record of such receipt, and that on July 21, 2003, Respondent dispensed that dronabinol to another purported patient but had no record of such dispensing; that on August 15, 2003, the Illinois Department of Financial and Professional Regulation (IDFPR) placed Respondent's medical license on probation for three years because Respondent failed to supervise an unlicensed employee who illegally handled phentermine, a Schedule IV stimulant controlled substance; that Respondent disclosed the 2003 probation on his September 2006 renewal application; that on July 5, 2005, the Illinois Department of Professional Regulation served Respondent with an administrative subpoena seeking to obtain patient records and that Respondent did not fully comply with the subpoena in that he redacted patient identification information and all dates of treatment; that on July 28, 2007, the administrative subpoena was re-issued to Respondent; and that from February 2006 through August 2007, Respondent diverted OxyContin, a brand name product containing the Schedule II narcotic controlled substance oxycodone, to a patient by giving the patient a prescription that Respondent wrote in the name of the patient's mother.

Respondent, through counsel, timely requested a hearing on the allegations in the Order to Show Cause. On October 9, 2009, Respondent's counsel requested leave to withdraw as counsel because of a conflict of representation; I granted counsel's request on October 13, 2009; and sent a copy of the memorandum granting that request to Respondent by Federal Express that same day. Following prehearing procedures, a hearing was held in Chicago, Illinois, from November 3 through November 6, 2009, with the Government represented by counsel and Respondent appearing *pro se.* Both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law, and argument. All of the evidence and posthearing submissions have been considered, and to the extent the parties' proposed findings of fact have been adopted, they are substantively incorporated into those set forth below.

Issue

Whether a preponderance of the evidence establishes that, pursuant to 21 U.S.C. 824(a)(l) and (a)(4), Respondent's registration with the Drug Enforcement Administration should be revoked and any pending applications for renewal or modification of that registration denied, because Respondent made material misstatements on an application for registration and because his continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).

Findings of Fact

I. Background

Respondent is a physician licensed to practice medicine and to handle controlled substances in Illinois. He has held a DEA registration since April 13, 2004, with a registered address at Oakbrook Center Mall in Oak Brook, Illinois. [GX 1]

II. The Illinois Department of Financial and Professional Regulation

The Illinois Department of Financial and Professional Regulation (IDFPR) is a state agency that licenses physicians and investigates complaints regarding licensed physicians. Upon conclusion of an investigation, the information is forwarded to a medical coordinator, who is a physician, for review. That individual then determines whether to recommend the case to the Medical Disciplinary Board. [Tr. 151–152] D. M., a medical investigator and controlled substance inspector for the IDFPR, testified that the IDFPR was previously known as the Department of Professional Regulation but was merged with several stand-alone agencies to eventually become the IDFPR. [Tr. 155]

III. The Evidence Pertaining to Respondent

A. Respondent's Illinois Department of Professional Regulation 1998 Consent Order

Investigator D.M. testified that he and two representatives of the DEA were involved in a 1994 investigation of Respondent regarding the diversion of Dilaudid. [Tr. 154, 733] On February 26, 1998, Respondent entered into a Consent Order with the Illinois then-Department of Professional Regulation. The Consent Order stated that Respondent ''may have prescribed Dilaudid to four (4) patients under questionable circumstances, i.e. for pain related to old injuries or for pain in which surgery may have provided relief and that two (2) of the patients may have sold some of the Dilaudid back to Respondent.'' [10] Respondent did not admit or deny the allegations but, for the purposes of the Consent Order only, agreed not to contest the allegations. Respondent testified in the instant hearing that he does not agree that his actions were unlawful and that his position is that he acted lawfully. [Tr.743, GX 2]

Under the terms of the Consent Order, Respondent's Illinois physician and surgeon and controlled substances licenses were both placed on probation for one year with several conditions, including completion of a course in controlled substances management and a requirement that Respondent make and submit controlled substance logs to the Department of Professional Regulation for a period of time. [GX 7]

B. Respondent's Illinois Department of Financial and Professional Regulation 2003 Consent Order

Investigator D.M. testified that another IDFPR investigation of Respondent began in 1999 and concerned the ''aiding and abetting in the unlicensed practice of medicine.'' [11] According to Investigator D.M., an A.D. had ''dispensed'' [12] to patients in Chicago phentermine that Respondent

[10] GX 7.

[11] Tr. 157.

[12] Agent D.M. testified that his use of the term ''dispense'' referred to ''providing the actual pills.'' Tr. 159.

had ordered and received at his Oakbrook office.

At the hearing in the instant case, Respondent testified that he had a ''deal for pay'' with his friend Mr. D., who owned a weight loss clinic in Chicago. Pursuant to this agreement, Respondent used his DEA registration to purchase phentermine at his registered Oakbrook location and then took the phentermine to Mr. D.'s clinic in a locked bag that Respondent would sometimes leave at the clinic; Respondent saw patients and created records at the clinic and sold the phentermine to Mr. D. who in turn sold the phentermine to the patients at a higher cost. Respondent testified that one day he left his bag filled with his stock of phentermine at the clinic although he was not there, and when patients came in Mr. D. provided them with phentermine from the bag and instructed them to come back in a few days to see Respondent.[13] Respondent testified that once he was notified that some of those patients were state investigators, he immediately resigned from the clinic and offered to cooperate.

Respondent testified that at a state hearing regarding the matter, he admitted that he had guilt because he technically aided in Mr. D.'s ''practice of medicine by not securing my controlled substances'' [14] but that he ''didn't actually aid and abet.'' [15] On August 15, 2003, Respondent entered into a Consent Order with the IDFPR with regard to Mr. D.'s provision of phentermine from the Chicago clinic. The Consent Order stated that Respondent failed to supervise an unlicensed employee and Respondent admitted that the allegations were true. As a result of the Consent Order, Respondent's Illinois physician and surgeon and controlled substances licenses were placed on probation for a period of three years with several conditions, including completion of continuing medical education in the area of prescribing and dispensing controlled substances and allowing the IDFPR to inspect Respondent's controlled substance log book and inventory record book upon request. [GX 8]

C. Respondent's Activity During the 2003–2006 Probation Period

The IDFPR filed a complaint against Respondent on April 5, 2007, alleging that he violated the terms of his probation as set forth in the 2003 Consent Order by failing to make available for inspection his controlled substance log and inventory records; receiving dronabinol, a Schedule III controlled substance, from a purported patient and re-dispensing it to another purported patient, and failing to keep any records of the receipt and dispensing of the dronabinol; providing incomplete records in response to an IDFPR subpoena issued by the IDFPR; aiding and abetting the unlicensed practice of medicine relating to a June 2005 incident; and issuing prescriptions for OxyContin to patients without examining them and failing to keep and maintain records of those patients and the controlled substances.

1. The IDFPR Inspection of Respondent's Controlled Substances Log

Investigator D.M. testified that in April 2005 he interviewed Respondent regarding his controlled substances logs and that Respondent stated that he did not have any logs for the years 2003, 2004, or 2005 because he had not ordered any controlled substance medications and therefore had no occasion to dispense [16] them or maintain a log of them. [Tr. 194] Investigator D.M. further testified that when he again met with Respondent in May 2005, Respondent iterated that he did not have a log because he had not dispensed any controlled substances in 2003, 2004, or 2005. Investigator D.M., however, was aware from the transcript of a Chicago Police Board hearing held on August 10 and October 13, 2004, that Respondent had testified in that proceeding about dispensing dronabinol to a patient on July 21, 2003; this incident is further discussed below. [Tr. 165] Respondent testified in the instant hearing that ''my assumption when D.M. was in there was that I knew that I had not ordered anything for years, and not recalling these three patients, I simply filled out a handwritten log and zero.'' [17]

Respondent further stated that at the time he knew that he had not ordered anything from drug wholesalers for many years and therefore had not dispensed anything, and that he did not recall that he had made a controlled substances log for 2003, which included three entries and had been stored in his sample cabinet; later that evening he realized his error and notified his attorney, who in turn notified Investigator D.M. and produced the log that included three entries for 2003. [Tr. 622, RX 2]

2. Respondent's Dispensing of Dronabinol

D.S. was a Chicago police officer who tested positive for tetrahydrocannabinol [18] (THC) after a random drug test performed by the Chicago Police Department on July 24, 2003. [Tr. 163] At Officer D.S.'s subsequent police board hearing on August 10, 2004, Respondent testified that he treated Officer D.S. on July 21, 2003, at Respondent's office and gave him eight 10-milligram gelatin capsules of Marinol [19] to control nausea and vomiting; that he did not write a prescription for Marinol for Officer D.S. but gave him ''samples'' of the drug that he had in his office; [20] [GX 5 at 98] that it is his practice to ask patients to give him their unused medications, so that he can ''recycle'' them ''as much as I possibly can''; [21] [GX 6 at 146] and that when he receives medications from patients, he puts the medication in a bottle, labels it, and stores it, but does not keep a record of which patient provided the medication. [GX 6 at145]

In a continuation of the police board hearing on October 13, 2004, Respondent testified that the Marinol he gave to Officer D.S. was not a manufacturing sample but came from another of Respondent's patients, although Respondent had no record of who that patient was; [GX 6 at 144] when asked at the police board hearing which patient provided the Marinol, Respondent replied that ''[i]t could be anyone of a number of patients''; [22] and that the Marinol ''probably came from either a leukemia or lymphoma treatment patient * * * the *other possibility is this could have come from an AIDS* patient.'' [23] In response to a question regarding the frequency with which he had prescribed or given Marinol to patients, Respondent said: ''I have a number of patients that use chemotherapeutic agents for lymphomas and malignancies, leukemias. I also have a large number of AIDS patients

[13] Tr. 587.

[14] Tr. 589.

[15] Tr. 589.

[16] Investigator D.M. stated that in this instance, ''dispensing'' means providing or prescribing. Tr. 194. *But see supra* note 3. The Illinois Compiled Statutes defines ''dispense'' as ''the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to or use by a patient in accordance with applicable State and federal laws and regulations.'' 225 ILCS 85/3.

[17] Tr. 622.

[18] THC is a Schedule I controlled substance.

[19] Marinol is a brand name product containing dronabinol, a Schedule III controlled substance, the active ingredient of which is a synthetic form of tetrahydrocannabinol, which naturally occurs in the Schedule I controlled substance marijuana.

[20] *See* GX 5 at 98.

[21] GX 6 at 146.

[22] GX 6 at 144–145.

[23] Id.

that I use Marinol for.'' [24] Respondent then testified, however, that he had prescribed or given samples of Marinol only a few times in the last several years and that he had the Marinol in his office because it might have come from a patient who obtained it pursuant to a prescription from another doctor.

In the instant hearing, the Government entered into evidence Respondent's medical record for Officer D.S., which indicates that Respondent ''sampled'' Marinol 10 mg to Officer D.S. [GX 4] Respondent testified that he both received and dispensed the Marinol in a plastic pill case without a label but that he recognized the pills as Marinol and used a picture in the Physician's Desk Reference (PDR) to verify what the pill was. Respondent further testified that he remembered the patient from whom he had received the Marinol because he had never received Marinol from a patient before. [Tr. 767] Respondent entered into evidence an affidavit dated May 2, 2008, and signed by a J.W.; Respondent testified that Mr. J.W. was a former patient of his who had AIDS.[25] Mr. J.W.'s affidavit states that he was HIV positive; that Respondent was one of several physicians who treated him; and that he took Marinol to stimulate his appetite but because he did not like the way it made him feel and he could not control its effects, he stopped taking the Marinol and gave the remaining pills to Respondent. The affidavit does not identify Mr. J.W.'s source for the Marinol but states that the cost is high and that Mr. J.W. did not want to dispose of the pills by flushing them down the toilet or putting them in the garbage. [RX 17]

Respondent testified that as of the date of the hearing he understood that he was not authorized to acquire Marinol from a patient, although he had not thought about it before, and that he was not authorized to provide that Marinol to Officer D.S.. Respondent further testified that he did not tell Officer D.S. that he had acquired the Marinol from another patient rather than as a manufacturing drug sample. [Tr. 765] Respondent further testified that he did not keep any record of receipt of the Marinol because at the time he thought that he was only required to maintain records of drugs that he purchased.

