Wholesale Distributors be, and it hereby is, dismissed. This Order is effective immediately.

Dated: July 16, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–17688 Filed 7–23–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06–77]

Gregory D. Owens, D.D.S.; Suspension of Registration; Grant of Restricted Registration

On August 7, 2007, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Gregory D. Owens, D.D.S. (Respondent), of Abingdon, Virginia. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration as a practitioner on the ground that his continued ''registration would be inconsistent with the public interest, as that term is defined under 21 U.S.C. 823(f).'' Show Cause Order at 1.

More specifically, the Show Cause Order alleged that in 1986, when Respondent moved his dental practice from Tennessee to Virginia, he had failed to obtain a new registration as required by 21 U.S.C. 822. *Id.* The Order further alleged that in 1992, Respondent did not renew his State ''controlled dangerous substances license'' and that he only acquired the proper State and Federal registrations in 1996 after a Virginia Board of Dentistry (''the Board'') inspection. *Id.* Relatedly, the Order alleged that in 1996 and 1997, Respondent had ''continued to prescribe controlled substances in violation of law,'' using his ''long-expired DEA Tennessee registration to facilitate this illegal activity.'' *Id.*

Next, the Show Cause Order alleged that in both November 1997 and May 2000, the Board had placed Respondent's dental license on probation and subjected him to certain conditions. *Id.* at 1–2. The Order also alleged that in August 2005, the State Board had ''issued an Order which concluded that [Respondent] had continuously demonstrated disregard for the Board's orders,'' reprimanded him, and continued him on probation. *Id.* at 2.

Finally, the Show Cause Order alleged that in October 1999, DEA had issued an Order to Show Cause to revoke Respondent's registration, and that on August 2, 2002, my predecessor had issued a Decision and Final Order which granted Respondent a registration which was ''subject to restrictions and conditions'' including ''recordkeeping requirements.'' *Id.* at 1. The Show Cause Order further alleged that in November 2005, Respondent applied for a renewal of his registration and that a compliance review found ''that in 2004 and 2005, [Respondent had] failed to submit the required controlled substance recordkeeping information to DEA in violation of the conditions of [the] previously granted registration.'' *Id.* at 2.

Respondent, through his counsel, timely requested a hearing. The case was assigned to a DEA Administrative Law Judge (ALJ), who conducted a hearing in Abingdon, Virginia, on June 27, 2007. At the hearing, both parties called witnesses to testify and introduced documentary evidence. Following the hearing, both parties submitted briefs containing proposed findings of fact, conclusions of law, and argument.

On March 6, 2009, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ found that Respondent had violated the terms of my predecessor's Final Order by failing to file quarterly reports of the controlled substances he dispensed between the effective date of the Order (Sept. 3, 2002) and December 31, 2002, the date stated as the expiration date on a registration which was subsequently issued to him several months after the expiration date and which was the result of a clerical error. ALJ at 37–39. However, the ALJ further found that Respondent's failure to file the reports after that date should be excused because the Government did not clearly communicate to him that this registration was issued in error and that a registration issued to him on September 8, 2003 (which expired on December 31, 2005) was the ''newly renewed registration'' to which the reporting requirement imposed by the 2002 Order applied. *Id.* at 39. However, she also found that because Respondent did not present evidence that he had submitted the required drug activity logs from August 2002 through December 2002, Respondent's ''lack of evidence proving good faith compliance weigh[ed] against the Respondent's continued registration.'' *Id.* at 40.

The ALJ also found that Respondent had not complied with a second requirement of the 2002 Order—that he notify DEA within thirty days of any action taken against his State ''medical license.'' *Id.* at 40–41. According to the ALJ, Respondent violated this provision because he failed to report the 2005 Board action which continued his probation upon finding that he had committed additional violations. *Id.* at 41. In so holding, the ALJ specifically rejected Respondent's contention that because the 2002 Order had used the term ''medical license'' rather than ''dental license'' in imposing the condition, he had no obligation to report the proceeding to DEA. *Id.*

While the ALJ found that the Government had made out a *prima facie* case to revoke Respondent's registration, she concluded that other factors counseled against a revocation. *Id.* at 47. More specifically, she noted that Respondent treated ''many patients from underserved counties, and a substantial portion of his patients have limited incomes,'' that there was no evidence of diversion or irresponsible prescribing practices on Respondent's part, that Respondent had instituted procedures to ensure the accuracy of his dental records, and that he had begun filing drug activity reports with this Agency following a 2006 inspection. *Id.* at 48. The ALJ thus recommended the revocation of Respondent's registration but that the revocation be stayed for twelve months, and that ''[d]uring pendency of the stay, the Respondent should be allowed to handle controlled substances,'' subject to certain restrictions. *Id.*

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the record as a whole, I hereby issue this Decision and Final Order. I adopt the ALJ's findings of fact and conclusions of law except as noted below. While I accept Respondent's contention that the March 13, 2003 registration was the ''newly renewed registration'' for purposes of the 2002 Order, I note that Respondent did not comply with the Order's requirement pertaining to the submission of quarterly reports even during period in which there is no dispute that he was required to do so. I also hold that Respondent violated the 2002 Order because he failed to report the 2005 Board action to DEA. While I agree that the record does not support an outright revocation of his registration, I conclude that Respondent's lengthy history of regulatory troubles supports the suspension of his registration as well as the imposition of conditions on his new registration. I make the following findings.

Findings

Respondent graduated from the Medical College of Virginia Dental

School, now the Virginia Commonwealth University Dental School, in 1981. Tr. 151. Respondent is licensed to practice dentistry in the State of Virginia and practices in Abingdon (Washington County), Virginia. *Id.* at 150–52, 163. Respondent performs root canals and tooth extractions and often issues a prescription for a controlled substance to treat a patient's post-operative pain. *Id.* at 160.

Respondent's last DEA Certificate of Registration was issued on September 8, 2003, and had an expiration date of December 31, 2005.[1] RX 3; GX 1, at 1. On or about November 21, 2005, however, Respondent submitted a renewal application. GX 2, at 1–2. Accordingly, Respondent's registration has remained in effect throughout the course of this proceeding.

