

operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) The quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country(ies)* since the *Order Date*, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country(ies)*, and such merchandise from other countries.

(13) (Optional) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry*; if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: These reviews are being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.61 of the Commission's rules.

By order of the Commission.

Issued: July 24, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012-18441 Filed 7-31-12; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Pistoia Alliance, Inc.

Notice is hereby given that, on June 29, 2012, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Pistoia Alliance, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Certara L.P. Portugal, Funchal, Madeira, PORTUGAL; Deloitte Consulting LLP, New York, NY; Mary Chitty (individual member), Needham, MA; and Hewlett-Packard Company, Palo Alto, CA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Pistoia Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On May 28, 2009, Pistoia Alliance, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 15, 2009 (74 FR 34364).

The last notification was filed with the Department on April 17, 2012. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on May 14, 2012 (77 FR 28404).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2012-18769 Filed 7-31-12; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11-45]

Decision and Order; Perry T. Dobyns, M.D.

On November 2, 2011, Administrative Law Judge (ALJ) Gail A. Randall issued the attached recommended decision. Therein, the ALJ found that while the Government had established grounds for

denying Respondent's application, ALJ at 22, Respondent has been sober since December 2008, that he has been in compliance with his Indiana Physicians' Assistance Program Continuing Care Contract since November 2009, *id.* at 20, and that he "has consistently taken responsibility for his misconduct." ¹ *Id.* at 21. The ALJ thus recommended that Respondent be granted a restricted registration subject to multiple conditions. The Government did not file exceptions to the ALJ's decision.²

Having reviewed the record, I have decided to adopt the ALJ's findings of fact, conclusions of law, and recommended Order. Accordingly, I will order that Respondent be granted a registration subject to the following conditions:

(1) Respondent shall be limited to prescribing controlled substances and may not administer or dispense directly any controlled substances. In addition, Respondent may not order any controlled substances or accept any samples of controlled substances. If Respondent is employed at a practice in which controlled substances are stored on the premises, Respondent shall not have access to the cabinet in which the controlled substances are stored. Respondent shall inform any medical practice at which he becomes employed of this restriction on his registration.

(2) Respondent is prohibited from prescribing controlled substances to himself or any family member.

(3) Respondent shall maintain a log of all controlled substance prescriptions he authorizes and shall file a report listing in chronological order all such prescriptions by date, and including the following information: the name and address of the patient, name and dosage of the drug, quantity of the drug, and number of refills authorized. Each report shall be filed with the local DEA field office no later than ten (10) calendar days after the end of the previous quarter, *e.g.*, April 10 (for the quarter ending on March 31), July 10

¹ No evidence was put forward showing that Respondent diverted controlled substances to others.

² In its post-hearing brief, the Government cites a prior decision of this Agency, which after having already ordered that the practitioner's application be granted, then noted "evidence of the community's need for a physician of his specialty with prescribing capabilities." Gov. Br. 11 (quoting *David M. Headley*, 61 FR 39469, 39471 (1996)). However, the Agency has since held in multiple cases that community impact evidence is not relevant in the public interest determination and provided an extensive explanation as to why. See *Linda Sue Cheek*, 76 FR 66972, 66973 (2011); *Mark De La Lama*, 76 FR 20011, 20020 n.20 (2011); *Bienvenido Tan*, 76 FR 17673, 17694 n.58 (2011); *Gregory D. Owens*, 74 FR 36571, 36757 & n.22 (2009).

(for the quarter ending on June 30), October 10 (for the quarter ending on September 30), and January 10 (for the quarter ending on December 31). If Respondent issues no controlled substance prescriptions during a quarter, a report indicating that no prescriptions were issued shall also be filed no later than ten (10) calendar days following the end of the quarter.

(4) If Respondent opens his own practice, he shall consent to unannounced inspections by DEA personnel of any medical office he maintains and shall waive his right to require DEA personnel to obtain an Administrative Inspection Warrant prior to conducting an inspection.

(5) Respondent shall enter into an agreement with the Indiana Physicians' Assistance Program pursuant to which he agrees *that it shall* disclose any violation of the conditions of his contract (including any failed drug screens) to the local DEA field office. In the event Respondent tests positive for a drug for which he does not hold a valid prescription, or fails to report for drug screening upon being ordered to do so, such acts shall constitute grounds for the *immediate suspension* of his registration.

(6) Respondent shall report to the local DEA field office any relapse within forty-eight hours of such occurrence.

(7) These conditions shall remain in effect for a period of three years, except that in the event Respondent successfully completes his contract with the Indiana Physicians' Assistance Program, condition number five shall terminate upon completion of said contract. However, if said contract is renewed, condition number five shall continue in effect until three years from the date of issuance of this registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Perry T. Dobyns, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, granted, subject to the conditions set forth above. This Order is effective immediately.

Dated: July 24, 2012.

Michele M. Leonhart,
Administrator.

D. Linden Barber, Esq., and

Jonathan P. Novak, Esq., for the
Government

Robert E. Saint, Esq., for the
Respondent

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

I. PROCEDURAL BACKGROUND

Gail A. Randall, Administrative Law Judge. The Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration ("DEA" or "Government"), issued an Order to Show Cause ("Order") dated March 7, 2011, proposing to deny the DEA Certificate of Registration application of Perry T. Dobyns, M.D., ("Respondent"), as a practitioner, pursuant to 21 U.S.C. § 823(f) (2006), because to grant the Respondent's registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). [Administrative Law Judge Exhibit ("ALJ Exh.") 1 at 1].

The Order alleged that on June 25, 2010, the Respondent submitted an application for a DEA registration as a practitioner with authority to handle controlled substances in Schedules II–V. [*Id.*].