[24] GX 6 at 146.

[25] The affidavit is signed by a J.W.; there is no witness signature and the document is not notarized.

3. Respondent's Response to the IDFPR Subpoenas

Investigator D.M. testified that the IDFPR Medical Disciplinary Board issued to Respondent a Subpoena *Duces Tecum* dated June 15, 2005, pursuant to the Illinois Medical Practice Act of 1997. [GX 10] The subpoena commanded Respondent to surrender certain documents and records concerning his treatment of ten individuals, identified on the subpoena by name and date of birth. The documents were to be surrendered on or before June 30, 2005, to one of two identified individuals for inspection by the medical disciplinary board.

Investigator D.M. prepared and attached to the subpoena an affidavit advising that, according to a profile received from the Illinois Department of Human Services, [GX 28] Respondent issued multiple prescriptions of OxyContin 80 mg to the ten individuals whose records were requested, and that some of those individuals also were identified as having received Dilaudid from Respondent in the 1994 investigation. The affidavit states that Respondent issued the prescriptions in question between January 1, 2004, and April 2005, and, specifically, that during this period Respondent issued 124 prescriptions for Schedule II controlled substances, 123 of which were for 60 dosage units each of OxyContin 80 mg.

Investigator D.M. testified that in response to the subpoena, Respondent's attorney provided records from which the names of the individuals and the dates of treatment were redacted. [GX 3] Further, Investigator D.M. stated that the documents provided indicated that one patient had her records sent to a family doctor who agreed to continue OxyContin and that Respondent did not have copies of those records, and that after Respondent advised another patient that the Medical Disciplinary Board had asked to review the patient's records, the patient strongly objected to such a review and took the records, and Respondent did not have copies of them. [Tr. 170]

Investigator D.M. further testified that on June 20, 2007, the Medical Disciplinary Board issued a second subpoena to Respondent, again requesting the medical records for the ten previously identified individuals and requiring that no information other than the patient identity be removed. [Tr. 171] Investigator D.M. testified that he did not know whether Respondent had provided that information, [Tr. 311] but that he had seen documents in the possession of an IDFPR attorney that appeared to include the dates of treatment and other information that had been previously redacted. [Tr. 175] Respondent testified that he eventually complied with the subpoena after the remaining patients gave him permission to provide copies of their records.[26]

4. Respondent's Issuance of OxyContin Prescriptions

Investigator D.M. testified that he met with Respondent in June 2005 at Respondent's office and that during that interview Respondent said that he issued to chronic pain patients prescriptions for 60 OxyContin 80 mg and for Tylenol 3 or Tylenol 4,[27] and that he instructed the patients to take a half tablet of OxyContin twice a day. Respondent further said that he used to prescribe Dilaudid 2 or 4 mg. [Tr. 198] Investigator D.M. further testified that, at that meeting, Respondent indicated that a number of his patients were employed at Balmoral horse racing track and, when Investigator D.M. asked Respondent whether any of the ten patients listed on the subpoena discussed above knew one another, Respondent stated that two of the patients, S.P. and C.G., worked at Balmoral. Respondent did not, however, mention the relationships among I.S., E.M., and C.G., all of whom were also identified on the subpoena and who, as discussed below, shared a household. [Tr. 202] Respondent testified in the instant hearing that he had a personal relationship with Ms. E.M. and went to high school with her son, Mr. I.S.; Ms. C.G. was identified as Mr. I.S.'s girlfriend. [Tr. 485]

Investigator D.M. testified that he and Diversion Investigator C.R. of the DEA's Chicago office interviewed Mr. I.S. in July 2005. Mr. I.S. told them that he was on the board of directors for harness racing at Balmoral Park; that approximately sixty percent of the employees there had drug abuse and/or dependency problems; that he had sustained some injuries from horse racing accidents; that he had been friends with Respondent for about 25 or 30 years; that Respondent issued him OxyContin prescriptions either at Respondent's office or when they met for lunch; and that Respondent also

[26] As evidence of his compliance with the subpoena, Respondent admitted into evidence Respondent Ex. 1, which includes the first page of multiple patient files that appear to have the patients' names and dates of birth and dates of treatment redacted, although a name is handwritten at the top of each page.

[27] I take official notice from the 2007 edition of the Physicians' Desk Reference that Tylenol 3 and Tylenol 4 are brand names for products containing acetaminophen with codeine, a Schedule III controlled substance.

prescribed OxyContin for Mr. I.S.'s girlfriend, C.G., and his mother, E.M., who both lived with him. [Tr. 212]

Investigator D.M. testified that at the July 2005 interview, Mr. I.S. showed him OxyContin vials for Ms. E.M., Ms. C.G., and himself, all of which indicated that they had contained 60 dosage units of 80 mg strength and that Respondent issued the prescriptions. The label had been removed from Mr. I.S.'s vial; he explained that it could be embarrassing for anyone, particularly at the race track, to know that he was taking OxyContin inasmuch as he was promoting a program to help people at the track who might have addiction problems. Mr. I.S. further told the investigators that he had helped to create rules regarding drug use in both humans and horses; and that he did not think that he was abusing the medication because he was able to function and he did not have needle marks, which he said would be a sign of an addict. [Tr. 224]

Mr. I.S. testified in the instant hearing, however, that he removed the label from his OxyContin bottle so that ''the kids wouldn't know what was in the bottles''; [28] [Tr. 721] he received his pain medication from Respondent, whose office was one hour and 25 minutes away from Mr. I.S.'s residence, [Tr. 722] and that ''if I couldn't get my pain medication from [Respondent], then I would get medication wherever I could if I had to, but I don't recall even having to.'' [29] Mr. I.S. then testified that ''there was a time when [Respondent] was having a problem with the DEA, and I couldn't get my medication, and at that time when I was getting medication whatever way I could, and I went to another doctor once''; [30] and before Ms. E.M. began getting the OxyContin prescriptions, he ''would take her to the doctors and I would take her to a clinic'' and ''[y]ou only had to look at my mother and write her something right away, because she was crippled.'' [31]

D. E.M.

1. E.M.'s Medical Conditions

Investigator D.M. testified that he interviewed Mr. I.S. again in August 2005 at Mr. I.S.'s home. Investigator D.M. testified that Mr. I.S. advised him that Ms. E.M. had recently suffered a stroke and had been hospitalized at St. Mary's Hospital and treated by V.P., M.D.; [Tr. 226] that Respondent was Ms. E.M.'s primary physician prior to her admission to St. Mary's Hospital and that S.D., M.D., treated Ms. E.M. while she was at a senior care center. [Tr. 312] Mr. I.S. showed Investigator D.M. prescriptions that Respondent had issued to Ms. E.M. for various medications, including Plavix, Micardis, Prevacid, aspirin, Lipitor, nitroglycerin patches, Remeron, Toprol, and Vicodin [32] which Mr. I.S. typically filled near his home at a pharmacy called Doc's Drugs. Mr. I.S. stated that after the stroke Ms. E.M. had difficulty getting around and was responding to stimuli differently than before and was no longer doing household chores.

Dr. S.D., an internal medicine physician experienced in treating geriatric patients and in the medical use of controlled substances, testified that Ms. E.M. suffered from medical problems such as tachycardia (an irregular heartbeat), lower back pain, arthritis in multiple joints, and dementia; [Tr. 79] he also noted that Ms. E.M. had kyphoscoliosis, which he said was not uncommon for a patient of Ms. E.M.'s age, and often occurs after a person develops osteoporosis; and that she had been admitted to the hospital at various times for such ailments as urinary tract infection, pneumonia, chest pain, and possible seizure disorder. C.K., a licensed practical nurse specializing in geriatrics and end-of-life care and employed by Hospice of Kankakee Valley (Kankakee Hospice), testified that when Ms. E.M. was admitted to Kankakee Hospice, she suffered from ''adult failure to thrive,'' [33] arthritis, a steel rod in her right arm, a hump in her back, and some dementia, as indicated by her difficulty remembering people, including her son whom she confused with her husband.

Respondent testified that Ms. E.M. suffered from vascular dementia, known as Binswanger's disease, which he characterized as a small vessel disease of the white matter; and benign myalgic encephalomyelitis, which causes fatigue, bowel disorders, and cognitive deficits. Respondent testified that because of the dysfunction of the white matter in the brain, Ms. E.M. found it difficult to walk and perform organizational tasks. [Tr. 480] Mr. I.S. testified that Ms. E.M.'s problems of loss of memory and failure to recognize her family were caused by and occurred only when Ms. E.M. was taking certain medication. [Tr. 725]

Respondent testified that he treated Ms. E.M. ''in concert with the whole patient''; [34] that diabetes affects every organ in the body and causes kidney failure, high blood pressure, coronary disease, peripheral artery disease, and cerebral vascular disease; [Tr. 472] and that Ms. E.M. suffered a series of transient ischemic attacks (TIAs), a closing of a small blood vessel in the brain, around 2004, and had elevated blood sugar levels. Respondent testified that all of these factors taken together led him to ''try everything that I could to reverse the arterial sclerosis in the carotid arteries.'' [35]

Respondent testified that he prescribed to Ms. E.M. a combination of high-dosage drugs, including Actos [36] and Metformin,[37] to shut down her body's glucose production and to re-sensitize the peripheral resistance to insulin, Lipitor to reverse the arterial sclerotic changes in the neck, and Lycinapro, Morvasc, and Zetia [Tr. 477] with Metformin to open up her arteries, all of which was part of an anti-inflammatory treatment to stop the progression of her carotid artery disease. [Tr. 600] Dr. S.D., however, testified that if Ms. E.M. had the blood sugar and glycosulated hemoglobin levels Respondent described, it would not have been necessary to medicate her for diabetes, and that the proper treatment would have been to try to control the condition with diet. Dr. S.D. testified that he has never prescribed Actos or Metformin for ''off-label'' use; and that in his opinion, Actos and Metformin

[28] Tr. 720

[29] Tr. 715.

[30] Tr. 715.

[31] Tr. 716.

[32] Lipitor is a brand name product containing atorvastatin calcium, a non-controlled substance and synthetic lipid-lowering agent. I take official notice of the following information from the 2007 edition of the Physicians' Desk Reference: Plavix is a brand name product containing clopidogrel bisulfate, a non-controlled substance and inhibitor of platelet aggregation that helps protect against future heart attack or stroke; Micardis is a brand name product containing telmisartan, a non-controlled substance that is a nonpeptide name product containing lansoprazole, a non-controlled substance, the active ingredient of which is a compound that inhibits gastric acid secretion, typically prescribed to treat and prevent stomach and intestinal ulcers; nitroglycerin patches contain an organic nitrate, a non-controlled substance, that helps prevent chronic chest pain caused by heart disease; Remeron is a brand name product containing mirtazapine, a non-controlled substance and tetracyclic antidepressant used primarily in the treatment of depression; Toprol is a brand name product containing metoprolol succinate, a noncontrolled substance that is indicated for the treatment of hypertension; and Vicodin is a brand name drug containing hydrocodone bitartrate, a Schedule III controlled substance, and acetaminophen, and is indicated for the relief of moderate to moderately severe pain.

[33] Tr. 34.

[34] Tr. 472.

[35] Tr. 486.