While Respondent currently holds both a DEA registration and a State license, he is not a stranger to either DEA or Board proceedings (nor to Federal criminal proceedings either). Indeed, Respondent has been disciplined by the Virginia Board on three occasions and has been the subject of DEA proceedings on two occasions.

The State Proceedings

The first of these proceedings began in October 1997, when the Board's Executive Director gave notice and ordered Respondent to appear at an informal conference based in part on allegations that an inspection of four of his patient records had found that in two of them, he had ''failed to list drugs prescribed, dispensed, administered and the quantity.'' GX 4, at 2. In the notice, the Board also alleged that ''on divers occasions since March 31, 1986, [Respondent] ha[s] prescribed various controlled substances for patients, including but not limited to Demerol, Percocet, Percodan, Endocet (all Schedule II), and hydrocodone (Schedule III), without a current DEA number.'' *Id.* The Board further alleged that ''from December 31, 1992 to July 1996, [Respondent had] issued said prescriptions without having a current Controlled Substance Registration Certification.'' *Id.* Finally, the Board alleged that ''[o]n or about June 30, 1997, in the United States District Court, Abingdon, Virginia, [Respondent] w[as] found guilty of one count of Failure to report change of address to DEA, a misdemeanor.'' [2] GX 4, at 2. *See also* GX 14 (judgment finding that defendant had pled guilty to violations of 21 U.S.C. 842(a)(5) & (c)(2), fining him $5000, and sentencing him to two years of supervised release).

On November 5, 1997, the Board found the above allegations (as well as others) proved. GX 5, at 2–3. The Board imposed various sanctions including a reprimand, subjected him to one unannounced inspection annually, and placed him on probation indefinitely.[3] *Id.* at 3.

On March 21, 2000, the State Board commenced a second proceeding. This proceeding was based, in part, on a September 9, 1998 review of Respondent's drug inventory and records which found that Respondent had on hand two boxes, which had originally contained twelve bottles each of dihydrocodeine tablets but, at the time of the inspection, held only eight bottles each. GX 6, at 2. The Board further alleged that Respondent had ''failed to take a complete and accurate biennial inventory of the schedule III and V drugs maintained,'' that he ''failed to maintain a record of drugs received to include the date of receipt, the name and address from whom received and the kind and quantity of drugs received,'' and that he had ''failed to maintain a record of drugs received to include the date of receipt, the name and address for which the drugs were dispensed, and the kind and quantity of drugs.'' GX 6, at 2–3.[4]

On May 8, 2000, the Board found that Respondent had violated certain terms of its 1997 Order as well as various provisions of the Virginia Code and the Board of Dentistry Regulations. GX 7, at 1–2, 4. Pertinent to the Controlled Substances Act, the Board specifically found proved the allegations pertaining to Respondent's handling of the dihydrocodeine tablets, including his failure to take biennial inventories of schedule III and V drugs, and to maintain proper records of both the drugs received and dispensed. *Id.* at 3. The Order reprimanded Respondent and continued his probation ''INDEFINITELY,'' subjected him to two unannounced inspections annually and a reporting requirement,[5] and imposed a monetary penalty of $ 5000. *Id.* at 4–5 (emphasis in original).

On July 26, 2005, the Board commenced a third proceeding. This proceeding was initiated ''to receive and act upon [Respondent's] petition for termination of [his] probation, to review [his] compliance with the terms and conditions imposed on [his] license by [the Board's 2000 Order], and to receive and act upon evidence that [he] may have violated certain laws and regulations governing the practice of dentistry.'' GX 8. More specifically, the Board alleged that Respondent had been delinquent in submitting multiple reports, and that an unannounced inspection on February 9, 2005 had found that he ''may have violated'' State law and regulations pertaining to the practice of dentistry.[6] *Id.* at 1–2.

On September 6, 2005, the Board entered an Order which found each of the allegations proved. GX 9, at 2–3. The Order further found that Respondent ''has continuously demonstrated disregard for the Board's Orders.'' *Id.* at 3. The Board thus reprimanded Respondent, levied an $11,000 penalty, and denied Respondent's request to terminate his probation, which was continued indefinitely.[7] *Id.* at 3–4. The Order provided that Respondent's probation ''shall continue from the date this Order is entered and shall continue indefinitely.'' *Id.* at 4.

[1] Respondent previously held a DEA registration which was issued on February 4, 1997, and which expired on December 31, 1999. ALJ at 5. On October 1, 1999, the first DEA proceeding was initiated. RX 42, at 2. On November 8, 1999, Respondent filed a renewal application, *id.* at 9, the effect of which was to extend the expiration date of his registration until the Agency issued its Decision and Final Order resolving the first proceeding, which it did on July 24, 2002. *See Gregory D. Owens,* 67 FR 50461, 50465 (2002) (RX 1, at 5).

On March 13, 2003, Respondent was issued a new Certificate of Registration. RX 2. However, the Certificate stated that it had expired on ''12–31–2002.'' *Id.* According to the registration history, this Certificate was issued in error. Tr. 85. However, the fact that it was issued in error was not communicated to Respondent. *Id.* at 85–86. It is not clear whether Respondent filed a further application to obtain the Certificate which was issued on September 8, 2003.

It is also noted that registration certificate which expired on December 31, 2005, did not contain any indication that it was subject to restrictions. Tr. 53. DEA does not, however, indicate on the face of a certificate whether a registration is subject to restrictions. *Id.* at 53–54.

[2] On or about January 30, 1997, in the United States District Court, Abingdon, Virginia, Respondent pled guilty to five (5) misdemeanor counts of Failure to File Federal Tax Returns, and was sentenced to five months of home detention and fined $10,000. GX 13, at 1, 2 & 5.

[3] The November 24, 1997 order was part of the grounds of the prior DEA action. *See* RX 1, at 2; *see also Owens,* 67 FR 50461, 50462.

[4] The proceeding was also based on the results of a September 8, 1999 inspection, which revealed various deficiencies related to Respondent's alleged violation of the laws and regulations governing the practice of dentistry. GX 6, at 1–2.

[5] Respondent was required to submit quarterly reports of his address and current employment as part of this Order as well as the 1997 Order. *See* GX 7, at 4.

[6] More specifically, the Board alleged that Respondent had ''failed to consistently provide the signature of the dentist completing laboratory work order and the address of the dental practice,'' and that he had kept expired drugs (none of which are controlled under Federal law) in his working stock. GX 8, at 1–2.