The Order further alleged that the Respondent had entered into an agreement with the North Carolina Medical Board in 2007, because of his misuse of drugs, including controlled substances. The Respondent also agreed not to use mood-altering drugs that had not been prescribed to him by a physician. However, a urine screen submitted on October 31, 2008, tested positive for tetrahydrocannabinol, indicating that he had unlawfully possessed and used a Schedule I controlled substance. Further, the Respondent's urine screen submitted on November 22, 2008, tested positive for oxycodone and oxymorphone, indicating that he had unlawfully possessed and consumed two Schedule II controlled substances. [*Id.*].

Next, the Order asserted that, on December 2, 2008, the Respondent forged a prescription for oxycodone in order to illegally obtain this Schedule II controlled substance. He filled this prescription. [ALJ Exh. 1 at 2].

The Order noted that, on August 3, 2010, the Respondent was interviewed by DEA personnel, and he admitted that: (a) in 2002 the Respondent was admitted to a hospital due to abuse of alcohol and narcotics, and he subsequently entered into an agreement with the Indiana State Medical Association's Physicians Assistance Program; (b) in 2008, the Respondent had used narcotics that had been prescribed to one of his family members; (c) in September of 2008, he smoked marijuana; and (d) in late 2008,

he issued a forged prescription for oxycodone to himself. [*Id.*].

Lastly, the Order asserts that the Respondent returned to Indiana in June of 2010, and began practicing medicine. Although he did not possess a DEA registration, on November 15, 2010, the Respondent or his medical office staff issued two prescriptions for controlled substances using an electronic prescribing program. [*Id.*].

The Deputy Assistant Administrator then gave the Respondent the opportunity to show cause as to why his application should not be denied on the basis of those allegations. [*Id.* at 2].

On April 25, 2011, the Respondent¹ filed a request for a hearing in the above-captioned matter. [ALJ Exh. 2].

On May 31, 2011, the Government filed Government's Motion to Terminate Proceeding Due to Untimely Request for Hearing, [Motion]. [ALJ Exh. 3]. On June 17, 2011, I denied the Government's Motion. [ALJ Exh. 5].

On July 20, 2011, Jonathan P. Novak entered his appearance on behalf of the Government in the above captioned matter. [ALJ Exh. 6].

The hearing was conducted on August 23, 2011, in Lafayette, Indiana. [ALJ Exh. 7]. At the hearing, counsel for the DEA called one witness to testify and introduced documentary evidence. The Respondent testified and introduced documentary evidence. [Transcript ("Tr.") Volume I].

After the hearing, the Government submitted Proposed Findings of Fact, Conclusions of Law and Argument ("Govt. Brief"). The Respondent also submitted Proposed Findings of Fact, Conclusions of Law and Argument ("Resp. Brief").

II. ISSUE

The issue in this proceeding is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration ("DEA" or "Government") should deny the application for a DEA Certificate of Registration, of Perry T. Dobyns, M.D., ("Respondent"), as a practitioner, pursuant to 21 U.S.C. § 823(f) (2006), because to grant his application would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). [ALJ Exh. 4; Transcript ("Tr.") at 8].

¹ On May 26, 2011, the Respondent filed his Pre-Hearing Statement. Mr. Saint entered his appearance by filing this document.

III. FINDINGS OF FACT

A. Stipulated Facts

The parties have stipulated to the following facts:

1. Respondent applied for a DEA registration on June 25, 2010. [Government Exhibit (“Govt. Exh.”) 1].
2. Respondent previously held a DEA registration but allowed it to expire without renewal in 2009.
3. Respondent was hospitalized for alcohol and drug abuse in 2002, and entered into the Physicians Assistance Program in Indiana because of his abuse of alcohol and narcotic controlled substances.
4. In 2007, Respondent entered an agreement with the North Carolina Physicians Health Program that required him to submit to drug testing.
5. In the fall of 2008, Respondent unlawfully possessed marijuana, oxycodone and oxycodone, and used these drugs.
6. On October 31, 2008, Respondent tested positive for marijuana in a drug test performed under his agreement with the North Carolina Physicians Health Program.
7. On November 22, 2008, Respondent tested positive for oxycodone and oxycodone in a drug test performed under his agreement with the North Carolina Physicians Health Program.
8. On December 2, 2008, Respondent filled a prescription for oxycodone which he had forged using the name and DEA number of another physician. [ALJ Exh. 4].

B. Respondent’s Addiction History

In late 2001, the Respondent’s medical practice in Oklahoma was failing. The Respondent’s alcohol intake increased at home, and he began taking a controlled substance, hydrocodone, “to help (him) during the day.” [Tr. 44]. The Respondent used hydrocodone samples given to the clinic by drug representatives. [Tr. 45]. He failed to maintain distribution records for these controlled substances. [Tr. 88].

In 2002, the Respondent moved to Indiana. He continued to drink during the night and use narcotic prescription medications during the day. [Tr. 44–45]. The narcotics were taken from the practice’s sample cabinet. [Tr. 46]. In November of 2002, the Respondent’s “depression, exacerbated by the alcohol and drug dependence, came to an extreme, and (he) attempted suicide.” [Tr. 46]. His employers at the Harrison Family Practice referred him to the Indiana Physician Assistance Program, (PAP), who recommended that he seek inpatient treatment. [Tr. 46–47].

In late 2002, the Respondent was admitted to the Rush Memorial Behavioral Health program in Chicago, Illinois, which was a specific program for impaired physicians. [Tr. 47]. The Respondent attended this in-patient program for 10 weeks. [Tr. 20, 47, 87]. He was initially diagnosed as chemically dependent on opiates and alcohol along with a diagnosis of depression. [Respondent’s Exhibit (“Resp. Exh.”) D].