[36] *See* RX 22. Actos is a brand name product containing pioglitazone hydrochloride, a non-controlled substance, and is an oral antidiabetic agent that acts primarily by decreasing insulin resistance. [GX 40]

[37] I take official notice that Metformin is a non-controlled substance.

have no use other than to treat diabetes. [Tr. 133]

Investigator R. testified that she visited the Kankakee Hospice central office on April 30, 2009, [Tr. 354] where she spoke to Executive Director D.L., Patient Care Coordinator P.L., C.K., and C.D., another nurse who treated Ms. E.M. Investigator R. testified that none of the people she interviewed had any knowledge of Ms. E.M. ever having diabetes [Tr. 355] and there was no record of Ms. E.M. receiving medication such as Actos and Metformin. [Tr. 356] Investigator R. also obtained from Doc's Drugs pharmacist E.U. a prescription profile listing all the prescriptions issued to Ms. E.M. and filled at that pharmacy from January 1, 2006, through August 29, 2008, [Tr. 347] that indicates that Respondent wrote prescriptions for Ms. E.M. for Actos, Metformin, Lipitor, Plavix, and Zetia.[38] Dr. S.D. testified that a home health nurse caring for Ms. E.M. once asked him about giving Ms. E.M. Coumadin and Plavix, both blood thinners, but he advised that Ms. E.M. should not take either drug because she had suffered multiple falls and those medications increased the danger of bleeding in the brain.

Dr. S.D. testified that he told the nurse that Ms. E.M. should just continue taking aspirin. [Tr. 87]

2. E.M.'s Treating Physicians

Respondent testified that he began treating Ms. E.M. around 2003, when she was approximately 92 years old, and that he had ''a lot invested in E.M.,'' [39] with whom he had had a personal relationship since he attended high school with Mr. I.S. [Tr. 485] Mr. I.S. testified that the hospice to which Ms. E.M. was admitted only allowed patients to use the hospice doctors; that hospice personnel told him that the only doctor Ms. E.M. could have was Dr. S.D.,[40] [Tr. 661] and that he nonetheless admitted his mother to hospice care because he needed someone to care for her and he could not afford financially to provide that care himself. Mr. I.S. further testified that Dr. S.D. was ''strictly a hospice doctor that she saw whenever she was admitted to the hospital, and he helped her get into hospice''; that Respondent was Ms. E.M.'s primary doctor, [Tr. 677] and that if another physician prescribed something for Ms. E.M., Mr. I.S. would discuss the issue with Respondent and follow his advice as to what medication Ms. E.M. should be prescribed. [Tr. 730] Mr. I.S. testified that he would have Ms. C.G. ''ask Dr. S.D. to write it, and most of the time he would.'' [41] Mr. I.S. also testified that he took Ms. E.M. to see G.M., M.D., or T.M., M.D.[42] ''on an emergency basis, and because we didn't want to see Dr. S.D.''; [43] and if Ms. E.M. was sick, which, according to Mr. I.S., occurred ''maybe once or twice in her life,'' [44] he took her to see Dr. M. Mr. I.S. initially testified that he believed Dr. M. was aware that Respondent was treating Ms. E.M., [Tr. 698] but later said that he did not think that either Dr. T.M. or Dr. G.M. knew that Respondent was treating Ms. E.M. [Tr. 699]

Dr. S.D. testified that he, along with Dr. V.P., B.D., M.D., and M.S., M.D., all treated Ms. E.M. for approximately four years prior to her death in 2009. Dr. S.D. further testified that Ms. E.M. was admitted to St. Mary's Hospital in Kankakee, Illinois, several times and also was a patient at Manor Care Nursing Home in Kankakee and at times had hospice care and home health care; that he was listed as Ms. E.M.'s primary care physician at each of those institutions; and that he does not know Respondent and was never informed that Respondent was treating Ms. E.M. [Tr. 98] Dr. S.D. further testified that Ms. E.M. was under hospice care for the last two-and-a-half to three years of her life, during which time he was her primary care physician; that although he only saw Ms. E.M. a few times in his office and in the hospital, he gave telephone orders and communicated with the hospice nurse regarding Ms. E.M.'s condition; he had no reason to believe that Ms. E.M. was seen by any other doctor or was taking medications not included on the medication list that he approved; [Tr. 102] and that any other physician who was treating Ms. E.M. should have informed him that he or she was prescribing OxyContin to her. [Tr. 140] Dr. S.D. testified that it is out of the range of normal practice for a physician to prescribe medications to a patient without consulting with other treating physicians of which he is aware. [Tr. 144]

Ms. E.M. was first admitted to Kankakee Hospice, which provides care in the patient's home, on June 9, 2006.[45] Ms. C.K. testified that she cared for Ms. E.M. in her home in late 2007 and early 2008, seeing her twice per week for approximately one hour per visit. [Tr. 30] At each visit Ms. C.K. performed a physical assessment of Ms. E.M. (taking her blood pressure, heart and respiration rate; listening for lung sounds, bowel sounds; assessing her skin, cognition, etc.). [Tr. 32] Ms. C.K. testified that every visit from and telephone call or other conversation with Kankakee Hospice personnel was recorded and that the hospice also kept hospital records, laboratory test results, and records received from the doctor.

Ms. C.K. further testified that Kankakee Hospice needs to know of every physician ''who is on board to treat the patient''; [46] that there is a primary physician and usually a secondary physician; and that Kankakee Hospice prefers to have its personnel accompany the patient to doctor appointments. Ms. C.K. testified that while she cared for Ms. E.M., none of her family members ever mentioned that Respondent was treating her, but the family did mention that Ms. E.M. saw Dr. S.D. and Dr. M. Ms. C.K. also was not aware of any physicians making home visits to Ms. E.M., although that information should have been disclosed to Kankakee Hospice.

3. Ms. E.M.'s Prescriptions and Treatment

Respondent testified that when he began treating Ms. E.M. in 2003, she was taking multiple pain medications, such as Tylenol No. 4, Lorcet,[47] and Vicodin; that she sometimes took as many as 10 or 12 pills per day; and that he changed her regimen to a more potent and controlled dosage on a regular schedule. [Tr. 498] Respondent testified that Ms. E.M. suffered from low back pain; that treatment with medication on an as-needed basis was not sufficient to relieve her pain; and that the appropriate treatment was to increase the amount of opioid medication until either the pain went away or the side effects became too drastic to continue. [Tr. 514] According to Respondent, instead of tapering a patient off a drug while he still has symptoms, a doctor should increase the level of the drug in order to extinguish the symptoms; tolerance with regard to symptoms requires an increased dosage that relieves the pain, which is different from increasing dosage to extinguish pain. [Tr. 517] Respondent testified that all patients develop dependence, which

[38] Zetia is a brand name product containing ezetimibe, a non-controlled substance that inhibits the intestinal absorption of cholesterol. [RX 36]

[39] Tr. 487.

[40] In his brief, Respondent asserts that the hospice requirement was to use a doctor located in Kankakee. *See* Respondent's Closing Argument Brief at 11.

[41] Tr. 673.

[42] G.M. and T.M. are physicians who practice together and appear to have each treated Ms. M. The testimony is not always clear as to which Dr. M. the witnesses are referencing.

[43] Tr. 698.

[44] Tr. 698.

[45] *See* GX 17.

[46] Tr. 35.

[47] I take official notice that Lorcet is a brand name product containing hydrocodone bitartrate and acetaminophen.

means that if the medicine is abruptly withdrawn, the patients will become antsy, shaky, and complain of nervousness, and that although some anti-anxiety agents or antihistamines may be used to treat the withdrawal symptoms, the best option is to withdraw the medication slowly over a period of time. Respondent testified that addiction ''is the unworkable lifestyle that is created by a person that escalates the intake of narcotics and opioids,'' [48] and is always exhibited by anti-social behavior.

Dr. S.D. testified that he never prescribed OxyContin to Ms. E.M. because he was afraid that she could not handle a strong pain medication, but that he prescribed Aricept for dementia, Toprol XL and Micardis for cardiac issues, [Tr. 83] and Tylenol, and that he maybe prescribed Darvocet, and occasionally Vicodin for pain.[49] Dr. S.D. testified that Ms. E.M.'s pain, although chronic, was not so severe that she needed constant pain medication. [Tr. 89]

Mr. I.S. testified that OxyContin seemed to work better than the other medications Ms. E.M. had tried, and that before she started taking OxyContin, Ms. E.M. sometimes took as many as four or five pills per day'' [50] of Vicodin, Lorcet, or ''whatever I had.'' [51] Mr. I.S. testified that Respondent started prescribing OxyContin 80 mg to Ms. E.M. in 2003, and that Mr. I.S. was not surprised by the high dosage because he ''didn't know much about it.'' [52] Mr. I.S. further testified that Respondent never changed the strength or quantity of OxyContin he prescribed to Ms. E.M. [Tr. 708]

Mr. I.S. testified that he initially filled Ms. E.M.'s OxyContin prescriptions with the brand name drug but because it was very expensive, he then tried the generic form. According to Mr. I.S., however, Ms. E.M. insisted that she wanted the brand name product'' [53] and the pharmacist had told him that the ''deliver[y] mechanism of oxycodone was that it delivers all at once, and that the OxyContin was more of a time release thing over 12 hours.'' [54] Mr. I.S. further testified that because the generic drug was not a time release product and Ms. E.M. insisted that she wanted ''the other one,'' [55] [Tr. 695] he thereafter filled the prescriptions with OxyContin. [Tr. 672]

Investigator R., however, testified that she spoke with Mr. E., the pharmacist from Doc's Drugs, who informed her that if a patient presents a prescription written for a brand name drug and requests a generic, or the prescription allows a generic to be substituted for the brand name product, then the pharmacist must provide the patient with a generic medication that has the same properties as the brand name drug, including any time release effect; and that oxycodone 80 mg is not available as an immediate release tablet because it could be fatal. [Tr. 840] The Government offered into evidence copies of prescriptions Respondent issued to Ms. E.M. that investigators obtained from Doc's Drugs; [Tr. 340; Tr. 412; Tr. 231] each prescription was written for OxyContin with substitution permitted. Respondent testified that breaking an OxyContin tablet in half only somewhat obviates the time release effect and that the active ingredient may release more quickly. [Tr. 797]

According to a Physician's Desk Reference excerpt for OxyContin that the Government offered into evidence, ''OxyContin tablets are to be swallowed whole and are not to be broken, chewed, or crushed. Taking Broken, Chewed, or Crushed OxyContin tablets leads to rapid release and absorption of a potentially fatal dose of oxycodone.'' [56]

Investigator D.M. testified that there is a large price differential between the brand drug and the generic, and that the OxyContin brand can sell on the street for approximately one dollar per milligram. [Tr. 297] Investigator R. testified that Mr. E. told her that Mr. I.S. always picked up Ms. E.M.'s prescriptions and that although insurance covered the prescriptions, Mr. I.S. paid the co-pay, which was sometimes as much as $400 for the brand name drug, in cash. Mr. E. further told Investigator R. that it was unusual for a customer to request a brand name with such a high co-pay when a generic alternative was available; [Tr. 414] and that the time release generic of OxyContin had been available at relevant times except for a period of approximately six months around 2007. [Tr. 840] Mr. I.S. testified that he submitted the insurance claims for the OxyContin prescriptions to Ms. E.M.'s insurance carrier and that he paid Respondent in cash for his services to Ms. E.M. [Tr. 695]

4. Administering OxyContin to E.M.

On January 18, 2006, Ms. E.M. was admitted to St. Mary's Hospital; at that time, a home medication list indicated that she received OxyContin 80 mg every 12 hours. [GX 21 at 9] Respondent testified that he arranged to have a family member see that OxyContin was included on Ms. E.M.'s home medication list because he ''wanted somebody to figure out that she was on pain medication.'' [57] Dr. S.D. testified that he ordered that the OxyContin not be continued and that he was not aware of OxyContin ever again being listed on Ms. E.M.'s medication lists, [Tr. 90] but that if Ms. E.M. had been on OxyContin and it was stopped, she would suffer from withdrawal symptoms such as abdominal pain, diarrhea, and vomiting. [Tr. 106]

Dr. S.D. also testified that Ms. E.M. did not receive OxyContin while in the hospital because family members are not permitted to give medication to patients, that patients receive only those medications prescribed by the attending physician, and that he was Ms. E.M.'s attending physician and did not prescribe OxyContin to her. [Tr. 107]

Dr. S.D. testified that he never spoke with Mr. I.S. but would call his home and leave messages regarding Ms. E.M.'s condition. Dr. S.D. testified that Mr. I.S. did not return calls, but that he did speak with Mr. I.S.'s girlfriend. [Tr. 109] Mr. I.S. testified that although Dr. S.D. issued prescriptions to Ms. E.M. for Vicodin, he did not fill those prescriptions because his mother was already taking OxyContin.