[7] Respondent was again required to submit quarterly report noting his address and current employment. GX 9, at 4.

In October 2006, the Board conducted an inspection of Respondent's dental practice and found no deficiencies. RX 13, at 5. Subsequently, in April 2007, the Board notified Respondent that he was in compliance with the Board's Order of September 6, 2005, and that no action would be taken against his dental license. RX 23.

The First DEA Proceeding

On October 1, 1999, the Deputy Assistant Administrator of the Office of Diversion Control issued an Order to Show Cause which sought the revocation of Respondent's registration on the ground that Respondent had committed various acts which rendered his registration inconsistent with the public interest. RX 1, at 1 (*Gregory D. Owens*, 67 FR 50461 (2002)). More specifically, the Show Cause Order alleged that: (1) Between January 1990 and January 1997, Respondent had prescribed approximately 8,600 dosages units of controlled substances using his DEA Registration number, which had expired on August 5, 1986; (2) Respondent had issued controlled-substance prescriptions between May 1 and November 14, 1996, without holding a valid State controlled-substance registration; and (3) Respondent had pled guilty to failing to report his change of address to DEA. RX 42, at 2–3.

Following a hearing, on May 4, 2001, the ALJ issued her recommended decision. *Id.* at 1. Therein, the ALJ found that between January 1990 and January 1997, Respondent had issued controlled-substance prescriptions without a valid DEA registration; she also found that from January 1993 until July 1996, he had issued controlled-substance prescriptions without a valid State registration. *Id.* at 14–15. While in the first proceeding Respondent testified that he did not intend to violate Federal law, the ALJ also found significant that Respondent had prescribed Darvocet (also a controlled substance) at the time when his 1996 application was pending but had yet to be renewed. *Id.* at 15. The ALJ, however, recommended that my predecessor consider ''Respondent's acceptance of responsibility for past offenses and rehabilitation when deciding the likelihood that [his] future conduct * * * will be consistent with the public interest,'' and that Respondent be allowed ''to demonstrate that he can now handle the responsibilities a DEA registrant.'' *Id.* at 18. The ALJ thus recommended that my predecessor grant Respondent a new registration subject to various conditions.[8] *Id.* at 19–20.

On July 24, 2002, the Deputy Administrator issued his final decision in the matter, which was effective no later than September 3, 2002. *See Gregory D. Owens*, 67 FR 50461, 50465 (2002). The Order granted Respondent's application for renewal of his registration subject to the following conditions:

(1) During the duration of the *newly renewed registration,* the Respondent must provide the local DEA office with a log of activities on a quarterly basis that shall state: (1) The date that a controlled substance prescription was written, or such substance was administered; (2) the name of the patient for whom the prescription was written, or to whom the substance was administered; (3) the patient's complaint; (4) the name, dosage, and quantity of the substance prescribed, dispensed, or administered; and (5) the date that the medication was last prescribed, dispensed, or administered to that patient, as well as the amount last provided to that patient. If no controlled substances are prescribed, administered, or dispensed during a given quarter, the Respondent shall indicate that fact in writing, in lieu of submission of the log.

(2) Within 30 days of the event, the Respondent must inform the local DEA of any action taken by any State upon his medical license or upon his authorization to handle controlled substances in that State.

(3) Should the Respondent change employment during *this registration* period, he shall immediately notify the local DEA office that is monitoring his log of activities.

Id. at 50464.

Respondent's Compliance With the 2002 DEA Order

After receiving the ALJ's recommended decision (and before the 2002 Decision and Final Order was issued), Respondent began filing quarterly drug activity logs with the Agency. Tr. 43 & 169; *see also id.* at 70–71 (Respondent's counsel asking DI whether Respondent had started sending in the drug logs following his receipt of the ALJ's decision). While not part of the ALJ's recommended sanction (or subsequently required by the Agency's Final Order), Respondent started using a carbon-copy prescription pad and faxing prescriptions to pharmacies so that the original prescription could go in the patient file and the carbon copy could be maintained as a record to double-check the drug activity log. *Id.* at 135 & 169.

However, following the issuance of the Final Order, Respondent stopped sending in the quarterly activity logs. *Id.* at 42–43; 51. When asked by the Government on cross-examination how many quarterly reports he had sent to DEA following the issuance of the Final Order and the date he thought his obligation to file the reports had ended, Respondent testified that he did not know and did not have that information with him because he was ''just prepared to talk about 2004 and 2005.'' *Id.* at 186. On redirect examination, Respondent further maintained that he was not prepared to testify about what happened in 2001 and 2002 because the Government had not given him notice that this would be at issue in the Show Cause Order and other documents. *Id.* at 191.

Yet on direct examination, Respondent had testified that when he received the ALJ's May 2001 decision, he ''began sending in our quarterly reports.'' *Id.* at 169.[9] He also testified that he believed—and had told the DI—''that the newly renewed registration referred to in the DEA's decision had expired.'' *Id.* at 162.

Regarding the 2002 Order's requirement that he notify the Agency ''within 30 days'' of ''any action taken by any State upon his medical license,'' 67 FR at 50464, Respondent testified that he has never had a medical license and that he has a dental license. Tr. 163 & 178. With respect to the 2005 State Board proceeding, in which the Board had reprimanded him, fined him, rejected his petition to terminate and continued him on probation, Respondent maintained that the Board had not taken action against his license because there was no change in the status of his license. *Id.* at 165. Amplifying this testimony, Respondent stated: ''My license was under probation and it did not change. Nothing changed

[8] My predecessor adopted the ALJ's recommended conditions nearly verbatim with the exception of the first recommended condition which was that Respondent take a course in the identification and handling of controlled substances. RX 42, at 19.