The Respondent enrolled in the Indiana PAP and signed a Continuing Care Contract (“Contract”). [Tr. 48; Resp. Exh. D]. He was required to have regular contact with the PAP through in-person meetings in Indianapolis. [Tr. 48]. He was also required to attend regular meetings of Alcoholics Anonymous or Narcotics Anonymous three times per week. [Id.]. He was also to attend weekly meetings of the Caduceus Group, a treatment group for doctors with substance abuse issues, in Indianapolis. [Id.]. The Contract also required the Respondent to participate in random urine drug screens. [Tr. 48–50]. While in Indiana, the Respondent remained in compliance with the Contract. [Tr. 49].

In 2007, the Respondent moved to North Carolina, enrolled in the North Carolina PAP, and signed a new five-year contract. [Tr. 51; Resp. Exh. D]. Similar to the Indiana PAP, this program is intended to “help[] physicians overcome an addiction issue.” [Tr. 19]. As a requirement of this program, the Respondent was to refrain from consuming any controlled substances that were not legitimately prescribed to him or given to him for medical purposes. [Tr. 20]. He was also to submit to urine drug screens as dictated to by the program. [Id.].

While in North Carolina, the Respondent worked in Chapel Hill during the week and spent his weekends in Fayetteville with his family. [Tr. 52–53]. He was also caring for his dying brother. [Tr. 53]. The stress of caring for his brother contributed to his relapse. [Tr. 21–22]. This was his first relapse since beginning the recovery process in 2002. [Tr. 22, 93]. The Respondent’s brother used medical marijuana, and the Respondent used it in October of 2008. [Tr. 53–54]. The Respondent also consumed oxycodone from his brother’s prescription, and subsequently he issued a prescription to himself using another doctor’s DEA number. [Tr. 22]. This doctor did not know of the Respondent’s conduct until the DEA informed him. [Tr. 22]. The Respondent also wrote a prescription for his sister using his DEA registration and

consumed the controlled substances himself. [Tr. 94].

The Respondent then had a positive drug screen for marijuana in October of 2008, and another positive drug screen for oxycodone and oxycodone in November of 2008. [Tr. 55–56, 88–89]. The North Carolina PAP reported these positive test results to the North Carolina Medical Board. [Tr. 56]. Ultimately, the Respondent’s North Carolina medical license was indefinitely suspended. [Tr. 22].

The DEA did not know about the Respondent’s sobriety between November of 2008 until November of 2009, when he reentered the Indiana Physician Assistance Program. [Tr. 31, 58]. He then applied to renew his Indiana medical license. On the application for such renewal, the Respondent disclosed the action that had been taken against his North Carolina medical license. [Tr. 58–59]. The Indiana Medical Board renewed the Respondent’s medical license with probationary conditions. [Tr. 23]. In August and December of 2009, those terms and conditions were altered slightly. [Resp. Exh. A]. The Respondent is to remain compliant with the Indiana’s Physician Assistance Program (PAP), and he is to notify the Indiana Medical Board within twenty-four hours of any relapse. [Tr. 23]. The Respondent is only allowed to work a forty hour work week, and, prior to the Board’s removal of this condition, there had to be another physician on-site when the Respondent was working. The Respondent has remained compliant with the terms of his probation. [Tr. 23, 28].

On November 23, 2009, the Respondent signed a second Continuing Care Contract with the Indiana PAP. [Resp. Exh. D]. This is a five-year agreement. [Id.]. The Respondent agreed, among other provisions, to participate in supervised urine/hair/blood drug screens, and agreed to abstain from mood-changing chemicals except those prescribed by a treating physician. [Id.]. In the event of a relapse, the Respondent is to notify the PAP. [Id.]. The Respondent also agreed to attend Caduceus meetings and to attend “mutual self-help meetings” such as AA or NA at a frequency of three times per week. [Tr. 68; Resp. Exh. D]. The Respondent also agreed to attend individual therapy bi-weekly for a period of time and to see a psychiatrist for medication management. [Resp. Exh. D; Tr. 69–70].

In August of 2010, Diversion Investigator (DI) Gary L. Whisenand² interviewed the Respondent. [Tr. 19]. I find DI Whisenand's testimony consistent with the documentary exhibits and credible. DI Whisenand credibly testified that Indiana's Physician Assistance Program was a reliable program that cooperated with the DEA. [Tr. 30]. During the interview with DI Whisenand, the Respondent admitted to smoking marijuana and consuming oxycodone. [Tr. 21, 84]. The Respondent had explained that he had moved to North Carolina to care for an ailing brother, who had Stage IV lung cancer, and the stress of tending to his brother had caused the Respondent to relapse. [Tr. 21–22]. This was his first relapse since beginning the recovery process in 2002. [Tr. 22, 93].

Dr. Fred W. Frick submitted an affidavit in this proceeding. [Resp. Exh. D]. Dr. Frick is board certified in internal medicine with an extensive record as an addictionologist. [Id.]. Since 2004, he has been the contract Medical Consultant and Director of the Indiana State Medical Association's Physicians Assistance Program. [Id.]. He explained that the PAP "is currently recognized as an acceptable monitoring and advocacy program by the Indiana Medical Licensing Board." [Id.]. Dr. Frick oversees the program, "which directs the monitoring and advocacy for chemically dependent physicians in the State of Indiana." [Id.]. Dr. Frick was familiar with the Respondent's history of drug use and addiction. [Id.].