Investigator R. testified that on October 23, 2006, she met with Kankakee Hospice's executive director, D.L., who told her that the Hospice's policy requires that the nurses be informed of all of a patient's medications and treating physicians. Investigator R. further testified that at that meeting she also spoke with other Hospice personnel who told her that OxyContin did not appear on Ms. E.M.'s medication list and her Kankakee Hospice records did not mention that she was in pain or that Respondent

[48] Tr. 519.

[49] I take official notice of the following information from the 2007 edition of the Physicians' Desk Reference: Aricept is a brand name product containing donepezil hydrochloride, a non-controlled substance, indicated for the treatment of mild to moderate dementia; Tylenol is a brand name over-the-counter medication containing acetaminophen and is indicated for the temporary relief of minor aches and pains; propoxyphene and acetaminophen and is used to relieve mild to moderate pain.

[50] Mr. I.S. later testified that Ms. E.M.s took ''[a]t least three pills a day,'' in the range of three to seven pills, ''whatever it took to kill her pain, that is as many pills as I gave her for the day.'' Tr. 717.

[51] Tr. 669.

[52] Tr. 668.

[53] Investigator D.M. testified that in the August 2005 interview, Mr. I.S. had stated that he filled his mother's prescriptions with generic drugs because his mother had suffered a stroke and would not recognize the difference between generic and brand name drugs. Tr. 244.

[54] Tr. 671.

[55] Tr. 671.

[56] GX 40 at 17.

[57] Tr. 821.

treated her. [Tr. 352] Ms. C.K. testified that Ms. E.M. complained of pain in her knees and arm and sometimes had difficulty standing and some stiffness, but that Mr. I.S. or Ms. C.G. gave her Tylenol to alleviate the pain and that Mr. I.S. said that the Tylenol worked and he did not want his mother to have anything else. Ms. C.K. testified that it seemed unusual for the caregivers to insist that only they would administer certain medications. [Tr. 40, Tr. 45] Ms. C.K. further testified that as far as she knew, the only controlled substance that Ms. E.M. took was Valium [58] for seizures; and that Ms. E.M.'s family never mentioned that she was taking OxyContin. Ms. C.K. testified that she was not aware of any controlled substances that were prescribed to Ms. E.M. on a chronic or recurring basis; that she never saw any medications prescribed by Respondent or any OxyContin vials or pills at Ms. E.M.'s home; and that the only medication that the hospice team attempted to count was Valium, which they had difficulty accessing from Ms. E.M.'s family. [Tr. 35; Tr. 42] Mr. I.S. testified that he did not want to tell the Kankakee Hospice personnel about his mother having OxyContin because Kankakee Hospice had told him that it must have control over any controlled substances Ms. E.M. took and thus hospice personnel must have access to those drugs, but that he did not want to leave the OxyContin ''in a cabinet for some punk or something that may be coming in my house after school to take or whatever.'' [59] Mr. I.S. also testified that Ms. E.M. did not want anyone to know that she was on pain medication because ''she was very old-fashioned, and * * * she just didn't think it was anybody else's business.'' [60]

Investigator R. testified that on October 23, 2008, she interviewed Ms. D., who had treated Ms. E.M. in her home in 2006–2007. Ms. D. told Investigator R. that Ms. E.M. complained of mild arthritic pain; that Ms. D. asked Mr. I.S. whether they should look into getting something stronger to alleviate the pain; and that Mr. I.S. said that he had previously given Ms. E.M. one-half tablet of Vicodin, but that that medicine was too strong for her and she should continue to take Aleve.[61] [Tr. 448]

Mr. I.S. testified that Kankakee Hospice only allowed patients to use the hospice ''system for drugs,'' [62] and therefore either he or someone in his family gave Ms. E.M. OxyContin while she was admitted to Kankakee Hospice and when she was in St. Mary's Hospital, at Manor Care Nursing Home, at Heritage Village Nursing Home, and at St. James Hospital. [Tr. 680] Mr. I.S. testified that Ms. E.M. received one OxyContin pill in the morning and one at night but for the two weeks before his mother died he gave her only the nighttime dose because he worried that she may have been too weak to receive more; [Tr. 682] OxyContin was the only prescription medication that the family gave to Ms. E.M.; [63] and to his knowledge, the hospital never gave Ms. E.M. any pain medication, not even Aleve, and that he did not know why she should need Aleve.[64] [Tr. 668]

Respondent's patient chart for Ms. E.M. includes treatment notes for at least one day each month beginning September 15, 2003, and ending on the date of her death, June 13, 2009, [RX 16] but indicates that Ms. E.M. ''missed appointments'' with Respondent on both February 28 and March 28, 2006.[65] Respondent explained that ''at this point in time when I write missed appointment, that will mean that I did not give her a prescription for pain medication.'' [66] Respondent later testified that ''I may have issued it at their home at a later appointment, at a later point in time, but I don't think I issued it.'' [67] The Government offered into evidence [GX 14] photocopies of prescriptions Respondent issued to Ms. E.M. for 80 mg OxyContin and dated February 28 and March 28, 2006. Respondent's patient chart for Ms. E.M. indicates, and Respondent testified, that he saw her on October 20 and November 17, 2006, but records from St. Mary's Hospital in evidence as a Government exhibit show that Ms. E.M. was admitted to that hospital on October 7, 2006, that she was discharged on October 12, 2006, [GX 21 at 203] and immediately admitted into Manor Care Nursing Home, where she remained until December 8, 2006. [GX 21 at 203, GX 27B at 956, GX 43 at 108]

Respondent testified that he completed the continuing medical education course required under his 2003 Consent Order and that during that course he learned that it is unlawful ''for a pharmacist to refill a blank and give two dispenses on the same single blank'' [68] for a Schedule II controlled substance. Respondent further testified that he believes that a physician can authorize another prescription without seeing the patient and that it is ''even legal under the information that I go by that you can even predate a controlled substance prescription''; [69] [Tr. 739] but that he has never predated prescriptions and has never written refills although he has written new prescriptions without seeing the patient. Respondent testified that he also learned that a physician should ensure that patients to whom he prescribes a controlled substance do not obtain controlled substances from another source and that such patients should be tested to verify that they are actually taking that medication. [Tr. 740] Respondent had earlier testified that if the Government suspected diversion of OxyContin with regard to E.M. then either the Government or Dr. S.D. should have tested her for it. [Tr. 577]

Mr. I.S. testified that he discussed with Respondent the concern that Ms. E.M. receive ''her proper pain medicine'' [70] when she was in a nursing home or hospital. [Tr. 674] Mr. I.S. further testified that Dr. S.D. prescribed Vicodin for Ms. E.M. but that she never asked for it because she did not need it; and that when Ms. E.M. was in the nursing home or hospital he hired his girlfriend's daughter to visit her twice a day and to give her medication and food and to sit with her. [Tr. 675] Respondent testified that he had instructed ''him'' [71] to be aware of other depressants, sleeping pills, narcotics, and opioids given Ms. E.M. so as to avoid an overdose. [Tr. 656] Mr. I.S. testified that in the three or four weeks before his mother died, he met with the St. Mary's Hospital administrator and asked that no new medications be given to Ms. E.M. without his knowledge. Mr. I.S. further testified that prior to that time, the hospital had no directions not to give pain medication to Ms. E.M. and that he reviewed her medication charts every day to make sure that she did not receive pain medication. [Tr. 711] Mr. I.S. testified that he never saw any pain medication listed in Ms. E.M.'s hospital

[58] I take official notice of information in the 2007 edition of the Physicians' Desk Reference that Valium is a brand name product containing diazepam, a Schedule IV controlled substance.

[59] Tr. 697.

[60] Tr. 680.

[61] I take official notice from the 2007 edition of the Physicians' Desk Reference that Aleve is a brand name product containing naproxen sodium, a non-controlled substance.

[62] Tr. 661.

[63] *But see* Section D.1. *supra:* Respondent prescribed Ms. E.M.'s Actos, Metformin, Lipitor, Plavix, and Zetia, all of which appeared on Ms. E.M.'s prescription profile from Doc's Drugs but not always on her home medication lists. GX 27.

[64] Ms. E.M. did receive pain medication such as Aleve and Tylenol.

[65] RX 16 at 5.

[66] Tr. 787.

[67] Tr. 787.

[68] Tr. 738.

[69] Tr. 739.

[70] Tr. 674.

[71] Presumably he is referring to Mr. I.S. *See* Tr. 656.

charts, not even over-the-counter medications. [Tr. 714]

Mr. I.S. later testified that in the thirty days before Ms. E.M. died, he reviewed the charts as many times as he went to the hospital and that he ''left orders with them to not introduce any new medications to my mother. * * *'' [72] Mr. I.S. then testified that he always gave directions to the hospital to not give Ms. E.M. any new medications, and that he had previously told the DEA that both he and Ms. E.M. were receiving OxyContin. Mr. I.S. testified that he knew that DEA personnel could go to the hospital to see whether Ms. E.M. received any other pain medication, so he made sure that she did not get any. [Tr. 719] Mr. I.S. also testified that if an emergency arose when Ms. E.M. was in a hospital or nursing home, such as if she were to fall, then the hospital or nursing home would call him and he would issue instructions not to give her any pain medication. [Tr. 728]

Respondent testified that at times, depending on the conditions, he would omit or reduce the amount of OxyContin he prescribed to Ms. E.M. or change the dosing schedule based on her clinical situation, and that if she was suffering certain symptoms, such as from a stroke, he would have ''them'' [73] withhold the pain medication for up to 24 hours. Mr. I.S. testified that he did not recall whether Respondent ever asked him to delay the dosage or to hold back Ms. E.M.'s pain medication when she was hospitalized.

E. Respondent's 2006 DEA Renewal Application and Registered Location

On September 25, 2006, Respondent submitted to the DEA an application to renew his registration. [Tr. 318; GX 31] Respondent's registered location on that renewal application was listed as 120 Oakbrook Center Mall, Oakbrook, Illinois.[74] In response to question number three of the application, ''Has the applicant ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'', Respondent provided an affirmative answer. In his explanation for that answer, submitted with the application, Respondent identified and explained the 2003 IDFPR Consent Order but did not refer to the 1998 Consent Order. [GX 31] Respondent testified that his omission of the 1998 order was inadvertent and that he had included the 1998 incident on previous renewal applications. [Tr. 618, GX 18]

Investigator R. testified that on March 13, 2009, she and another diversion investigator served upon Respondent the DEA Order to Show Cause that gave rise to this proceeding. [Tr. 323] Investigator R. testified that she served the Order to Show Cause at Respondent's residence in Riverside, Illinois, because the investigators had not succeeded in serving it at his registered location, and that when the investigators went to Respondent's residence and ''before we had the opportunity to identify ourselves, [Respondent] slammed the door in our face when I said, 'Dr. Herbert, I have something for you,' and he said that 'I am not Dr. Herbert. I am R.S.' '' [75] Investigator R. further testified that a few minutes later Respondent telephoned her, indicating that he was returning one of her earlier calls.