[9] Respondent objected to the Government's questioning the DI regarding Respondent's failure to submit the drug logs in the years prior to 2004 and 2005 on the ground that neither the Show Cause Order nor the Government's pre-hearing statement had disclosed that this would be at issue. Tr. 44–46. Respondent, however, did not object when the Government had previously asked the DI: ''What log of activities were received by DEA from [Respondent] after the date of the issuance of this order on August 2, 2002?'' and the DI answered: ''There were no activity logs or drug logs submitted after August of 2002 until after we visited Dr. Owens' office in 2006.'' *Id.* at 42–43. Notably, when the DI continued with his answer and the Government's counsel interrupted him, Respondent's counsel did not object to the line of questioning but only that ''the witness be allowed to complete his answer.'' *Id.* at 43. The DI then explained that in 2007, Respondent's attorney had ''submitted all the drug logs that were kept.'' *Id.*

Respondent's objection was untimely and was properly overruled for this reason as well.

on my license itself. I guess you could split hairs.'' *Id.* at 181. He also maintained that his obligation to report any Board actions against his license had expired on December 31, 2002, based on the expiration date of the registration certificate, although he acknowledge that ''I don't think it's quite as clear as on the other one.'' *Id.* at 188.

The 2006 DEA Investigation

On November 21, 2005, Respondent submitted an application to renew his registration. GX 2, at 2. On January 19, 2006, two DEA DIs, who were accompanied by a member of the Virginia State Police, inspected Respondent's office and inquired as to why Respondent had not submitted the drug activity logs in 2004 and 2005. Tr. 23, 33–34. Respondent told the investigators that ''he wasn't aware of that'' and showed them a copy of the ALJ's ruling. *Id.* at 65–66. The investigators also determined that Respondent did not have any Federally controlled substances on the premises and reviewed a drug log that he had kept since September 18, 2005. *Id.* at 34–35; *see also* GX 10.

The DIs then looked at Respondent's appointment book and selected sixty-eight patient records to review to determine whether the controlled substances Respondent had prescribed had been recorded in the drug log. *Id.* at 38–39. According to the DI, there were seven instances in which a prescription which was recorded in a patient file was not listed in the drug log. *Id.* at 39, 60–61. The DI further acknowledged that Respondent consented to the inspection and was cooperative, *id.* at 54–55, and that he had no evidence that Respondent engaged in the diversion of controlled substances. *Id.* at 58.

The next day, Respondent had a telephone conversation with one of the DIs and asked him ''exactly what was the term of a newly renewed registration.'' *Id.* at 63. The DI did not directly answer the question and instead told Respondent that ''we would take a look at'' the information that had been obtained. *Id.* According to the DI, during the conversation, Respondent told him that he had found a letter which explained what the requirements were.[10] *Id.* at 67. Respondent testified that he ''didn't believe'' that he was required to submit records in 2004 and 2005 because he thought the ''newly renewed registration referred to in the DEA's decision had expired.'' *Id.* at 161–62.

In his testimony, the DI further testified that the Certificate of Registration which was issued on March 13, 2003, and which had expired on December 31, 2002, was not his new registration, but rather ''a continuation of his previous registration.'' *Id.* at 84. He further maintained that this registration certificate was issued in error and pointed to an administrative code, which indicated as much, on Respondent's registration history. *Id.* at 85; *see also* GX 15. However, the DI was aware of no evidence that this information had been communicated to Respondent. *Id.* at 86.

On March 16, 2006, Respondent's counsel submitted the drug activity logs from July 2002 through December 2005 to the DI. RX 22. In his letter forwarding the logs, Respondent's counsel maintained that, based on the 2002 Order, Respondent ''is under no duty to provide these to the DEA.'' [11] *Id.* Relatedly, Respondent testified that he submitted the drug activity logs out of ''an abundance of caution'' because it was ''difficult to know exactly what [he was] supposed to do.'' Tr. 183.

Respondent's Evidence Regarding Remedial Measures

On September 2, 2006, Respondent entered into a consulting agreement with a registered nurse, who was to review his compliance with DEA regulations on a monthly basis. RX 5, at 1, 5. Moreover, at the end of each month, the consultant audits all the patient charts that are listed in the drug activity log. Tr. 106. The consultant also goes through the appointment book and randomly selects twenty-five patient charts which she reviews to see if any prescriptions were not entered into the drug activity log. *Id.* The entries in the drug activity log are also checked against the patient charts for accuracy. RX 6. The consultant then provides a monthly report of both the drug activity log audit and the random patient chart audit. Tr. 106; RXs 7–13. According to the consultant, Respondent's recordkeeping is now ''well organized'' and ''efficient'' and Respondent is capable of providing ''accurate'' records to this Agency.[12] Tr. 113–14.

Discussion

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

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

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

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

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

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

21 U.S.C. 823(f).

These factors are considered in the disjunctive; I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[] appropriate'' in determining whether a registration should be revoked and/or an application should be denied. *Robert A. Leslie,* 68 FR 15227, 15230 (2003). Moreover, case law establishes that I am ''not required to make findings as to all the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).[13]

[10] The letter is not in the record.

[11] Most of the logs pertaining to this period (including those pertaining to the period between the issuance of the 2002 Order and December 31, 2002) are not in evidence.

The ALJ found that these drug activity logs did not meet the requirements of the 2002 Decision and Order as they ''failed to record when and the amount of controlled substances that had last been provided to the patient.'' ALJ at 18 (citing Tr. 185; RX 42, at 19; RX 1, at 4). It is noted that the Drug Log for the period September 18, 2005, through January 18, 2006, was frequently missing information such as ''the patient's complaint,'' as well as the date the medicine was last prescribed to the specific patient and the quantity. *Compare* GX 10 with GX 3, at 6–7. Neither party, however, submitted the drug logs for the period between the issuance of the 2002 Order and December 31, 2002.

[12] Respondent offered into evidence affidavits of three other dentists, who variously declared that he is ''an asset to the dental community in the Abingdon, Virginia area,'' ''an excellent asset to the dental and general community,'' and an ''excellent dentist who uses good dental techniques.'' RXs 15–17.

Respondent also put on extensive evidence regarding the socioeconomic status of his patients and the shortage of dentists in the area where he practices. However, for reasons discussed below, I conclude that it is not necessary to engage in fact-finding on these issues.

[13] DEA has the burden of proving that the requirements for revocation are met. 21 CFR 1301.44(e). However, if the Government makes out a *prima facie* case, the burden shifts to the Respondent to demonstrate that the continuation of his registration is consistent with the public interest.

Factor One: The Recommendation of the State Licensing Board

As found above, Respondent had been the subject of three separate State board proceedings and been disciplined on each occasion. Moreover, the first two proceedings involved violations which did not simply involve violations of State rules pertaining to the practice of dentistry but also violations of the CSA and DEA's regulations.