Dr. Frick wrote that each of the Respondent's drug screens have been negative since November 23, 2009, except for the presence of Ultram, "which was prescribed for Dr. Dobyns by a treating physician." [Id.]. Lastly, Dr. Frick wrote that to the best of his knowledge, the Respondent "has been compliant with all other aspects of his Continuing Care Contract since November 23, 2009." [Id.].

C. Respondent's DEA Application

In his DEA application, the Respondent disclosed that his North Carolina medical license had been placed on indefinite suspension. [Tr. 18; Govt. Exh. 1]. No charges are pending before the North Carolina medical board. [Govt. Exh. 1]. The Respondent also disclosed that he had had a positive drug test in 2008. [Id.].

The Respondent also disclosed that he had applied to renew his medical license in Indiana, and that the Indiana Medical Board agreed to do so on a

probationary basis. [Id.]. The Respondent agreed to participate in the Indiana State Medical Association's Physician Assistance Program (PAP). [Id.]. The Respondent also wrote that his participation in Indiana has continued to the date of his application without incident. [Id.].

D. Electronic Prescriptions

In June of 2010, the Respondent accepted a position at the Madison County Health Center ("Center") as a staff physician. [Tr. 75]. He made a full disclosure to that employer about his drug use history. [Tr. 62]. There, if a patient needed controlled substances, the Respondent would take a medical history, perform a physical examination, and determine whether the prescription was appropriate for the patient. [Tr. 64]. At that point, the Respondent would refer the patient to the Center's medical director for issuance of the controlled substance prescription. [Id.].

The DEA received two electronic prescriptions for controlled substances written under the Respondent's name and dated in November of 2010. [Tr. 26–28; Govt. Exh. 2]. These prescriptions contained the Respondent's electronic signature. [Tr. 31]. These two prescriptions were for a patient who had seen the Respondent's supervisory physician previously, and she was issued these two prescriptions for ongoing treatment of chronic pain and anxiety. [Tr. 78].

At the time of these prescriptions, the Respondent was working at the Center. [Tr. 75]. The Center had an electronic medical records system. [Tr. 31, 65]. The default for the Respondent was for the system to send prescriptions to the printer for the Respondent to then take to the medical director to issue. [Tr. 65].

The two electronic prescriptions for controlled substances were inadvertently sent by the system to the facsimile machine rather than to the printer. As soon as the Respondent became aware of the computer error, he took corrective action. He credibly testified that "the measure that we took was to disconnect the fax function from the computer entirely so that the computer could no longer physically access the fax line." [Tr. 67]. It was DI Whisenand's assumption that the Respondent's electronic signature was affixed by that system. [Tr. 32]. The prescriptions were then faxed to a pharmacy by the electronic medical records system without the Respondent's knowledge. [Tr. 33]. DI Whisenand credibly testified that he did not have any evidence that the Respondent knowingly transmitted controlled substance prescriptions via

facsimile to a pharmacy. [Tr. 35]. After this time, DI Whisenand never received any complaints from a pharmacy or a pharmacy worker regarding the Respondent. [Tr. 34].

E. Respondent's Current Situation

The Respondent received his medical degree with honors in 1995 from the University of Tennessee at Memphis, Tennessee. [Tr. 42]. The Respondent completed a residency in family medicine in 1997, and he became board certified by the American Board of Family Practice the same year. [Tr. 43]. In 2005, the Respondent recertified for a ten-year period. [Id.]. However, due to the North Carolina action against his medical license, his certification was invalidated. [Id.].

The Respondent has been clean and sober since December 20, 2008. [Tr. 98]. The Respondent is unemployed, and he does not have a DEA registration number. [Tr. 24–25]. The Respondent is currently active in AA and has a sponsor. [Tr. 70–71]. He attends at least two meetings a week with his sponsor and engages in one or two phone calls during the week. [Tr. 71].

The Respondent currently has an active, in all substances, controlled substances registration with Indiana. [Tr. 40, 61–62]. He also has an active Indiana medical license which is on probation. [Tr. 40–41; Resp. Exh. A]. In July of 2011, the Indiana Medical Board modified the Respondent's probationary conditions of December 2009. [Resp. Exh. C]. Currently the Respondent's probationary conditions include: (a) the Respondent must maintain and remain in compliance with a contract from the Indiana PAP; (b) the Respondent shall report any relapse regarding chemical dependency to the Board within twenty-four hours; (c) the Respondent shall not work more than forty hours a week and for the next year shall submit quarterly written reports to the Board from his employer concerning his employment, and from the Respondent concerning his DEA status; and (d) the Respondent shall comply with the statutes and rules governing the practice of medicine. [Resp. Exh. B; Resp. Exh. C].

In April of 2011, the Respondent was discharged from the Center. The primary reason for that action was the difficulties experienced by the Center in handling the Respondent's lack of a DEA registration. [Tr. 67].

The Respondent credibly testified that he has never had a medical malpractice judgment entered against him, he has never settled a medical malpractice claim, and that the disclosed adverse actions taken against his medical license

² DI Whisenand has been a DEA diversion investigator for just over six years. [Tr. 15].

were the only such actions taken. [Tr. 67–68].

Today, the Respondent's North Carolina medical license is indefinitely suspended. [Tr. 56]. The Respondent does not plan to return to North Carolina. [Tr. 56]. The Respondent intends to become gainfully employed as a physician in Indiana. [Tr. 71]. Without a DEA registration, the Respondent is not able to have a meaningful medical practice. [Tr. 72]. The Respondent is not seeking any employment where he would have access to mood altering substances on the worksite. [Tr. 96].