Investigator R. testified that during that telephone conversation she arranged to serve the Order to Show Cause through Respondent's attorney the next day; that Respondent informed her that he had moved his registered location to 2910 South Harlem Avenue, Riverside, Illinois; [Tr. 324] that she then advised Respondent that in order to modify his registered location he needed to submit a modification request along with a copy of his Illinois controlled substance license showing the new location; and that she provided him a fax number to use to send the documents. Investigator R. further advised Respondent that he needed to wait until his modification was approved before he could handle controlled substances at the new location. [Tr. 327]

Investigator R. testified that prior to March 13, 2009, the DEA had not received any notification from Respondent or anyone else that he had moved his medical practice from his DEA registered location in Oakbrook to Riverside; [Tr. 326] that she had previously made several failed attempts to contact Respondent at his registered address (she went to 120 Oakbrook Center and knocked on Suite 711; telephoned Respondent's office and left messages requesting a call back; and identified herself in those messages and indicated that she needed to deliver something); but that she had never been able to locate Respondent at his registered location except when she arranged to do so by appointment. [Tr. 325] Investigator R. testified that on March 26, 2009, the leasing office at the Oakbrook Center Mall informed her that as of July 31, 2008, the locks had been changed on Respondent's Oakbrook office because he had abandoned the location. [Tr. 324]

Respondent testified that in July 2008 he moved his office to 2910 Harlem Avenue; [Tr. 577] that the DEA would not send him any address modification forms; that he could not access the forms on-line; and that he called the DEA office in Chicago multiple times and left messages in an attempt to get a change of address form.

Investigator R. testified that Respondent's attorney filed with the DEA a request dated April 7, 2009, to modify Respondent's registered location. [RX 15] That same day, counsel for the Government sent a letter to Respondent indicating that since he had already moved his office, he was not authorized to handle controlled substances at the new location until the DEA approved the modification of his address. [GX 9] Investigator R. testified that she served that letter in person to Respondent's attorney and left for Respondent a telephone message summarizing the contents of the letter. [Tr. 331] On June 8, 2009, counsel for the Government sent another letter to Respondent's attorney indicating that the registered location modification request had not yet been approved and that, until it was approved, any controlled substance prescriptions issued by Respondent would be unlawful. [GX 33] Investigator R. testified that the letter was personally delivered to Respondent and was faxed to Respondent's attorney. [Tr. 333]

Investigator R. further testified that she obtained from the Illinois Department of Human Services Prescription Monitoring Program, to which Illinois pharmacies are required to report information pertaining to controlled substance prescriptions, a prescription profile identifying controlled substance prescriptions that Respondent issued from June through August 2009. [GX 34] During that period, according to the prescription profile, Respondent issued 29 controlled substance prescriptions to 13 different people: 60 dosage units of OxyContin 80 mg to each of seven different people, one of whom also received 30 diazepam 10 mg; 40 oxycodone 5 mg and 30 Adderal 30 mg to one person; 90 hydrocodone 7.5 mg to one person; 10 hydrocodone 5 mg to one person; 30 phentermine 37.5 mg (via two separate prescriptions written on the same day) to one person; and 14 phentermine 37.5 mg to one person. [GX 34]

Respondent testified that Investigator R. had told him on March 13, 2009, that he could not handle controlled

[72] Tr. 712.

[73] Tr. 656. Presumably Respondent was referring to Ms. E.M.'s family.

[74] GX 31.

[75] Tr. 327.

subscriptions but he ''didn't take it all that seriously with the word handling, because I had not ordered any prescriptions, and I had no samples'' [76] but he did not ask her what she meant by ''handling.'' Respondent further testified that he did not see anything about prescribing until he saw the letters from Government counsel, and that his attorney reviewed the letters and told him that it appeared that the DEA did ''have the power to withhold the registration'' [77] but he nonetheless continued to issue original controlled substances prescriptions until October 2009, ''when the gravity of what was going on here became absolutely clear.'' [78] [Tr. 778]

The Parties' Contentions

I. The Government

The Government contends, in substance, that the Deputy Administrator should revoke Respondent's DEA registration and that any pending applications for renewal or modification of that registration should be denied, ''because Respondent made material misstatements on an application for registration and because his continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).'' [79]

The Government contends that Respondent has had controlled substances violations dating back to 1994 and resulting in consent orders with the Illinois Medical Board in 1998 and 2003. The 1998 consent order involved the unlawful prescribing of Dilaudid and required Respondent to complete a course pertaining to the handling of controlled substances. The Government contends that this course had little effect on Respondent's prescribing, that he continues to violate applicable law, and that he is evading the allegations rather than responding to them candidly.

The Government next asserts that Respondent unlawfully received dronabinol from a patient's prescription, failed to properly record that receipt, and maintained a misleading and inaccurate record of his subsequent dispensing of the dronabinol. Further, the Government argues that Respondent's 2003 Consent Order with the IDFPR arose because the unlawful dispensing was inevitable based on the arrangement between Respondent and the clinic owner and Respondent's conduct therefore enabled and abetted the clinic owner. As with the 1998 Consent Order, Respondent was again required to complete a course on proper prescribing and dispensing of controlled substances but, according to the Government, Respondent ignored this education and continued to collect violations.

The Government goes on to contend that Respondent violated state law when he failed to disclose records demanded in an IDFPR subpoena. The Government argues that the Illinois Medical Practice Act provides the IDFPR with the authority to serve an administrative subpoena *duces tecum* pursuant to a Medical Board investigation and that the Health Insurance Portability and Accountability Act (HIPAA) provides an exception for the disclosure of information that is requested by an order of an administrative tribunal.

The Government further asserts that Respondent's omission of his 1998 Consent Order from his DEA controlled substances registration renewal application was a material omission because it involved the diversion of a Schedule II controlled substance and because Respondent was conversant with the facts of the Consent Order at the immediate hearing.

The Government argues that Respondent participated in a scheme that involved the diversion of OxyContin. It argues that there is a lack of medical history to justify issuing prescriptions for 80 mg OxyContin to Ms. E.M. and that Respondent's attempts to provide justification for prescribing to her are essentially *post hoc* rationalizations. Additionally, the Government contends, it is unlikely that someone from Ms. E.M.'s family was able to secretly administer OxyContin twice per day during the approximately 290 days that she was in a hospital or in-patient nursing home. According to the Government, Respondent's arguments are further diminished by not only the conflicts in testimony between Respondent and Mr. I.S. but also between the testimony and institutional records, as well as Respondent's questionable patient chart for Ms. E.M., which includes dates of Respondent's purported treatment of her when she was confined to a hospital or nursing home. The Government contends that if Ms. E.M. had received the OxyContin that Respondent prescribed, she would likely suffer withdrawal symptoms when institutionalized, but there is no such record. Also, the Government contends, Respondent's and Mr. I.S.'s claims regarding the time release properties of generic oxycodone are not credible because they were refuted by both the Physician's Desk Reference and a pharmacist.

The Government also argues that Respondent prescribed other drugs, in addition to OxyContin, in Ms. E.M.'s name but that these drugs were never administered to her and were likely diverted. The Government points out that, although Respondent claims that he prescribed Actos and Metformin to Ms. E.M. to treat diabetes, her other treating physicians and hospital records indicate that she did not have diabetes and Mr. I.S.'s testimony is again in conflict with Respondent's because he testified that the only prescription drug he or his family administered to Ms. E.M. was OxyContin. The Government further contends that Plavix was also diverted, relying again on the conflicting testimony of Respondent and Mr. I.S. and on the evidence that for some time both Dr. S.D. and Respondent prescribed Plavix but, although Dr. S.D. discontinued it because of injury risks, Respondent continued to prescribe it; and Respondent's patient chart for Ms. E.M. provided no information regarding such prescriptions.

Finally, the Government asserts that Respondent unlawfully prescribed controlled substances from an unregistered location because Respondent failed to timely request a modification of his registered address and continued to issue controlled substances prescriptions at his new location even after receiving numerous warnings against such action.

II. Respondent

Respondent contends that the omission of his 1998 state probation from his renewal application was not a material falsification because the omission was inadvertent. Respondent asserts that inasmuch as he accepted the 1998 state probation related to phentermine dispensing, the DEA should not ''seek additional retribution'' [80] for the incident. Respondent argues his disclosure of the 1998 probation on previous DEA applications, the DEA and state investigators' awareness of both the 1998 and 2003 disclosures, and the previous disclosures' existence ''permanently on the D.E.A. computerized files,'' ''clearly [indicate] no subterfuge motive.'' [81]

Respondent argues that in mid-August 2003, because of his 2003 state probation, he ''purposely discontinued all ordering of medications from wholesale suppliers for the purpose of

[76] Tr. 779.

[77] Tr. 777.

[78] Tr. 778.

[79] Government's Proposed Findings of Fact, Conclusions of Law and Argument at 3.

[80] Respondent's Closing Argument Brief at 8.

[81] Respondent's Closing Argument Brief at 3.

dispensing medications;'' [82] that, in the spring of 2005, when Investigator D.M. asked to inspect Respondent's controlled substance logs, Respondent did not recall any ordering or dispensing of controlled substances in 2003 and created a handwritten log indicating such; that later that same day, he found a controlled substance log from the first seven months of 2003 that showed three instances in which he had dispensed a controlled substance; and that Respondent's attorney contacted Investigator D.M. to notify him of that log and that Investigator D.M. was given a copy.

Respondent further contends that his dispensing of dronabinol did not violate 21 U.S.C. 844(a) because he was ''acting in the course of his professional practice.'' [83] Respondent argues that he had a patient who obtained dronabinol via a prescription issued by another physician; that the patient ''lawfully transferred the medication to me * * * to be used for the benefit of another patient * * *;'' and that he dispensed the dronabinol to another patient and recorded that action in the patient's chart and in his 2003 controlled substance log. Respondent argues that his actions fall under the exception in § 844(a) permitting a physician to possess or obtain a controlled substance when ''acting in the course of his professional practice'' [84] and that there is no prohibition against obtaining medication from a patient to use for another patient.

Respondent then asserts that this entire proceeding was initiated against him as a form of revenge by the City of Chicago because Respondent testified on behalf of Officer D.S. at the Chicago Police Board hearing. Respondent asserts that his right to due process has been violated because Illinois and the DEA have violated the Illinois Medical Practice Act and because he was not represented by counsel at the instant hearing. Respondent argues that any evidence that was not ''generated by [Investigator] R. alone or directly subpoenaed by D.E.A. has no place in evidence at this hearing.'' [85]

Respondent contends that the DEA has failed to meet its burden of proof of showing that he failed to comply with the IDFPR administrative subpoenas issued in 2005 and 2007; Respondent asserts that he provided the requested records but redacted all identifying information as required by 225 ILCS 60/22(A)(38). Respondent argues that because the statute provides that ''all information indicating the identity of the patient shall be removed and deleted'' and that because records of prescriptions he issued and to which Illinois and the DEA have access include patient names and the date the prescriptions were issued, he was required to redact the names and treatment dates in order to allow Illinois to ''review the records without tying a specific chart to a patient.'' [86] Respondent further argues that he complied with the subpoena prior to March 2009 because his attorney supplied codes revealing the names and Respondent obtained permission from his patients to provide the relevant medical charts. Respondent contends that the allegation that he failed to comply with the subpoenas is another example of revenge-seeking by Chicago because of Respondent's testimony in the Police Board hearing; that the DEA and Illinois are ''doing the bidding of the City of Chicago;'' [87] that the records that were the subject of the subpoenas should not have been available to the DEA because 225 ILCS 36 bars the DEA from having or using information compiled by Illinois; that Respondent was not represented by counsel at the instant hearing; and that Respondent relied on the advice of his previous counsel with regard to the redacted information provided in response to the subpoenas.