The ALJ noted that in the 2002 Decision and Order, the Agency had concurred with her conclusion that because the Board had not restricted Respondent's ability to handle controlled substances, this ''demonstrate[d] that the Board does not believe Respondent poses a danger to the public health and safety, to the extent that he cannot be trusted with the serious responsibilities of practicing dentistry and handling controlled substances.'' ALJ at 34–35 (quoting *Owens*, 67 FR at 50463). Remarking on the 2005 Board proceeding and the April 2007 Board letter which closed the case, the ALJ found it ''significant that in all orders, the Board chose not to restrict Respondent's handling of controlled substances,'' and that this factor ''weighs in favor of continuing the Respondent's DEA Certificate of Registration.'' *Id.* at 35–36.

While DEA has frequently considered State board proceedings which do not result in a revocation or suspension under this factor, the Agency ''maintains a separate oversight responsibility with respect to the handling of controlled substances and has a statutory obligation to make its independent determination'' as to whether the continuation of an existing registration is in the public interest. *Mortimer B. Levin*, 55 FR 8209, 8210 (1990); *see also Jayam Krishna-Iyer*, 74 FR 459, 462 (2009).[14] Accordingly, while I concur in the ALJ's conclusion regarding this factor, I give it only nominal weight in the public interest inquiry. *See Martha Hernandez*, 62 FR 61145, 61147 (1997) (finding that State board decisions are relevant, although not dispositive, on the issue of granting or denying a DEA application).

Factors Two and Four: Applicant's Experience in Dispensing Controlled Substances and Compliance With Applicable State, Federal or Local Law

The record in this matter establishes a pattern of Respondent's non-compliance with the requirements of both State and Federal Law relating to controlled substances. More specifically, for at least seven years, Respondent violated Federal law by issuing prescriptions for both schedule II and III controlled substance based on an expired registration.[15] *See* 21 U.S.C. 822(a)(2); *see also* 21 U.S.C. 843(a)(2). He also violated Virginia law, which at the time required that he also hold a State registration, for more than three years.

Subsequently, the Virginia Board found that Respondent was in violation of various State rules because he had on hand a stock of schedule III controlled substances and was not taking inventories and maintaining both receiving and dispensing records.[16] Moreover, the findings of the Board establish that Respondent could not account for eight bottles of dihydrocodeine, a schedule III controlled substance.[17] GX 7, at 3.

The central issue in this case was, however, Respondent's compliance with the terms of this Agency's 2002 Order. More specifically, the Government contended that Respondent had failed to comply with the requirements that he submit drug activity logs each quarter and notify DEA of any action taken against his ''medical license.''

With respect to the first issue, Respondent raises several contentions. First, he argues that his rights under the Due Process Clause and the Administrative Procedure Act were violated because the Government was allowed to introduce evidence regarding his compliance with the 2002 Order pertaining to years which were not alleged in the Show Cause Order (which alleged that he had not complied during the years 2004 and 2005) or in the Government's Pre-Hearing Statement. Resp. Br. at 21. Respondent also argues that ''he had no notice to prepare for or to rebut the testimony as to the years before 2004.'' *Id.* Relatedly, Respondent contends that ''[o]ver [his] objection, the ALJ allowed the Government to inquire into [his] reporting before 2004.'' *Id.* at 25.

Respondent did not, however, timely object to the Government's questioning the DI as to what logs have been received after the issuance of the Order on August 2, 2002. Tr. 42–43. Indeed, Respondent's counsel objected that the Government had not allowed the DI to complete his answer. *Id.* at 43. Nor did Respondent object to the Government's subsequent question as to what logs he had submitted prior to the issuance of the 2002 Order. *Id.* Rather, Respondent did not object until after the Government had asked several additional questions. *Id.* at 43–44. I thus conclude that Respondent waived his objection to the admission of this evidence.[18]

Finally, even if it was error for the ALJ to allow the Government to pursue this line of questioning, the error was not prejudicial. *See* 5 U.S.C. 706. Notably, on direct examination, Respondent testified that after receiving the ALJ's recommended decision, which was issued in May 2001, ''[W]e began sending in our quarterly reports.'' Tr. 168–69. Thus, Respondent went into areas that pre-dated the time-frame referenced in the Show Cause Order and Government's Pre-Hearing Statement. Moreover, on direct examination, Respondent maintained that he was not required to file the reports because he believed ''that the newly renewed registration referred to in the [2002] decision had expired.'' *Id.* at 162. Given his testimony that he had started sending in the reports after receiving the ALJ's May 2001 decision and that he believed his obligation ended based on the expiration of the erroneously issued registration, the contention that his compliance during the four-month period in which it is undisputed that he was required to submit the reports is not properly at issue, amounts to trying to have his cake and eat it too.[19]

I am also unpersuaded by Respondent's contention that he was ''not prepared to testify about what happened in 2001 and 2002'' because

[14] As my predecessor noted in the 2002 Decision and Order, the various orders issued in the State board proceedings are not in any sense an ''official recommendation regarding this proceeding's outcome.'' 67 FR at 50463. Moreover, a State board may apply a different standard than the public interest standard applicable under the CSA and thus consider factors which DEA does not consider relevant. Thus, I give this factor only nominal weight.

[15] I further note Respondent's misdemeanor conviction for failing to notify DEA of his address change. *See* 21 U.S.C. 823(f)(3).

[16] Under DEA regulations, ''[a] registered individual practitioner is required to keep records * * * of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.'' 21 CFR 1304.03(b).

[17] It is unclear, however, how many tablets were in each bottle.

[18] Moreover, on cross-examination Respondent's Counsel asked the DI whether Respondent had started sending in the drug logs following his receipt of the ALJ's Decision. Tr. 70–71.

[19] Furthermore, while the ALJ denied Respondent's request for a continuance to gather the evidence that would show that the logs were sent in during the period between the issuance of the 2002 Order and December 2002, the ALJ made clear that Respondent could renew his request at ''the conclusion of the presentation of [the] evidence'' and noted that the record could be left open for this purpose. Tr. 48–49. Respondent did not, however, request that the record be left open or submit any such reports.

the Government failed to give notice. Tr. 191. Respondent's testimony that he started sending in the reports after receiving the ALJ's May 2001 decision demonstrates that he was obviously prepared to discuss what happened in 2001 and 2002. I therefore reject Respondent's contention that his rights under the Due Process Clause and APA were violated because the Government introduced evidence regarding his non-compliance with the Order.