IV. STATEMENT OF LAW AND DISCUSSION

A. Position of the Parties

1. Government's Position

The Government asserts that the appropriate remedy in this matter is denial of the Respondent's application. [Govt. Brief at 12]. Looking to the factors defining the public interest, the Government first proposes that factor one is applicable, for the North Carolina licensing board has indefinitely suspended the Respondent's medical license. [Govt. Brief at 6]. Further, the State of Indiana only granted the Respondent a medical license with restrictions and monitoring requirements. [*Id.*]. The Government argues that such conditions reflect "a systematic concern for Respondent's professional and personal well-being. As such, this factor weighs in favor of denying Respondent's application for a DEA Certificate of Registration." [*Id.*].

As to factor two, the Government asserts that the Respondent admitted to a lengthy history of using illicit drugs for recreational purposes, and to obtaining controlled substances for personal use through illicit means. [Govt. Brief at 7]. Under this factor, the Government concludes that the "Respondent has shown a callous and cavalier attitude towards both using and prescribing controlled substances." [Govt. Brief at 8].

Under factor four, the Government asserts that the Respondent violated federal law when he fraudulently used a prescription pad belonging to another doctor to write a prescription for a controlled substance for himself. [*Id.*]. Also, the Respondent admitted to possessing and using marijuana that he obtained illicitly. [*Id.*]. Because of this conduct, the Government argues that factor four weighs heavily in favor of denying the Respondent's application. [Govt. Brief at 8–9].

Lastly, under factor five, the Government argues that the Respondent

has only been in monitored recovery for two years. [Govt. Brief at 10]. The Government notes that prior DEA precedent takes into account the length of time the Respondent has been in recovery. [Govt. Brief at 9]. Here, the Respondent had been clean and sober for six years before his relapse. In the context of this behavior, the Government argues that the Respondent's "risk of relapse should be considered high until such time (as) Respondent has shown a longer period of compliance with the restrictions of his substance abuse treatment by remaining sober, as well as a better understanding of the seriousness of his addiction and the danger it presents to himself and to others." [Govt. Brief at 10].

The Government also finds it significant that the Respondent failed to show any remorse or "even [an] understanding for the danger he presented to his patients by practicing under the influence of Schedule II narcotics." [*Id.*]. Therefore, the Government concludes, the Respondent's application should be denied. [Govt. Brief at 11–12].

In the alternative, the Government asserts, if the Respondent should be granted a restricted registration, the Government requests that (a) the Respondent's registration be limited to Schedule IV and V controlled substances only; (b) the Respondent be limited to prescribing controlled substances only, and not be authorized to prescribe to himself or any family members; (c) the Respondent shall only be authorized to obtain controlled substances from a treating practitioner who prescribes controlled substances to the Respondent for a legitimate medical purpose; (d) the Respondent maintain a prescription log which he would submit quarterly to the DEA; (e) Respondent shall consent to unannounced inspections without the need of an Administrative Inspection Warrant; and (f) the Respondent continue in his agreement with the Indiana PAP. [Govt. Brief at 12–13].

2. Respondent's Position

The Respondent asserts that granting his application would be in the public interest. [Resp. Brief at 11]. The Respondent argues that he has been in substantial compliance with his treatment for eight years except for a relapse during two months in 2008. [Resp. Brief at 10]. He notes that he has maintained an active probationary medical license in Indiana, and he has complied with the terms of that probation. [*Id.*]. The Respondent also

has an active Indiana Controlled Substance Registration. [*Id.*].

The Respondent next asserts that no evidence exists that the Respondent's medical care endangered patients or that his care deviated from any standard of care. [Resp. Brief at 11]. Instead, Respondent argues that his violations stemmed from his chemical dependency, which was exacerbated by unusual family circumstances, namely the terminal illness of his brother. [*Id.*]. Therefore, the Respondent proffers that the "issuance of a restricted registration" would resolve "[a]ny concern for the public health and safety" posed by the Respondent's violations. Lastly, the Respondent concludes that he should be granted a registration restricted as follows: (1) the Respondent must remain in compliance with the Indiana Continuing Care Contract; (2) and also with his probationary medical license; (3) and that the Respondent be required to immediately disclose any non-compliance with either of these two monitoring agreements. [*Id.*].

B. Statement of Law and Analysis

Pursuant to 21 U.S.C. § 823(f) (2006),³ 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 following factors are considered:

- (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.

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight she deems appropriate in determining whether a registration should be revoked or an application for registration be denied. See *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15,227, 15,230 (DEA 2003); *Henry J. Schwarz, Jr., M.D.*, 54 Fed. Reg. 16,422 (DEA 1989). Moreover, the Deputy

³ The Deputy Administrator has the authority to make such a determination pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2011).

Administrator is “not required to make findings as to all of the factors.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall v. DEA*, 412 F.3d 165, 173–74 (DC Cir. 2005).

The Government bears the burden of proving that the requirements for registration are not satisfied. 21 C.F.R. § 1301.44(d) (2011). The burden of proof shifts to the Respondent once the Government has made its *prima facie* case. See *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 380 (DEA 2008); see also *Thomas E. Johnston*, 45 Fed. Reg. 72,311 (DEA 1980).

DEA precedent has also held that “past performance is the best predictor of future performance.” *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995). Further, 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.” *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. at 387; see also *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (DEA 2007). In short, after the Government makes its *prima facie* case, the Respondent must prove by a preponderance of the evidence that he can be entrusted with the authority that a registration provides by demonstrating that he accepts responsibility for his misconduct and that the misconduct will not re-occur.

