Dated: June 4, 2012.

Joseph T. Rannazzisi,

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

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–44]

Kwan Bo Jin, M.D.; Decision and Order

On October 13, 2011, an agency Administrative Law Judge issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact and conclusions of law, except for his discussion of the role of community impact evidence in agency proceedings, *see* ALJ, at 14–16; [1] which is contrary to agency precedent.[2] *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). Nonetheless, my rejection of the ALJ's discussion of this issue has no effect on the outcome of this matter.

Here, the sole ground for revocation proven on this record was Respondent's having been mandatorily excluded from participating in federal health care programs pursuant to 42 U.S.C. 1320a–7(a). Respondent, however, has credibly accepted responsibility for the misconduct which led to his conviction for health care fraud, *see* 18 U.S.C. 1347, complied with the terms of his sentence, and also demonstrated that he has undertaken remedial measures. Accordingly, I have decided to adopt the ALJ's conclusion that his continued registration would be ''consistent with the public interest.'' ALJ at 20. Therefore, the Order to Show Cause will be dismissed.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that the Order to Show Cause issued to Kwan Bo Jin, M.D., be, and it hereby is, dismissed. This Order is effective immediately.

Dated: June 4, 2012.

Michele M. Leonhart,

Administrator.

D. Linden Barber, Esq., and *Jonathan P. Novak, Esq.,* for the Government

Glen D. Crick, Esq., and *Lillian Walanka, Esq.,* for the Respondent.

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

Introduction

This proceeding is an adjudication pursuant to the Administrative Procedure Act, 5 U.S.C. 551 et seq., to determine whether the Drug Enforcement Administration (''DEA'' or ''Government'') should revoke a practitioner's Certificate of Registration (''COR''), and deny any pending applications for renewal or modification. Without this registration, the practitioner, Kwan Bo Jin, M.D. (''Respondent''), of Palatine, Illinois, would be unable to lawfully possess, prescribe, dispense or otherwise handle controlled substances in the course of his practice.

On March 29, 2011, the Deputy Assistant Administrator, Office of Diversion Control, DEA, issued an Order to Show Cause (''OSC'') to Respondent, giving Respondent notice of an opportunity to show cause why the DEA should not revoke Respondent's DEA COR BJ1801580, pursuant to 21 U.S.C. 823 and 824, and deny Respondent's pending application as a practitioner for registration in Schedules II through V, alleging that Respondent has been excluded from participation in all federal health care programs as defined in 21 U.S.C. 824(a)(5). (ALJ Ex. 1, at 1.) The OSC alleged in substance: (a) Respondent is currently registered with DEA as a practitioner in Schedules II through V under DEA registration number BJ1801580, at 950 West Carolyn Drive, Palatine, Illinois; (b) Respondent's registration expired on December 31, 2009, and Respondent ''submitted a timely renewal on November 6, 2010;'' [1] (c) the United States Department of Health and Human Services (''HHS'') by letter dated April 30, 2010, notified Respondent of his exclusion from participation in all federal health programs based on his October 21, 2009 federal conviction for health care fraud pursuant to 18 U.S.C. 1347; and (d) the exclusion was effective on May 20, 2010, and remains in place until at least May 19, 2015.[2] (*Id.*)

Respondent, through counsel, timely requested a hearing, (ALJ Ex. 2), which

[1] All citations to the ALJ's Recommended Decision are to the slip opinion as originally issued.

[2] I also do not adopt the ALJ's statement at page 7 of the slip opinion stating his conclusion ''that the reference in Section 823(f)(5) to 'other conduct which may threaten the public health and safety' would as a matter of statutory interpretation logically encompass the factors listed in Section 824(a).'' ALJ at 7 (citing *Kuen H. Chen, M.D.,* 58 FR 65401, 65402 (1993)).

To be sure, the Agency decision in *Chen* stated that ''[t]he administrative law judge has concluded here that the reference in 21 U.S.C. 823(f)(5) to 'other conduct which may threaten the public health and safety' would as a matter of statutory interpretation logically encompass the bases listed in 21 U.S.C. 824(a).'' 58 FR at 65402. However, whether this constitutes a holding or merely dictum, *Chen* is totally devoid of any indication that the traditional tools of statutory construction (*i.e,* text, structure, statutory purpose, and legislative history) were employed in reaching this conclusion. Indeed, while factor five focuses on ''other conduct,'' several of the grounds for revocation are based on a registrant's status and do not require inquiry into the nature of the underlying conduct. *See* 21 U.S.C. 824(a)(3) (authorizing revocation where registrant ''has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized'' to engage in controlled substance activities or such sanction has been recommended by competent state authority); *id.* 824(a)(5) (authorizing revocation where registrant has been excluded or is subject to exclusion from participating in federal healthcare programs under mandatory exclusion provisions). In addition, construing factor five in this manner renders superfluous factor one, which authorizes the Agency to consider the recommendation of the state licensing board or disciplinary authority, as well as the provision of section 823(f) stating that the ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.''