As found above, the record establishes that Respondent did not submit any drug activity logs as required by the 2002 Decision and Final Order. I conclude, however, that Respondent cannot be deemed to have violated the terms of the Order subsequent to December 31, 2002.

The Order expressly stated that it was granting Respondent's renewal application and that it was effective ''no later than September 3, 2002.'' GX 3, at 7. Thus, while the certificate issued on March 13, 2003, indicated that it had expired on December 31, 2002, and the evidence indicates that it was issued in error, the registration could be reasonably interpreted as having granted authority to Respondent for the period between September 3 and December 31, 2002.[20]

Throughout this proceeding, the Government has contended that Respondent's obligation to submit the quarterly drug activity logs did not end with the expiration date indicated on this registration. The Government further contends that the actual registration the 2002 Order referred to was that which issued on September 8, 2003, and which expired on December 31, 2005.

It is acknowledged that my predecessor likely used the phrase—''[d]uring the duration of the newly renewed registration''—intending that the first condition would last for the period of a full registration. Under DEA's regulations, a practitioner's registration is typically valid for thirty-six months, *see* 21 CFR 1301.13(d)), and not for only four months.

The Government ignores, however, that Due Process requires that when the Agency imposes conditions on a registration, those conditions must be ''sufficiently clear to inform'' a registrant as to ''what conduct will result in'' a violation. *United States* v. *Ashland, Inc.,* 356 F.3d 871, 874 (8th Cir. 2004) (citing *United States* v. *Guagliardo,* 278 F.3d 868, 872 (9th Cir. 2002)). Relatedly, the Government ignores that it never informed Respondent that the March 13, 2003 registration was issued by mistake. It also ignores that it was not until more than three years later that it informed Respondent of its view that the September 8, 2003 registration was ''the newly renewed registration'' which governed the duration of his obligation to file the drug activity logs.

Respondent therefore cannot be held to have violated the 2002 Order because he failed to file the drug activity logs after December 31, 2002. Respondent did, however, violate the Order because he did not file the logs even during the period when it was clear that he was required to do so.

As found above, the record also establishes that Respondent did not report the 2005 Board proceeding to the Agency. Respondent offers three arguments in response. First, relying on the 2002 Order's mistaken reference to ''any action taken * * * upon his medical license,''[21] he contends that he ''has never held a medical license,'' and that ''[t]he [S]tate of Virginia has never taken any action against [his] non-existent medical license.'' Resp. Br. at 21.

The argument is too clever by half. Precisely because Respondent has never held a medical license, and the prior DEA proceeding discussed an action by the State Board of Dentistry which imposed conditions on his dental license, *see* RX 42, at 13–14, Respondent had ample reason to know that the 2002 Order had mistakenly referred to his ''medical license'' and that the purpose of the condition was to require him to report any action taken upon his dental license.

Next, Respondent contends that the 2005 Board action ''occurred long after [his] duty to report to the DEA lapsed.'' Resp. Br. at 21. However, in contrast to the other two conditions it imposed, the 2002 Order did not limit the duration that this condition would be in effect. *See* GX 3, at 6–7. This is hardly surprising given that at the time the Order was issued, the State Board had placed him on probation ''INDEFINITELY'' and had imposed various conditions. *See* GX 7, at 4–5. Nor is it surprising given Respondent history of non-compliance with the Board's orders. Most significantly, the 2002 DEA Order was ''sufficiently clear to inform'' Respondent as to his obligation to report the 2005 Board action. *Ashland,* 356 F.3d at 874.

Finally, Respondent maintains that he had no obligation to report the 2005 Board action because the Board ''took no action against [his] dental license'' and ''[h]e remained on probation throughout the relevant period.'' Resp. Br. at 21. In the 2005 proceeding, however, the Board (in addition to reprimanding and fining him), rejected Respondent's petition to terminate his probation, and again, continued his probation ''indefinitely.'' GX 9, at 3. Moreover, the Board stated that ''[v]iolation of this Order may constitute grounds for suspension or revocation of [Respondent's] license.'' *Id.* at 4. The Board's Order thus clearly constituted ''action taken by any State upon his * * * license.'' GX 3, at 7.

I therefore conclude that Respondent violated the terms of the Agency's 2002 Order by failing to report the 2005 Board action as well as by his failure to file the quarterly drug activity logs during the period between the issuance of the Order and December 31, 2002. These failures alone establish that Respondent has committed acts which ''render his registration * * * inconsistent with the public interest'' and which support the suspension or revocation of his registration. 21 U.S.C. 824(a). Moreover, even though Respondent's misconduct, which was the subject of the 2002 Order, occurred some time ago, it buttresses this conclusion. *See* 21 U.S.C. 823(f)(2) (directing the Attorney General to consider the registrant's experience in dispensing controlled substances).

Factor Five—Such Other Conduct Which May Threaten Public Health and Safety

Under this factor, the ALJ made extensive findings regarding the shortage of dentists in the region where Respondent practices and the percentage of his patients who come from underserved areas. The ALJ further noted that in *Pettigrew Rexall Drugs*, 64 FR 8855 (1999), a case involving a pharmacy, the Agency had considered that the ''pharmacy was located in an underserved community'' and that this was a factor that ''impacted the public interest.'' ALJ at 46 (citing 64 FR at 8860). The ALJ then reasoned that even though Respondent is not ''*physically* located in an underserved community * * * the focus should be on *who* is actually being served by the practice.'' *Id.* Because Respondent has 561 patients from underserved counties, and many of these patients have limited incomes, the ALJ concluded that this factor weighs

[20] Under the APA, Respondent's November 1999 renewal application provided authority only ''until the application ha[d] finally been finally determined by the agency.'' 5 U.S.C. 558(c). The final determination on this application was the 2002 Decision and Final Order which granted the application.

[21] *See also* RX 42, at 19 (ALJ' s recommended sanction that ''Respondent must inform the DEA of any action taken by any State upon his medical license'').

against the imposition of either a suspension or revocation of his registration. *Id.* at 48.