Respondent asserts that there is no evidence of diversion with regard to his prescribing OxyContin to Ms. E.M.; that he treated her for more than five and a half years prior to her death; that Ms. E.M. suffered from multiple medical problems (including severe kyphoscoliosis, cerebral vascular disease, Binswanger's Disease, and diabetes); that Ms. E.M. and seven other patients required the prescriptions he issued them for OxyContin 80 mg because that strength was not a high dose for them because of the form of chronic pain from which they suffered; and that he properly treated Ms. E.M. for diabetes and inflammatory vascular disease by prescribing Actos and Metformin. Respondent also asserts that Actos and Metformin are not controlled substances and are therefore outside the DEA's jurisdiction.

Respondent argues that it is not plausible that the OxyContin he prescribed to Ms. E.M. was diverted because: Respondent and his patients were aware of the DEA investigation and the patients produced their current medications when interviewed; the DEA and Dr. S.D. failed to perform opioid level tests on Ms. E.M., even though they were free to do so and she showed signs of clinical opioid usage and rarely complained of pain despite the presence of ''multiple and obvious pain sources;'' [88] if Respondent performed an opioid test on Ms. E.M. it would not disprove diversion; Mr. I.S. never filled the prescriptions that Drs. S.D. and V.P. issued to Ms. E.M. for Vicodin; and Respondent had previously prescribed OxyContin 80 mg to Ms. C.G. and, after Respondent stopped treating her, a Dr. M. continued the same prescriptions. Respondent further claims that the failure of the DEA, Dr. S.D., Dr. V.P., and Dr. M.[89] to test Ms. E.M. for opioids and thereby exonerate Respondent, cannot be used against him because, if they had suspicions of diversion, they should have ''[acted] to clear up this charge.'' [90] Respondent contends that Investigator R. conducted her investigation with ''obvious prejudice'' [91] to cast Respondent in an unfavorable light. Respondent asserts that Drs. S.D., P., and M. were aware that Ms. E.M. had pain because they prescribed pain medicines such as Vicodin and morphine; that Ms. E.M.'s not taking the pain medication should have alerted these doctors that her family was medicating her; that Ms. E.M.'s family asked Respondent not to communicate with her other doctors and he complied to avoid discharge as her physician; and that Respondent ''placed OxyContin on the record.'' [92]

Respondent contends that the DEA acted ''capriciously and in bad faith'' [93] by invalidating his DEA registration when he moved his office from his registered location and by refusing to reinstate his license pending the instant proceedings. Respondent argues that he was not permitted access to forms or other communication methods on the DEA Web site and that none of his calls to Investigator R. and the DEA's Chicago office were returned; that the DEA refused to transfer Respondent's registration to his new office after ''the D.E.A. finally figured out I moved''; [94] that Respondent sent a letter to the DEA advising it of his move in lieu of the forms he ''was not allowed to fill

[82] Respondent's Closing Argument Brief at 4.
[83] Respondent's Closing Argument Brief at 5.
[84] Respondent's Closing Argument Brief at 5.
[85] Respondent's Closing Argument Brief at 9.
[86] Respondent's Closing Argument Brief at 9.
[87] Respondent's Closing Argument Brief at 10.
[88] Respondent's Closing Argument Brief at 14.
[89] Although he refers to a ''Dr. M.'' in his brief, I presume that Respondent actually intended to refer to either Dr. G.M. or Dr. T.M. because there was no evidence presented that Ms. E.M. was ever treated by a Dr. M.
[90] Respondent's Closing Argument Brief at 15.
[91] Respondent's Closing Argument Brief at 15.
[92] Respondent's Closing Argument Brief at 17.
[93] Respondent's Closing Argument Brief at 17.
[94] Respondent's Closing Argument Brief at 17.

out'';[95] that Respondent ''essentially stopped practicing medicine''[96] after he received a second letter from Government counsel; and that the DEA allowed his registration to remain active on its website even though it had the power to ''shut off [his] registration by pulling it from the active list on their pharmacy access Web site,''[97] thereby creating ''an incident and another charge against me''[98] that occurred for no reason other than harassment. Respondent further claims that the cases counsel for the Government cited in his letter to Respondent regarding his change of address are not applicable in this situation because those cases involved ''two meth suppliers to convenience stores, a pharmacy, and a doctor whose state license had already been revoked''[99] and Respondent,[100] as a ''practicing MD with no criminal complaint''[101] does not fit into any of those categories. Respondent further argues that the DEA had the power to deactivate his controlled substance license on the DEA Web site, thereby ''shutting down [his] ability to issue any controlled substances''[102] and that because the DEA's failure to do so was more harassment which was ''clearly unethical if not illegal,''[103] Respondent should not be held responsible.

Discussion and Conclusions

I. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.[104] ''A separate registration shall be required at each principal place of business or professional practice where the applicant * * * dispenses controlled substances.''[105] DEA regulations provide that any registrant may apply to modify his registration to change his address but such modification shall be handled in the same manner as an application for registration.''[106]

It is unlawful for any person to possess a controlled substance unless that substance was obtained pursuant to a valid prescription from a practitioner acting in the course of his professional practice.[107] A registered individual practitioner is required to maintain records of controlled substances in Schedules II through V that are dispensed and received, including the number of dosage units, the date of receipt or disposal, and the name, address, and registration number of the distributor.[108]

A. Revocation of DEA Registrations

The Controlled Substances Act, at 21 U.S.C. 824(a), provides, insofar as pertinent to this proceeding, that the Deputy Administrator may revoke a registration if she finds that the registrant has materially falsified an application for registration or renewal of registration[109] and/or if she finds that the continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f).[110]

B. The Public Interest Standard

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

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

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

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

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

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

As a threshold matter, it should be noted that the factors specified in section 823(f) are to be considered in the disjunctive: The Deputy Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied.[111]

II. The Factors To Be Considered

A. Renewal of Respondent's DEA Registration

1. Material Falsification of a Renewal Application

Respondent materially falsified his 2006 renewal application for a DEA registration when he failed to disclose any information regarding his 1998 state probation, even though he did disclose his 2003 state probation. I find unpersuasive Respondent's argument that the omission is irrelevant due to the DEA's awareness of and Respondent's previous disclosure of the 1998 probation: The DEA has repeatedly held that '' '[t]he provision of truthful information on applications is absolutely essential to effectuating [the] statutory purpose' of determining whether the granting of an application is consistent with the public interest.''[112] A false statement is material if it ''has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.''[113] While the evidence must be ''clear, unequivocal, and convincing,'' the ''ultimate finding of materiality turns on an interpretation of the substantive law.''[114] The Deputy Administrator has also previously held that ''[t]he explanation given by an applicant who has affirmatively answered a liability question is * * * material because the public interest inquiry under section 303(f) requires, *inter alia,* that the Agency examine '[t]he applicant's experience in dispensing * * * controlled substances,' and its [c]ompliance with applicable State, Federal, or local laws relating to controlled substances.' ''[115]

Although Respondent claims that his omission of the 1998 probation from his registration renewal application was inadvertent, that is irrelevant because the Government only needs to show that the applicant ''knew or should have known that the response given to the liability question was false,'' not that the material falsification was intentional.[116] It is apparent that Respondent was aware of his 1998 probation because he

[95] Respondent's Closing Argument Brief at 17.
[96] Respondent's Closing Argument Brief at 17.
[97] Respondent's Closing Argument Brief at 17.
[98] Respondent's Closing Argument Brief at 18.
[99] Respondent's Closing Argument Brief at 18.
[100] Respondent's Closing Argument Brief at 18.
[101] Respondent's Closing Argument Brief at 18.
[102] Respondent's Closing Argument Brief at 18.
[103] Respondent's Closing Argument Brief at 18.
[104] 21 U.S.C. 822(a)(2).
[105] 21 U.S.C. 822(e).
[106] 21 CFR 1301.51.
[107] 21 U.S.C. 844(a).
[108] 21 CFR 1304.03(b), 1304.22(a)(2)(ix), 1304.21(a), 1304.22(c), and 1304.22(a)(2)(iv).
[109] 21 U.S.C. 824(a)(1).
[110] 21 U.S.C. 824(a)(4).
[111] *See Henry J. Schwarz, Jr. M.D.,* 54 FR 16,422 (DEA 1989).
[112] *The Lawsons,* 72 FR at 74338 (quoting *Peter H. Ahles,* 71 FR 50097, 50098 (2006)). *See also Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005) (''Candor * * * is considered by the DEA to be an important factor when assessing whether a * * * registration is consistent with the public interest.'').
[113] *Kungys* v. *United States,* 485 U.S. 759, 770 (1988) (int. quotation and other citations omitted).
[114] *Id.* at 772 (int. quotation and other citations omitted).
[115] *The Lawsons,* 72 FR at 74338 (citing 21 U.S.C. 823(f)).
[116] *The Lawsons,* 72 FR at 74339; *Samuel Arnold,* 63 FR 8687 at 8688 (1998).

admittedly disclosed it on previous DEA registration applications and because he entered into a consent order with the IDFPR and purportedly completed the required conditions. Respondent therefore knew or should have known that his response to the liability question was false.

Respondent's omitted 1998 probation was related to Respondent's handling of Dilaudid, which is directly related to the second and fourth factors listed in 21 U.S.C. 823(f). Regardless of whether DEA and Illinois had prior knowledge of that probation, the omission of an offense related to the handling of a schedule II controlled substance would certainly have a natural tendency to influence the decision of whether to grant Respondent's application when considering the applicant's experience in handling controlled substances and compliance with applicable State, Federal, and local laws relating to controlled substances. I thus conclude that Respondent's failure to disclose the 1998 state probation was a material misrepresentation because it ''ha[d] a natural tendency to influence the * * * decision'' of the DEA as to whether to grant his application for a new registration. Under DEA precedent, a material falsification ''provides an independent and adequate ground for denying'' Respondent's application.[117]

2. Candor and Admission of Fault

The DEA properly considers the candor of the physician and his forthrightness in assisting in the investigation and admitting fault important factors in determining whether the physician's registration should be revoked.[118] I find that Respondent has repeatedly failed to accept responsibility for his misconduct. This failure is evidenced by Respondent's consistent denial of any wrongdoing: Respondent asserts that his actions leading to his 1998 state probations were lawful even after he agreed to enter into a consent order with the IDFPR; with regard to his 2003 state probation, Respondent asserts (1) that his only blame was in leaving his bag, without a secure lock, at the clinic when he was not present and that he clearly ''could not prevent the owner's actions once I left medicine (Phentermine) in my locked bag'' and (2) that the DEA should not ''seek additional retribution'' with regard to the incident because he accepted the state probation; Respondent repeatedly claims that the immediate hearing is the result of a ''vendetta'' against him instigated by the City of Chicago; despite my previous rulings to the contrary, Respondent continues to assert that most of the evidence and testimony admitted in the instant hearing is inadmissible and should not be considered; and Respondent continues to assert that he was ''not afforded a capable attorney'' [119] although he was at any time free to procure the assistance of counsel, was notified of such, and he did not request a postponement of the instant hearing prior to its commencement in order to do so.[110]

B. The Public Interest Standard

As noted above, Respondent submitted a request to modify his registration, which is still pending. Pursuant to 21 CFR 1301.51, a request for a modification shall be handled in the same manner as an application for registration. Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA Certificate of Registration if she determines that such registration would be inconsistent with the public interest, consistent with the five factors described above.

In light of the circumstances of this case, I will consider Respondent's compliance with applicable law and experience in handling controlled substances together below.

1. The Recommendation of the Appropriate State Licensing Board

It is undisputed that Respondent is currently licensed as a physician and to handle controlled substances in Illinois. Inasmuch as Respondent is currently authorized to handle controlled substances in Illinois, I find that this factor weighs in favor of a finding that Respondent's registration would not be inconsistent with the public interest. However, I note that state licensure is a necessary but not sufficient condition for DEA registration, and I therefore find that this factor is not dispositive.