1. Recommendation of Appropriate State Licensing Board.

The DEA has long held that a practitioner’s reinstatement by a State board “is not dispositive,” because “DEA 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 granting of [a registration] would be in the public interest.” *Mortimer B. Levin, D.O.*, 55 Fed. Reg. 8,209, 8,210 (DEA 1990); see also *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459, 461 (DEA 2009). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.*, 72 Fed. Reg. 6,580, 6,590 (DEA 2007), *aff’d*, *Chein v. DEA*, 533 F.3d 828 (DC Cir. 2008). Although not dispositive, state board decisions are relevant on the issue of granting or denying a DEA application. See *Gregory D. Owens, D.D.S.*, 74 Fed. Reg. 36,751, 36,755 (DEA 2009); *Martha Hernandez, M.D.*, 62 Fed. Reg. 61,145, 61,147 (DEA 1997).

Here, the Indiana State Medical Board has not made a recommendation concerning the Respondent’s DEA application. The Respondent currently has an active, in all substances, controlled substances registration with Indiana. He also has an active Indiana medical license which is on probation. Nevertheless, the DEA has consistently held that a practitioner’s possession of State authority, while a prerequisite to registration, is not dispositive of the public interest determination. *Mark De La Lama, P.A.*, 76 Fed. Reg. 20,011, 20,018 (DEA 2011).

2. Applicant’s Conviction Record Relating to Controlled Substances, Experience With Controlled Substances And Compliance With Applicable State, Federal, Or Local Laws Relating To Controlled Substances.

The critical consideration in this proceeding is whether the circumstances that existed in 2008, have changed sufficiently to support a conclusion that Respondent’s registration would be in the public interest. See *Ellis Turk, M.D.*, 62 Fed. Reg. 19,603, 19,604 (DEA 1997). As this Agency has repeatedly held, a proceeding under the Controlled Substances Act “is a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused * * * their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility carried by such a registration.” *Jon Karl Dively, D.D.S.*, 72 Fed. Reg. 74,332, 74,334 (DEA 2007) (quoting *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (DEA 2007)).

As for Factor 3, the parties do not dispute that the Respondent has not been convicted of any offense relating to controlled substances. The Respondent also previously held a DEA registration but allowed it to expire without renewal in 2009.

In late 2001, the Respondent illegally used hydrocodone samples given to the clinic by drug representatives. He failed to maintain distribution records for these controlled substances. The Respondent continued this behavior of unlawful consumption of controlled substances through 2002.

In late 2002, the Respondent was hospitalized for alcohol and drug abuse. He was diagnosed as chemically dependent on opiates and alcohol. In March of 2003, when he completed the inpatient treatment, he entered the Physicians Assistance Program in

Indiana. He remained in compliance with his Contract during this time.

Under the Controlled Substances Act, it is “unlawful for any person knowingly or intentionally * * * to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.” 21 U.S.C. § 843(a)(3) (2006). In 2008, the Respondent began smoking marijuana and consuming other controlled substances unlawfully. The Respondent wrote a prescription for his sister, filled it, and consumed the controlled substances himself. He also wrote a prescription for controlled substances on another physician’s prescription pad, filled that prescription, and consumed those controlled substances. Subsequently the Respondent tested positive for marijuana use in October of 2008, and for oxycodone and oxymorphone in November of 2008. Such unlawful consumption of controlled substances weighs against the Respondent’s being granted a DEA registration.

Further, the Respondent’s use of another’s DEA registration to prescribe himself controlled substances is, itself, a violation of the Controlled Substances Act. See 21 U.S.C. § 843(a)(2) (2006) (“It shall be unlawful for any person knowingly or intentionally to use in the course of the * * * dispensing of a controlled substance * * * a registration number which is * * * issued to another person.”); see also *Patrick W. Stodola, M.D.*, 74 Fed. Reg. 20,727, 20,735–36 (DEA 2009); *Harrell E. Robinson, M.D.*, 74 Fed. Reg. 61,370, 61,376 (DEA 2009). This violation also weighs against the granting of the Respondent’s application for a DEA registration.

In June of 2010, a pharmacy received two electronic prescriptions for controlled substances electronically signed by the Respondent. The Respondent did not have a DEA registration. Such conduct also violates the Controlled Substances Act and its implementing regulations. See 21 U.S.C. § 841(a)(1) (2006) (“Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally to * * * dispense * * * a controlled substance.”); see also 21 C.F.R. § 1301.11 (2011) (requiring any person who dispenses a controlled substance to be registered unless exempted by law). However, I also note the nature of the offense, for the computer-generated prescriptions were sent to the facsimile machine in error. I also note that the Respondent took remedial actions to ensure such an error does not happen again. Further, although not an excuse

for this incident, I also note that the recipient of this prescription was being treated by the Respondent, who credibly testified that the prescriptions were issued for a legitimate medical purpose.

3. Other Factors Affecting the Public Interest

Another factor in this case is the fact that the Respondent unlawfully consumed controlled substances while caring for patients. Although this record contains no evidence of any harm coming to his patients, the fact that he was willing to risk such harm is inconsistent with the requirements of a DEA registrant.

Further, the DEA has long held that a practitioner's self-abuse of controlled substances constitutes "conduct which may threaten public health and safety." 21 U.S.C. § 823(f)(5) (2006); *see also Tony T. Bui, M.D.*, 75 Fed. Reg. 49,979, 49,990 (DEA 2010); *Kenneth Wayne Green, Jr., M.D.*, 59 Fed. Reg. 51,453 (DEA 1994); *David E. Trawick, D.D.S.*, 53 Fed. Reg. 5,326 (DEA 1988). Here, the Respondent self-abused hydrocodone products in 2001 and oxycodone products in 2008. Such unlawful ingestion of controlled substances, especially when a physician is caring for patients while under the influence of these drugs, places the public health and safety in jeopardy.