DEA has never applied this rule in a subsequent case, and I conclude that it would be ill-advised to extend it to the case of a prescribing practitioner. The public interest standard of 21 U.S.C. 823(f) is not a freewheeling inquiry but is guided by the five specific factors which Congress directed the Attorney General to consider; consideration of the socioeconomic status of a practitioner's patient population is not mandated by the text of either 21 U.S.C. 823(f) or 824(a)(4), which focus primarily on the acts committed by a practitioner.

Moreover, where, as here, the Government has made out a *prima facie* case that a practitioner has committed acts which render his registration inconsistent with the public interest, the relevant inquiry is (and the Agency's longstanding rule has been to examine) whether the practitioner has put forward ''sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility carried by such a registration.'' *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (citing cases). As noted in numerous cases, this inquiry looks to whether the registrant has accepted responsibility for his misconduct and undertaken corrective measures to prevent the re-occurrence of similar acts. Whether a practitioner treats patients who come from a medically underserved community or who have limited incomes has no bearing on whether he has accepted responsibility and undertaken adequate corrective measures.

Finally, contrary to the ALJ's understanding, extending the holding of *Rexall Pettigrew* would likely cause greater harm to the public interest. The diversion of prescription drugs has become an increasingly serious societal problem, which is particularly significant in poorer communities whether they are located in rural or urban areas. *See, e.g., George C. Aycock*, 74 FR 17529, 17544 n.33 (2009); *Laurence T. McKinney*, 73 FR 43260 (2008); *Paul H. Volkman*, 73 FR 30630 (2008); *Medicine Shoppe-Jonesborough,* 73 FR at 363. *See also* U.S. General Accounting Office, *PRESCRIPTION DRUGS: OxyContin Abuse and Diversion and Efforts to Address the Problem* 31–32 (Dec. 2003) (noting that ''the Appalachian region, which encompasses parts of Kentucky, Tennessee, Virginia, and West Virginia, has been severely affected by prescription drug abuse, particularly pain relievers * * * for many years''). The residents of this Nation's poorer areas are as deserving of protection from diverters as are the citizens of its wealthier communities, and there is no legitimate reason why practitioners should be treated any differently because of where they practice or the socioeconomic status of their patients.[22] I thus conclude that this factor does not support the continuation of Respondent's registration.

Sanction

Where, as here, the Government has made out a *prima facie* case that a practitioner has committed acts which render his registration inconsistent with the public interest, the practitioner must put forward ''sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility carried by such a registration.'' *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (citing cases). As noted in numerous cases, this inquiry looks to whether the registrant has accepted responsibility for his misconduct and undertaken corrective measures to prevent re-occurrence of similar acts.

As found above, Respondent violated the terms of the restricted registration which the Agency granted him by failing to submit a quarterly drug activity log during the four- month period over which there is no dispute that he was required to submit the log. Moreover, Respondent failed to report the 2005 Board Action. When coupled with the acts which gave rise to the 2002 Order, Respondent has demonstrated a disturbing record of non-compliance with both State and Agency requirements.

Respondent's evidence regarding his acceptance of responsibility is equivocal. While it appears that Respondent started sending in drug logs upon receipt of the ALJ's 2001 decision, he offered no explanation as to why he stopped upon receiving the 2002 Order. Moreover, while I acknowledge that a registrant can in good faith dispute whether a regulatory provision requires certain action, Respondent's arguments with respect to his failure to report the 2005 Board action (*e.g.*, that the Order did not apply to him because he has a dental license and that the State took no action against him when it rejected his petition to terminate and continued his probation) were generally disingenuous.

I acknowledge that Respondent also instituted corrective measures to improve his documentation of his prescribing practices, including bringing in a consultant to audit his records.[23] I also note that there is no evidence that Respondent has prescribed controlled substances without ''a legitimate medical purpose.'' 21 CFR 1306.04(a). I therefore conclude that the record as a whole does not support the revocation of Respondent's registration.

However, Respondent has a lengthy history of non-compliance with both DEA and State requirements and did not appreciate the forbearance which this Agency exercised in the 2002 Order. Moreover, in light of the wording of the 2002 Order and the circumstances surrounding the issuance of the registration certificate in March 2003, Respondent has not been required to comply with the intended requirements of that Order. I therefore conclude that Respondent should be granted a new registration subject to the following conditions.

(A) Respondent shall submit to the local DEA office, a drug activity log on a quarterly basis, no later than twenty (20) days from the last day of the quarter which shall be March 31, June 30, September 30, and December 31 of each calendar year. Each log must contain

[22] It is acknowledged that there is no evidence that Respondent has diverted controlled substances. However, in assessing what sanction to impose, the Agency already considers the extent and egregiousness of a practitioner's misconduct. Accordingly, it is not clear what principle exists for determining when evidence that a practitioner treats underserved patients should be considered and when it should not be.

Beyond this, the ALJ's reasoning suggests how unworkable applying this standard would be. As she explained: ''the focus should not simply be on whether a dental practice is *physically* located in an underserved community; this is simply too narrow a view. Rather, the focus should be on *who* is actually being served by the practice.'' ALJ at 46. The ALJ then noted that 561 of his patients (notably, only about ten percent of his patients) were from underserved areas, and that a majority of his patients have limited finances.

The ALJ's reasoning begs the question of how many patients from underserved areas would a practitioner have to treat to claim the benefit of the rule. As for her reliance on the fact that a majority of Respondent's patients have limited incomes, determining what constitutes a patient with a limited income or finances and how many patients (or what percentage of patients) a practitioner must have to claim entitlement to this rule, would inject a new level of complexity into already complex proceedings and take the Agency far afield of the purpose of the CSA's registration provisions, which is to prevent diversion. Finally, while I decline to extend the *Pettigrew* rule to prescribing practitioners, I further note that Respondent offered no evidence that he charges his patients who have ''limited finances'' lower fees for his services.