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

I conclude that Respondent's experience in handling controlled substances and Respondent's compliance with applicable State, Federal, or local laws relating to controlled substances weighs in favor of a finding that his registration would not be consistent with the public interest.

(a) Respondent's Prior State Disciplinary Actions

In the previously discussed 1998 Consent Order, the then IDPR alleged that Respondent ''may have prescribed Dilaudid to four (4) patients under questionable circumstances''; [120] Respondent did not admit or deny the allegations but did agree not to contest them. As a condition of his probation, Respondent was required to complete a remedial education course in controlled substance management. In his Closing Argument Brief, Respondent asserts that there was never any finding that the probation came about as a result of unlawful prescribing of Dilaudid, and in the instant hearing Respondent testified that his actions related to the incident were lawful.

In the 2003 Consent Order the IDFPR alleged, and Respondent admitted, that he failed to supervise an unlicensed employee. In the instant hearing and in his Closing Argument Brief, however, Respondent asserts that he was the employee and that he was unable to prevent the clinic owner from removing the phentermine from Respondent's locked bag, but that he accepted the probation because he should not have left the bag at the clinic when he was not there. As a condition of his probation, Respondent was required to complete ten hours of continuing education in the area of prescribing and dispensing controlled substances. I find that Respondent's conduct leading to the 2003 Consent Order and his apparent lack of understanding of proper methods, even after completing several hours of controlled substance handling education, weigh in favor of a finding that his continued registration would be inconsistent with the public interest.

(b) Respondent's Receipt and Dispensing of Marinol

I find no merit to Respondent's assertions that he lawfully received Marinol from a patient and also lawfully provided it to another patient. Pursuant to 21 U.S.C. 844(a), ''[i]t shall be 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 * * *'' except as otherwise authorized by the Controlled Substances Act.

Respondent's interpretation of 21 U.S.C. 844(a) is mistaken; Respondent apparently believes that, because he is

[117] *The Lawsons,* 72 FR at 74338; *Cf Bobby Watts,* 58 FR 46997 (1993).

[118] *Hoxie* v. *DEA,* 419 F.3d 477, 483 (6th Cir. 2005).

[119] Respondent's Closing Argument Brief at 10.

[120] GX 7 at 2.

a practitioner who was purportedly acting in the course of his professional practice at the time he received the Marinol, this section permitted him to receive the Marinol from a patient. Respondent, however, fails to recognize that 21 U.S.C. 844(a) requires that the controlled substance be obtained directly or pursuant to a prescription *from* a practitioner, not provided *to* a practitioner acting in the course of his professional practice. Respondent has made no assertion and provided no evidence that Mr. J.W., from whom Respondent admittedly obtained the Marinol, was a practitioner [121] acting in the course of his professional practice or that Mr. J.W. possessed the proper DEA registration to dispense or distribute controlled substances, as required by 21 U.S.C. 822(a)(1) and 21 CFR 1307.11(a)(1),[122] when he provided Respondent with the Marinol. Pursuant to 21 CFR 1307.12, however, a person in lawful possession of a controlled substance may, without a registration to do so, distribute such substance to the person from whom it was obtained or to the manufacturer of the substance. Respondent, however, testified at a police board hearing that the Marinol likely came from the prescription of another doctor, not Respondent. Mr. J.W., therefore, did not obtain the Marinol directly from or pursuant to a prescription from Respondent and there is no evidence indicating that Mr. J.W. possessed a DEA registration to distribute or dispense controlled substances so Respondent was subsequently not authorized to receive the Marinol from Mr. J.W. under 21 CFR 1307.12.

Respondent apparently recognizes, as indicated in his Closing Argument Brief, that he is required to record the receipt and subsequent dispensing of controlled substances. Pursuant to 21 CFR 1304.03(b), 1304.22(a)(2)(ix), 1304.21(a), 1304.22(c), and 1304.22(a)(2)(iv), a registered individual practitioner is required to maintain records of controlled substances in Schedules II–V that are dispensed and received, including the number of dosage units, the date of receipt or disposal, and the name, address, and registration number of the distributor. In his brief, Respondent asserts that he has a '' 'non monetary' receipt supplied by Mr. J.W.'' [123] The only document admitted into evidence that relates to the receipt of the Marinol, however, is an affidavit [124] with a signature reading ''J.W.'' and dated May 2, 2008, nearly five years after Respondent purportedly received and subsequently dispensed the Marinol. Not only is the general authenticity of that document suspect, but it also can not reasonably be viewed as a proper record of receipt, particularly considering that it was prepared nearly five years after the event and that Respondent previously claimed to have no recollection of the details of obtaining the Marinol. Respondent also entered into evidence a controlled substances log dated January 2003 through August 14, 2004, indicating that on July 21, Respondent dispensed 8 Marinol 10mg to Officer D.S., which, despite the questionable circumstances under which it was presented to the IDFPR investigator, may arguably be considered a record of dispensing.

Accordingly, I find that Respondent's receipt of the Marinol was unlawful under 21 U.S.C. 844(a) and 21 CFR 1304.03(b), 1304.21(a), 1304.22(c), 1304.22(a)(iv), 1304.22(a)(2)(ix), 1307.11, and 1307.12 because Respondent did not receive the Marinol directly from or pursuant to a prescription or order from a practitioner acting in the course of his professional practice or from a person who was in lawful possession of and originally obtained the Marinol from Respondent, or as otherwise authorized by the Controlled Substances Act, and because the receipt of the Marinol was not properly recorded. Additionally, as the Government points out, Respondent testified in the instant hearing that he has also in the past provided to patients Tylenol III and Tylenol IV that he had obtained from other patients to whom it had been prescribed by other physicians. I find that Respondent's unlawful receipt of a Schedule III controlled substance and failure to properly record such receipt weigh in favor of a finding that Respondent's continued registration would be inconsistent with the public interest.

(c) IDFPR Administrative Subpoenas

I find that the Government has not provided sufficient evidence to indicate that Respondent violated state law when he failed to comply with a subpoena *duces tecum* issued by the IDFPR requesting copies of patient records.

The Government correctly asserts that the IDFPR has the authority to ''subpoena the medical and hospital records of individual patients of'' [125] licensed physicians. Respondent, however, is essentially correct in his assertion that all information provided pursuant to such a subpoena and which indicates the identity of the patient, shall be removed and deleted prior to submission to the disciplinary board or department. Respondent further correctly asserts that the term ''all information indicating the identity of the patient'' includes patient names and dates of treatment because the IDFPR and the DEA have the ability to match that information with prescription records. Respondent also testified at the instant hearing that disclosure of the requested information, without first obtaining patient permission, would violate the federal Health Insurance Portability and Accountability Act (HIPAA).

Although neither party has submitted any relevant case law on the topic, the Illinois Supreme Court has provided some guidance regarding the disclosure of confidential patient information pursuant to an administrative subpoena. In *People* v. *Manos,* the court held that the Illinois legislature did not expressly provide for the investigatory power provided to the IDFPR to override the physician-patient privilege as codified in 735 ILCS 5/8–802. The IDFPR, therefore, cannot require a physician under an administrative investigation to produce confidential patient medical records unless one of the statutory exceptions set forth in 735 ILCS 5/8–802 applies.[126] Additionally, the court adopted a finding that the mere deletion of patient names and identifying information does not remove the records from protection under the physician-patient privilege when the department that issued the subpoena knows the names of the patients whose records were sought, those patients are not parties to the investigatory proceedings, and matching the records to the names would not be difficult even if the names and other identifying information were redacted.[127] I note that at the time that

[121] ''Practitioner'' is defined in 21 U.S.C. 802(21) as: ''a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.''

[122] 21 CFR 1307.11(a)(1) generally provides that a practitioner who is registered to dispense a controlled substance may distribute a quantity of such substance to another practitioner for the purpose of general dispensing to patients provided that both the distributing and the receiving practitioners record the distribution in accordance with 21 CFR 1304.22(c).

[123] Respondent's Closing Argument Brief at 5.

[124] Although the document is signed, it is neither witnessed nor notarized, and when the document was admitted, no witness was presented to verify the document's authenticity.

[125] 225 ILCS 60/38.

[126] *People* v. *Manos,* 202 Ill. 2d 563 (2002).

[127] *People* v. *Manos,* 202 Ill. 2d 563 (2002) *(citing Parkson* v. *Central DuPage Hospital,* 105 Ill. App. 3d 850 (1982)).

the IDFPR issued the subpoenas to Respondent on June 15, 2005, and June 20, 2007, no applicable exception applied under 735 ILCS 5/8–802.[128] An exception for subpoenas issued pursuant to the Medical Practice Act is now included in 735 ILCS 5/8–802,[129] however, that exception did not become effective until August 27, 2007 and is therefore not applicable.

I agree with the Government's assertion that Respondent's argument that compliance with the subpoenas would violate HIPAA is baseless because the subpoena was issued as an order of an administrative tribunal.[130] Nonetheless, I further find that because of the Illinois Supreme Court decision in *Manos,* it does not matter whether the disclosure would violate HIP AA because it was not disclosable under the physician-patient privilege law in effect in Illinois at the time of the issuance of the subpoena.[131] Accordingly, I find that the Government has not met its burden of proof that Respondent violated state law in failing to comply with a subpoena *duces tecum* issued by an administrative tribunal.

I note that I have already found no merit to Respondent's argument that the patient files and the testimony of Investigator D.M. in the immediate hearing are inadmissible in this proceeding and should not be available to the DEA.[132] Because Respondent is likely to present this argument again, however, I will add that, in addition to the reasons previously stated in my Memorandum to Parties and Rulings, dated February 12, 2010 and Memorandum to Parties and Ruling, dated April 9, 2010, the section of this opinion regarding the IDFPR subpoena *duces tecum* cannot provide the basis for an argument that the relevant patient files are inadmissible because Respondent obtained permission to provide the files, thereby waiving the physician-patient privilege.

(d) Prescribing From an Unregistered Location

I find that Respondent violated federal law by prescribing controlled substances from his new location without a valid registration. As provided in 21 U.S.C. 822(e), ''[a] separate registration shall be required at each principal place of business or professional practice where the applicant * * * dispenses controlled substances.'' Additionally, pursuant to 21 CFR 1301.51, any registrant may apply to modify his registration to change his address but such modification shall be handled in the same manner as an application for registration. Unlike a renewal application, which, when timely filed, remains in effect past the registration expiration date while the DEA makes a final determination on the application,[133] a request for a modification is treated as a new application; a registrant, therefore, is not authorized to dispense or prescribe controlled substances at his new location pending approval of a modification request to change a DEA registered address.[134]

The record demonstrates that even though Respondent moved from his registered address to a new location in July 2008, he failed to notify the DEA of this change until at least April 7, 2009,[135] after a DEA diversion investigator was unable to locate Respondent at his registered address and eventually located him at his residence. Additionally, Respondent admittedly continued to handle controlled substances not only while that modification was pending but after the DEA had notified him in writing at least two times, and Respondent's own attorney confirmed at least once, that he was not permitted to do so. Respondent's argument that the DEA actively prevented him from submitting a request for modification of his registered location is unconvincing, particularly considering that Respondent failed to provide any evidence indicating he ever attempted to submit the request.[136]

Respondent's act of continuing to handle controlled substances after numerous warnings shows a flagrant disregard for the requirements of the law governing the handling of controlled substances. Additionally, Respondent not only refuses to accept any blame whatsoever for failing to properly notify the DEA of his change of address but also claims that the DEA is responsible for him continuing to issue prescriptions for controlled substances and for pharmacies continuing to fill those prescriptions. I therefore find that Respondent's failure to comply with federal law regarding modification of his controlled substances registration and his additional refusal to accept responsibility for his actions strongly support a finding that Respondent's continued registration would be inconsistent with the public interest.

(e) Diversion of OxyContin

I find that the Government has met its burden in establishing diversion by a preponderance of the evidence and the Government has also shown that even if Respondent was unaware of the diversion, Respondent was involved in a scheme that created the opportunity for diversion of a Schedule II controlled substance.