Yet, I found the Respondent credible when he testified that he has been drug free since December of 2008. He has remained active in his recovery, and his drug screens have been negative. As the Deputy Administrator has previously determined, "[t]he paramount issue is not how much time has elapsed since [the Respondent's] unlawful conduct, but rather, whether during that time [the] Respondent has learned from past mistakes and has demonstrated that he would handle controlled substances properly if entrusted with a DEA registration." *Leonardo V. Lopez, M.D.*, 54 Fed. Reg. 36,915 (DEA 1989). Even though it has been previously found that time, alone, is not dispositive in such situations, it is certainly an appropriate factor to be considered. *See Robert G. Hallermeier, M.D.*, 62 Fed. Reg. 26,818 (DEA 1997) (four years); *John Porter Richards, D.O.*, 61 Fed. Reg. 13,878 (DEA 1996) (ten years); *Norman Alpert, M.D.*, 58 Fed. Reg. 67,420, 67,421 (DEA 1993) (seven years).

Here, the Respondent's Indiana medical license requires him to remain compliant with the Indiana's Physician Assistance Programs' Continuing Care Contract. The Respondent signed that five-year contract in November of 2009. The contract provides for supervised drug screens, and in the event of a

relapse, the Respondent is to notify the Indiana PAP. The Respondent agreed to attend Caduceus meetings, AA or NA meetings, to receive counseling, to abstain from consuming nonprescribed mood-changing chemicals, and to see a psychiatrist for medication management. The Medical Director, Dr. Frick, affirmed that the Respondent has been compliant with these requirements, and that his drug screens have been negative since November 23, 2009. The Respondent credibly testified that he has been clean and sober since December 20, 2008. This past conduct demonstrates the Respondent's ability to comply with his PAP contract and to continue to perform his daily functions drug-free.

After the Government "has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.'" *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (DEA 2008) (quoting *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (DEA 2007). "Moreover, because 'past performance is the best predictor of future performance,' *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. at 387; *see also Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23, 848, 23,853 (DEA 2007); *John H. Kennedy, M.D.*, 71 Fed. Reg. 35,705, 35,709 (DEA 2006); *Prince George Daniels, D.D.S.*, 60 Fed. Reg. 62,884, 62,887 (DEA 1995). *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).

Here, the Respondent has consistently taken responsibility for his misconduct. He disclosed his misconduct to the Indiana medical board and to the DEA in his applications and in his testimony at this proceeding. Further, requirements are in place to ensure the public interest is protected from the possibility of relapse by the Respondent. First, early detection will take place because of the urine screens and the requirement for the Respondent to disclose any violations of his Continuing Care Contract. Second, the DEA can restrict his registration to the prescribing of controlled substances only, and to prohibit his prescribing to

himself or to any other family member. Lastly, the situation that led to his relapse in 2008 no longer exists. The Respondent is no longer caring for his brother. These factors are also appropriate to consider when determining the appropriate use of the Deputy Administrator's discretion in this matter. *See Martha Hernandez, M.D.*, 62 Fed. Reg. 61,145 (DEA 1997) (holding that, in exercising his discretion in determining the appropriate remedy, the Deputy Administrator should consider all of the facts and circumstances of a particular case).

V. CONCLUSION AND RECOMMENDATION

Therefore, I conclude that the DEA has met its burden of proof and has established that grounds exist for denying the Respondent's DEA application for registration.

I do not condone nor minimize the seriousness of the Respondent's prior misconduct in 2001–2002, and again in 2008. However, based on this record, I recommend that the Respondent be afforded an opportunity to demonstrate that he can responsibly handle controlled substance prescriptions by the granting of a restricted registration. *See Cecil E. Oakes, Jr., M.D.*, 63 Fed. Reg. 11,907, 11,910 (DEA 1998) ("Such a resolution will provide Respondent with the opportunity to demonstrate that he can responsibly handle controlled substances, while at the same time protect the public health and safety, by providing a mechanism for rapid detection of any improper activity.").

Based on this record and the Respondent's actions since December of 2008, I recommend to the Deputy Administrator⁴ that the Respondent be granted a conditional DEA registration. I suggest that the conditions include: that the registration restricts his handling of controlled substances to merely prescribing and not storing or dispensing such drugs and that he be prohibited from prescribing controlled substances to himself or any family member. Further, I recommend the Respondent be subject to quarterly reporting of his prescribing of controlled substances to his local DEA office. I also recommend that the Respondent be ordered to consent to unannounced inspections by DEA personnel without requiring an administrative inspection warrant. Lastly, I recommend that the Respondent be ordered to continue with

⁴ The Deputy Administrator has the authority to make such a determination pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2011).

his agreement with the Indiana PAP and to notify the DEA should a relapse occur. I recommend these restrictions apply for three years from the date of the final order so directing this result. In this way, the Respondent may return to the full practice of medicine, and the DEA can assure itself of the Respondent's compliance with DEA regulations and of the protection of the public interest.

Date: November 2, 2011

/s/Gail A. Randall

Administrative Law Judge

[FR Doc. 2012-18750 Filed 7-31-12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12-27]

James William Eisenberg, M.D.; Decision and Order

On April 5, 2012, Administrative Law Judge Timothy D. Wing issued the attached recommended decision.¹ Neither party filed exceptions to the ALJ's decision.

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact and conclusions of law except as noted below.² Based on a recent action of the Arizona Medical Board, which is discussed more fully below, I reject the ALJ's conclusion that the Arizona Medical Board's "action reflects a determination that Respondent, notwithstanding findings of unprofessional conduct in the recent past, can be entrusted with a medical license" and that "this action * * * weigh[s] against a finding that Respondent's continued registration

would be inconsistent with the public interest under Factor One." ALJ at 21.