Finally, it should be noted that since shortly after the CSA's enactment and years before section 823(f) was amended to include the public interest factors, DEA ''has consistently held that where a registration can be revoked under section 824, it can, a fortiori, be denied under section 823 since the law would not require an agency to indulge in the useless act of granting a license on one day only to withdraw it on the next.'' *Serling Drug Co.* v. *Detroit Prescription Wholesaler, Inc.,* 40 FR 11918, 11919 (1975). *See also John R. Amato,* 40 FR 22852 (1975) (Denying application where practitioner's state license had been revoked, holding that section 823(f) ''must logically give the Administrator the authority to deny a registration if the practitioner is not authorized by the State to dispense controlled substances . . . . To hold otherwise would mean that all applications would have to be granted only to be revoked the next day under 21 U.S.C. 824(a)(3). This [A]gency has consistently held that where a registration can be revoked under section 824, it can, a fortiori, be denied under section 823.'').

Indeed, no court has ever questioned the Agency's longstanding and consistent interpretation that it has authority to deny an application on any of the grounds set forth in section 824(a). *Cf. National Muffler Dealers Assn., Inc.,* v. *United States,* 440 U.S. 472, 477 (2011) (''A regulation may have particular force if it is a substantially contemporaneous construction of the statute by those presumed to have been aware of congressional intent.''); *EEOC* v. *Associated Dry Goods Corp.,* 449 U.S. 590, 600 n.17 (1981) (''a contemporaneous construction deserves special deference when it has remained consistent over a long period of time'').

[1] Upon inquiry at hearing, the Government indicated that the date in the OSC was in error and should reflect November 6, 2009.

[2] At hearing, the Government raised an additional issue involving Respondent's prescribing of the Schedule II controlled substance Ritalin to a patient over a two to three month time period in or about 1996.

was held in Chicago, Illinois on August 2, 2011. Both parties called one witness to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law and argument. All of the evidence and post-hearing submissions have been considered, and to the extent the parties' proposed findings of fact have been adopted, they are substantively incorporated into those set forth below.

Issue

Whether the record establishes that Respondent's DEA COR BJ1801580 should be revoked pursuant to 21 U.S.C. 824(a)(5) and any pending applications for renewal or modification of that registration should be denied on the grounds that Respondent has been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a).

Evidence and Incorporated Findings of Fact [3]

I find, by a preponderance of the evidence, the following facts:

I. Background

Respondent graduated from medical school in Korea and completed his residency in psychiatry at the University of Illinois, prior to becoming licensed in Illinois in or about 1984. (Tr. 49–50.) Respondent is not licensed in any other states. Respondent's DEA registration has never been disciplined. (Tr. 53.) Respondent's medical license has been the subject of disciplinary action in or about 1996 [4] and in 2009. (Tr. 50, 53.) Respondent has specialized training and experience in internal medicine and psychiatry. (Tr. 53.) Respondent is not Board certified in psychiatry but is Board eligible. (*Id.*) Prior to September 2009, Respondent's practice focused mainly on a geriatric patient population, to include covering twelve nursing homes. (Tr. 54.) On September 28, 2009, Respondent pled guilty to ''one count of Health Care Fraud in violation of 18 U.S.C. 1347, in the United States District Court for the Northern District of Illinois, ...'' (Resp't Ex. B, at 1.) Respondent has not actively practiced medicine since his September 2009 conviction. (Tr. 55, 63–64.)

II. The Government's Evidence

In support of the allegations contained in the OSC, the Government presented at hearing the testimony of one witness: DEA Diversion Investigator John Pacella (''DI Pacella''). DI Pacella credibly testified that he has been a diversion investigator for twenty-two years, and was assigned to investigate Respondent in November 2009, following receipt of information from the State of Illinois ''regarding [Respondent's] conviction for Medicaid fraud back in September of 2008.'' [5] (Tr. 21.)

DI Pacella next testified that Respondent's registration is currently active to handle controlled substances in Schedules II through V ''[o]n a day to day basis.'' (Tr. 21–22; Gov't Ex. 1.) DI Pacella further testified that he received a copy of the judgment in Respondent's criminal case from the U.S. Attorney's office. (Tr. 24–25; Gov't Exs. 2, 3.) DI Pacella did not consult with the prosecuting attorney in Respondent's case at any time and his investigation was limited to a review of the records in the case, to include a letter dated April 30, 2010, from the HHS notifying Respondent that he was excluded from participation in federal health care programs for a five-year period. (Tr. 27–28; 33; 42; Gov't Ex. 4.)