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[128] The exceptions in effect during the applicable period are as follows: ''* * * (1) in trials for homicide when the disclosure relates directly to the fact or immediate circumstances of the homicide, (2) in actions, civil or criminal, against the healthcare practitioner for malpractice * * *, (3) with the expressed consent of the patient * * *, (4) in all actions brought by the patient, his or her personal representative, a beneficiary under a policy of insurance, or the executor or administrator of his or her estate wherein the patient's physical or mental condition is an issue * * *, (4.1) in all actions brought against the patient, his or her personal representative, a beneficiary under a policy of insurance, or the executor or administrator of his or her estate wherein the patient's physical or mental condition is an issue, (5) upon an issue as to the validity of a document as a will of the patient, (6) in any criminal action where the charge is either first degree murder by abortion, attempted abortion or abortion, (7) in actions, civil or criminal, arising from the filing of a report in compliance with the Abused and Neglected Child Reporting Act [325 ILCS *5/1* et seq.], (8) to any department, agency, institution or facility which has custody of the patient pursuant to State statute or any court order of commitment, (9) in prosecutions where written results of blood alcohol tests are admissible pursuant to Section 11–501.4 of the Illinois Vehicle Code [625 ILCS 5111–501.4], (10) in prosecutions where written results of blood alcohol tests are admissible under Section 5–lla of the Boat Registration and Safety Act [625 ILCS 45/5–11a], or (11) in criminal actions arising from the filing of a report of suspected terrorist offense in compliance with Section 29D–10(p)(7) of the Criminal Code of 1961 [720 ILCS 5/29D-l0].

[129] ''No physician or surgeon shall be permitted to disclose any information he or she may have acquired in attending any patient in a professional character, necessary to enable him or her professionally to serve the patient, except only * * * (12) upon the issuance of a subpoena pursuant to Section 38 of the Medical Practice Act of 1987 [225 ILCS 60/38]. * * *'' 735 ILCS 5/8–802.

[130] *See* 45 CFR 164.512(e)(1), (2), and (3).

[131] I also find no merit to Respondent's argument that he relied on the advice of counsel when he provided the redacted patient files to the IDFPR. Respondent has cited no relevant law to indicate that reliance on counsel would relieve him of responsibility for failing to comply with a subpoena.

[132] *See* Memorandum to Parties and Rulings, dated February 12, 2010 and Memorandum to Parties and Ruling, dated April 9, 2010. (Respondent relied on 225 ILCS 60/22(A)(5) and 60/23(B) to exclude the testimony of IDFPR Investigator D.M. and to exclude all evidence relating to Respondent's dispensing of Marinol to D.S. I denied Respondent's request and found that Section 60/23(B)'s constraint on the Medical Disciplinary Board's ability to further disclose reported information is limited to the confidentiality of medical reports and committee reports as otherwise protected by law.)

[133] *See* 5 U.S.C. 558(c).

[134] *See John J. Fotinopoulos,* 72 FR 24602 (2007).

[135] RX 15.

[136] Respondent submitted several documents with his brief, marked as ''Brief Exhibits.'' I have not considered these documents in reaching my findings and conclusions, however, because they were not offered or admitted into evidence. *See* 21 CFR 1316.57. Respondent also makes several references to testimony that was offered in related state proceedings; that information also will not be considered here for the same reason.

The DEA has held that a finding that a practitioner is reckless or negligent in ignoring the warning signs that a patient is either personally abusing controlled substances or diverting them to others is an indication that the practitioner's registration would be inconsistent with the public interest; misconduct that is ''unintentional, innocent or devoid of improper motivation * * * creates the opportunity for diversion and could justify revocation or denial.'' [137]

The evidence in this case clearly demonstrates that Respondent knowingly and willingly participated in a scheme to deceive other healthcare providers with regard to Ms. E.M.'s use of a Schedule II controlled substance and was at the very least reckless or negligent in ignoring the possibility of diversion and thereby created the opportunity for diversion of OxyContin. The record establishes that Respondent willingly agreed to continue to treat and to prescribe controlled substances to Ms. E.M. and to refrain from revealing his involvement to anyone other than Ms. E.M.'s family, even while Ms. E.M. was institutionalized and while she was being treated by other physicians. The numerous inconsistencies between the testimonies of Mr. I.S. and Respondent lead me to believe that neither is a credible witness with regard to Ms. E.M.'s medication and treatment and raises the questions of whether Respondent actually even treated Ms. E.M. and whether she received OxyContin.

The evidence shows that each month for several years, Respondent provided prescriptions for 60 OxyContin 80 mg tablets to three members of the same household, including Ms. E.M., who was over 90 years old and purportedly frail. As the Government points out, Ms. E.M. was confined to a hospital or nursing home for a total of approximately 290 days during that period.

I first find it difficult to believe that Ms. E.M.'s family was able to administer OxyContin twice a day for such an expansive time without ever arousing the suspicion of the facility staff. I also find it difficult to believe that for each of those approximately 290 days, although Ms. E.M. was purportedly receiving a total of 160 mg of OxyContin per day, two doses of 80 mg each,[138] Ms. E.M.'s family was able to prevent the possibility of an overdose simply by reviewing her daily charts (with the exception of the last three or so weeks of Ms. E.M.'s life when Mr. I.S. claims that he prohibited the facility from providing any type of pain medication to her).

Respondent ignored the warning signs of diversion by assisting in the family's scheme to conceal Ms. E.M.'s OxyContin prescriptions and by failing to test Ms. E.M.'s opioid levels to ensure that she actually received the drug. I find that Respondent was at least reckless or negligent in ignoring the warning signs of diversion with regard to the OxyContin he prescribed to Ms. E.M. and his conduct, intentional or not, thereby created the opportunity for diversion.

I find that Respondent did not issue OxyContin prescriptions for a legitimate medical purpose while acting in the scope of his professional practice. While I agree with Respondent that the DEA's governing regulations do not require him to perform a physical examination of a patient before providing each prescription, 21 CFR 1306.04(a), requires that controlled substance prescriptions be issued for a legitimate medical purpose by a practitioner acting in the scope of his professional practice.

The evidence also does not support a finding that Respondent issued OxyContin prescriptions to Ms. E.M. pursuant to 21 CFR 1306.12(b)(1), 1306.05, or 1306.04(a). What constitutes bona fide ''medical practice'' by a physician dispensing narcotic drugs must be determined upon consideration of the evidence and attending circumstances.[139] The Supreme Court of the United States clarified this issue in *Gonzales* v. *Oregon:* [140]

> Under DEA regulations, 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. As the Supreme Court 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.'' (Emphasis added).

Contrary to Respondent's assertions, the evidence does not support a finding that Respondent regularly saw Ms. E.M. as a patient; she therefore did not use controlled substances under his supervision. Mr. I.S.'s testimony combined with the discrepancies between Respondent's own records for Ms. E.M. and the admission and treatment dates for Ms. E.M. from hospice and treating hospitals indicate that it is unlikely that Respondent saw Ms. E.M. as a patient as frequently as he claims. Respondent even admitted that he relied on reports from Ms. E.M.'s family to determine the course of her treatment. Additionally, Respondent knowingly participated in a scheme to conceal Ms. E.M.'s alleged use of OxyContin from her treating physicians and other caregivers. Such actions certainly do not ''ensure patients use controlled substances under the supervision of a doctor,'' as explained by the Supreme Court. Because Ms. E.M. was not using OxyContin under the supervision of Respondent and Respondent's actions contributed to the prevention of her other physicians to supervise her use, Respondent did not issue OxyContin prescriptions to Ms. E.M. for a legitimate medical purpose while acting in the scope of his professional practice. I therefore find that the prescriptions that Respondent issued to E.M. for OxyContin were not issued for a legitimate medical purpose.

Accordingly, I find that Respondent was at least reckless or negligent in ignoring the warning signs of diversion and issued prescriptions for other than a legitimate medical purpose and that this conduct weighs in favor of a finding that Respondent's registration would not be consistent with the public interest.

3. Respondent's Conviction Record

There is no evidence that Respondent has ever been convicted under any federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances. I therefore find that this factor, although not dispositive, weighs against a finding that his continued registration would be inconsistent with the public interest.

4. Other Conduct

In light of my findings discussed above, I find it unnecessary to determine whether Respondent's prescribing of various noncontrolled substances to Ms. E.M. should weigh in favor of a finding that his continued registration would be inconsistent with the public interest.

[137] *See Paul J. Caragine, Jr.,* 63 FR 51592 (DEA 1998).

[138] According to the Physician's Desk Reference, 80 mg is the second-highest dosage of OxyContin available in a single pill.

[139] *Moore* v. *U.S.,* 128 F.2d 887 (1942).

[140] 126 S.Ct. 904, 925 (2006) *(citing Moore,* 423 U.S. 122, 135 (1975)).

Conclusion

I conclude that Respondent's registration with the DEA would be inconsistent with the public interest.

Recommended Decision

I recommend that Respondent's controlled substances registration be revoked and his application for renewal and modification of his DEA registration be denied.

Dated: June 15, 2010.

Mary Ellen Bittner,

Administrative Law Judge.

[FR Doc. 2011–22093 Filed 8–29–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated June 7, 2011, and published in the **Federal Register** on June 16, 2011, 76 FR 35241, Wildlife Laboratories, 1401 Duff Drive, Suite 400, Fort Collins, Colorado 80524, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Etorphine Hydrochloride (9059), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Wildlife Laboratories to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Wildlife Laboratories to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with State and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: August 16, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–22088 Filed 8–29–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 15, 2011, and published in the **Federal Register** on April 27, 2011, 76 FR 23627, Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of 4–Anilino-N-phenethyl-4–Piperidine (8333), a basic class of controlled substance listed in schedule II.

The company plans to use this controlled substance in the manufacturer of another controlled substance.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Cedarburg Pharmaceuticals, Inc., to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Cedarburg Pharmaceuticals, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: August 16, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–22089 Filed 8–29–11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Harold Edward Smith, M.D.; Revocation Of Registration

On April 17, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Harold Edward Smith, M.D. (Respondent), of Mt. Dora, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BS4681979, and the denial of any pending applications to renew or modify the registration, on the grounds that Respondent had materially falsified various applications for his DEA registration and had committed acts which render his registration inconsistent with the public interest. Show Cause Order at 1 (citing 21 U.S.C. 824(a)(1) & (4)).

The Show Cause Order alleged that Respondent has ''a documented substance abuse history dating back as far as 1982,'' when he ''entered treatment for alcohol and controlled substance abuse.'' *Id.* The Order alleged that on April 3, 1985, Respondent entered into a consent order with the Georgia Board of Medical Examiners (Georgia Board) based on his ''chemical dependency,'' which placed him on probation for four years and imposed various conditions including that he ''abstain from the consumption of alcohol or controlled substances,'' undergo random drug testing, and ''relinquish'' his controlled substance privileges. *Id.* The Order then alleged that in June 1990, Respondent tested positive for cocaine and that on October 10, 1990, he ''entered into an Interim Consent Order'' with the Georgia Board under which his medical license was suspended and he was ordered (1) Not to practice medicine, (2) not to use his DEA registration, and (3) ''to participate in a program for impaired physicians.'' *Id.* at 2.

Next, the Show Cause Order alleged that during 1999 and 2000, Respondent issued prescriptions for hydrocodone to J.R.S. and L.L.S., and had failed to maintain the ''records of any examinations, diagnoses, treatment[s] or * * * drugs prescribed to these individuals as required by Section 458.331(1)(q) of the Florida statutes.'' *Id.* The Order further alleged that based on this conduct, Respondent ''entered into a Consent Agreement with the'' Florida Board of Medicine, which required him to pay a fine of $5,000, desist ''from prescribing to family members'' and to