However, I do adopt the ALJ's findings and legal conclusions that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice when, on August 12, 2011, he prescribed both oxycodone and Xanax to an undercover officer, as well as on September 1, 2011, when he prescribed oxycodone to a second undercover officer. ALJ at 30-31. As the ALJ found, substantial evidence supports the conclusion that these were negotiated drug deals in which for an additional fee, Respondent, upon the requests of the undercover officers for the drugs, agreed to prescribe controlled substances and negotiated with the undercover officers over the quantity of the oxycodone and/or the strength of the drug.³ See *id.* 23-27. Indeed, with respect to the second undercover officer, Respondent agreed to write a prescription for oxycodone before he had even performed a physical examination. See *id.* at 25-26. The findings with respect to the two undercover officers alone establish a *prima facie* case that Respondent has committed acts which render his

³ While I adopt the ALJ's findings and legal conclusions that Respondent unlawfully distributed controlled substances to the undercover officers, I rely solely on the evidence regarding the circumstances of their visits with Respondent. To make clear, I reject the ALJ's legal conclusion that the hearsay statement of a former employee of AZ Go Green to the effect "that Respondent was illegally prescribing oxycodone" constitutes substantial evidence that Respondent was engaged in drug deals. ALJ at 27 n.35. Contrary to the ALJ's assertion, this information was initially provided by the informant to the Phoenix Police Department, which relayed it to the Arizona Attorney General's Office, which then passed it on to the DEA Special Agent, and was thus hearsay within hearsay within hearsay. Tr. 23.

While the Special Agent testified that he knew the informant had been a former employee, he offered no further evidence to support that the declarant was reliable. See *id.* Most significantly, the Government offered the testimony for the limited purpose of showing what prompted the investigation, *id.* at 69, and when on cross-examination, Respondent's counsel attempted to explore the issue of the informant's potential bias, the Government objected that the inquiry was not relevant to the issue of whether Respondent issued prescriptions for a legitimate medical purpose in the usual course of professional practice. *Id.* at 70-71. Indeed, the Government itself later objected to a further question on cross-examination contending that the informant's statements were hearsay, explaining that it had offered the statements "just to show why the agents were at AZ Go Green." *Id.* at 74.

I agree with the Government and conclude that the statement does not constitute substantial evidence that Respondent was engaged in drug deals. See *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938) (Substantial evidence * * * means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."). Instead, I rely on the evidence pertaining to the specific undercover visits.

registration inconsistent with the public interest. See 21 U.S.C. 824(a)(4); see also *MacKay v. DEA*, 664 F.3d 808, 821 (10th Cir. 2011); *Jayam Krishna-Iyer*, 74 FR 459, 463 (2009) (citing *Alan H. Olefsky*, 57 FR 928, 928-29 (1992)).

While I do not rely on the hearsay evidence cited by the ALJ as support for his conclusion that Respondent was engaged in drug deals, there is other evidence to support the conclusion that Respondent is a drug dealer. I take official notice⁴ that on April 4, 2012, the Arizona Medical Board issued to Respondent an Order For Decree Of Censure And Practice Restriction And Consent To The Same. See *In re James W. Eisenberg, M.D.* No. MD-11-1351A (Az. Med. Bd. Apr. 4, 2012). Therein, the Board found, with respect to four patients (including the owner of the clinic where he worked), that Respondent:

Failed to document any attempt to verify the diagnoses or to obtain medical records, imaging, diagnostic work up or specialty consultation. Respondent failed to consider any non-opioid management other than cannabis, and failed to review the Controlled Substance Prescription Monitoring Program (CSPMP); perform urine drug testing; counsel the patients regarding precaution, risks and safe opioid use; or obtain a standard opioid treating agreement.

Id. at 2. The Board further found with respect to these patients, that Respondent:

Deviated from the standard of care by performing an extremely limited pain history and physical exam, by failing to perform a medical record review or risk assessment for opioid use, by failing to perform a diagnostic evaluation or consider a multidisciplinary approach outside of cannabis and daily opioid, by failing to verify a medical diagnosis appropriately treated with daily high dose opioid, and by failing to monitor for compliance by urine drug testing or review of the CSPMP.

Id. at 3. The Board thus concluded that Respondent had committed "unprofessional conduct," by engaging in conduct "that is or might be harmful or dangerous to the health of the patient or the public" and by "failing or refusing to maintain adequate records

⁴ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.

¹ All citations to the ALJ's decision are to the slip opinion as originally issued.

² I do not adopt the ALJ's footnote 25. See *Kwan Bo Jin*, 77 FR 35021, 35021 n.2 (2012).

Moreover, regarding the ALJ's discussion of whether the Arizona Board's 2011 order, see GX 11, which provided that Respondent's admissions were "not intended or made for any other use, such as in the context of another State or Federal government regulatory proceeding," is binding on this Agency, see ALJ at 20 n. 29, I further note that DEA has previously held that "[s]tate officials * * * lack authority to resolve a matter pending before the [Agency] and [a] stipulated settlement [between state officials and a Registrant] cannot bind this Agency." *Edmund Chein*, 72 FR 6580, 6590 (2007), *pet. for rev. denied*, 533 F.3d 828 (DC Cir. 2008)). See also *Fourth Street Pharmacy v. DEA*, 836 F.2d 1137, 1139 (8th Cir. 1988) (absent proof of an agency relationship between a state Attorney General and the Agency regarding an agreement between the State and a registrant, a state Attorney General "could not and did not have authority to bind the DEA to a promise to refrain from instituting lawful regulatory action to revoke" a registration).