[23] In setting this sanction, I place no weight on the DI's testimony that during the 2006 inspection, he found seven discrepancies between the drug activity logs and Respondent's patient records because the discrepancies did not involve the period in which it is clear that Respondent had an obligation to maintain the logs. I also place no weight on Respondent's evidence regarding the drug logs he eventually submitted for the period in which the requirement clearly applied. Even were I to ignore that the logs were submitted years late, because Respondent did not submit copies of these documents for the record, it is unclear whether they contained all of the information required by the 2002 Order.

the following: (1) The date that a controlled substance was administered, or dispensed (whether by prescription or actual delivery of the drug); (2) the name of the patient to whom a controlled substance was administered or dispensed (whether by prescription or actual delivery); (3) the patient's dental complaint; (4) the name, dosage, and quantity of the substance prescribed, dispensed or administered; and (5) the date that the medication was previously prescribed, dispensed or administered to that patient if the medication was prescribed, dispensed or administered in the last year, as well as the amount last provided to that patient. If no controlled substances are prescribed, administered, or dispensed during a given quarter, Respondent shall submit a letter to the DEA office indicating that there was no activity to report during the quarter.

(B) Within 15 days of the event, Respondent shall inform the local DEA office of any proceeding initiated against him by a State licensing board, whether the board regulates his professional practice or his authority to prescribe controlled substances. In addition, within 15 days of the event, Respondent shall inform the local DEA office of any interim or final order of a State licensing board which imposes a sanction, whether the sanction be a reprimand, a fine, a civil penalty, a probationary period, a rejection of a petition for termination of probation, an imposition of a condition, a suspension, or a revocation of any State professional license or authority to prescribe a controlled substance.

(C) In the event that Respondent changes employment during this three-year period, he shall immediately notify the local DEA office that is monitoring his drug activity logs.

To ensure that there is no confusion as to the duration of these conditions, all three conditions shall remain in effect for a period of three years from the date of this Order's publication in the **Federal Register**.

Moreover, because Respondent has not previously appreciated the seriousness of these proceedings and his obligation to comply with the CSA, the Agency's rules, and the conditions imposed pursuant to the 2002 Order, I further conclude that a period of outright suspension of his registration is warranted. Accordingly, while I grant Respondent a new registration, said registration will be suspended outright for a period of three months.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823 and 824, as well as 28 CFR 0.100(b) and 0.104, I hereby order that the application of Gregory D. Owens, D.D.S., to renew his DEA Certificate of Registration, be, and it hereby is, granted subject to the conditions set forth above. I further order that the DEA Certificate of Registration issued to Gregory D. Owens, be, and it hereby is, suspended for a period of three months from the effective date of this Order. This Order is effective August 24, 2009.

Dated: July 16, 2009.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–59]

Roy E. Berkowitz, M.D.; Revocation of Registration

On August 26, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Roy E. Berkowitz, M.D. (Respondent), of Slidell, Louisiana. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BB0492912, as a practitioner, and the denial of any pending applications to renew or modify his registration, on the grounds that Respondent does ''not have authority to prescribe controlled substances in the State of Louisiana,'' and that his ''continued registration is inconsistent with the public interest.'' Show Cause Order at 1.

More specifically, the Show Cause Order alleged that as a result of prescriptions for controlled substances which Respondent issued in 2006 and 2007 that were inconsistent with State rules and regulations, Respondent entered into a Consent Order with the Louisiana State Board of Medical Examiners, which ''strips [Respondent] of authority to handle controlled substances in the State of Louisiana, the state in which [he is] registered with DEA.'' *Id.*

Respondent requested a hearing on the allegations, and the matter was assigned to an Administrative Law Judge (ALJ), who commenced pre-hearing procedures. Thereafter, the Government moved for summary disposition on the ground that Respondent ''currently lacks authority to handle controlled substances in the State of Louisiana—his state of registration.'' Gov. Mot. at 1.

In support of its motion, the Government attached a declaration of a DEA Diversion Investigator (DI). Therein, the DI stated that on October 15, 2008, she had queried the Louisiana State Board of Pharmacy's Web site to determine Respondent's license status, and found that ''the Controlled Dangerous Substance license #33853 of Roy E. Berkowitz, M.D. was delinquent, having expired on September 25, 2008.'' *Id.* at Appendix I.

The ALJ allowed the Respondent to file a response to the motion through October 30, 2008. Moreover, on October 29, 2008, the ALJ granted Respondent an extension of the due date until November 6, 2008, on which date Respondent filed his response.

Therein, Respondent noted that while the Show Cause Order had relied on the State Board's Consent Order, the motion for summary disposition relied on a ''declaration * * * asserting that a license issued by the Louisiana Board of Pharmacy to [Respondent] expired on September 25, 2008.'' Resp. at 1. Respondent maintained that the Government was improperly changing its theory of the case, and argued that ''[t]he DEA without leave to amend the Order to Show Cause has sought to change the underlying basis of the case.'' [1] *Id.* at 2–3.

Next, Respondent argued that the Agency lacks authority to revoke his registration because in his view, 21 U.S.C. 824(a)(3) requires *both* a suspension, denial or revocation of the state license or registration, and that the practitioner no longer be authorized by state law to handle controlled substances. *Id.* at 3–4. In support of his contention, Respondent attached his declaration in which he stated that he submitted his application for renewal of his Louisiana Controlled Dangerous Substance License in July 2008, and that he was ''advised by the Louisiana Board of Pharmacy that this agency was unable to process'' his application. *Id.,* Ex. A at 1. The declaration further asserted that the Louisiana Board of Pharmacy ''did not enter an order'' denying, suspending or revoking Respondent's application. *Id.* at 1–2. Thus, Respondent argued that the Government's motion should be denied ''[b]ased upon a failure to establish the elements required under 21 U.S.C. 824(a)(3) and 21 U.S.C. 824(a)(4).'' Resp. at 5.

On January 27, 2009, the ALJ issued her Opinion and Recommended

[1] Respondent also invoked the ''mend the hold doctrine,'' an obscure common law rule which prohibits a party to a contract from changing its position on the contract's meaning during the course of litigation over it. *Id.* at 3 (citing *Utica Mut. Ins. Co.* v. *Vigo Coal Co., Inc.,* 393 F.3d 707, 716 (7th Cir. 2004)). Specifically, Respondent contended that the Government's reliance on the expiration of Respondent's lack of a state controlled substance license was ''analogous to an attempt to mend the hold,'' presumably because the Show Cause Order had cited the consent agreement rather than the expiration. *Id.* at 3 (citation omitted). Respondent did not renew this argument in his exceptions, and in any event, the analogy is misplaced.