During questioning by Respondent's counsel, DI Pacella testified that he was aware that Respondent had been reprimanded by the State of Illinois for not keeping records for the Schedule II controlled substance Ritalin for a particular patient, and overprescribing to that patient, resulting in one year of probation. (Tr. 33–34.) [6]

DI Pacella's testimony also included a general explanation of diversion, to include Congress' intent to create ''basically a closed system of distribution.'' (Tr. 28–29.) DI Pacella further explained that a ''small percentage [of doctors] . . . do end up diverting drugs for[] monetary benefits . . . or even self addiction . . .'' and concluded that ''doctors and/or pharmacies . . . make fraudulent documents to cover up diversion.'' (Tr. 30, 31.) DI Pacella acknowledged that his testimony regarding what a doctor may do with regard to diversion is just speculation insofar as Respondent is concerned, since he did not review any of Respondent's prescribing information and does not know what Respondent is doing. (Tr. 36–37.)

III. Respondent's Evidence

Respondent testified at hearing that in 1996, his Illinois medical license was reprimanded as a result of his over prescribing Ritalin to a patient. (Tr. 50–51.) Respondent explained that the patient had tricked him into prescribing a little more than he intended, but admitted that he prescribed more than he intended and should have been more attentive. (Tr. 51–52.) Respondent further explained that initially his license was revoked because he did not attend the scheduled hearing due to lack of notice, but the revocation was vacated, and following a hearing with Respondent present, his license was reprimanded. (*Id.*)

Respondent next testified that his medical license in Illinois had recently been subject to discipline due to his September 28, 2009, federal health care fraud conviction, and that his medical license was currently under probation. (Tr. 53, 55.) Respondent testified that with regard to the discipline of his medical license, he has completed a four-month suspension, paid a $1,000 fine, and completed a continuing medical education requirement. (Tr. 60–61.) Respondent is in compliance with the terms of his medical license probation. (Tr. 61.)

Respondent testified that he pled guilty to health care fraud ''[b]ecause I did wrong.'' (Tr. 56.) Respondent further explained the nature of the misconduct,[7] stating ''that's what I pled guilty for and I feel very bad about it.'' (Tr. 57.) Since his conviction, Respondent explained that he has paid a fine of $10,000, a $100 assessment, and restitution of $28,349. (Tr. 57–58.) Respondent also successfully completed a four month period of work release at the Salvation Army, along with 250 hours of community service. (Tr. 58–59.) Respondent testified that he has completed all of the terms of his federal probation and sentencing, and his probation was terminated on January 29, 2011, approximately eight months earlier than scheduled. (Tr. 59.)

Discussion and Conclusions

I. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act (''CSA'') specifies in 21 U.S.C. 824(a) five factors that the Administrator may consider when suspending or revoking

[3] In addition to the evidence discussed in this Section, additional evidence and findings of fact are discussed in later sections of this Recommended Decision.

[4] *See infra* note 18.

[5] The evidence of record reflects that Respondent signed a plea agreement with the United States dated December 9, 2008, and entered a plea of guilty on September 28, 2009. (*Compare* Gov't Ex. 2, *with* Gov't Ex. 3.)

[6] Respondent's counsel did not object to the testimony or raise any issue with regard to lack of notice during hearing, but instead elicited further explanation of the issue from Respondent during Respondent's direct examination.

[7] Respondent testified that the offense conduct for which he pled guilty related to charging Medicare for patients that he had not seen, to include on occasion deceased patients. (Tr. 56–57.) There is no evidence of record to indicate that the offense conduct related to controlled substances.

a DEA registration.[8] Despite the lack of an explicit provision applying these factors to a denial of an application

[t]he agency has consistently held that the Administrator may also apply these bases to the denial of a registration, since the law would not require an agency to indulge in the useless act of granting a license on one day only to withdraw it on the next.[9]

In addition, I conclude that the reference in Section 823(f)(5) to ''other conduct which may threaten the public health and safety'' would as a matter of statutory interpretation logically encompass the factors listed in Section 824(a).[10]

In an action to revoke a DEA COR, the Government has the burden of proving that the requirements for such revocation are satisfied.[11] Similarly, in an action to deny an application for registration, the Government bears the burden of proving that the requirements for granting such registration are not satisfied.[12] The burden of proof shifts to the respondent once the Government has made its *prima facie* case.[13]

The CSA, 21 U.S.C. 824(a)(5), provides, insofar as pertinent to this proceeding, that the Administrator may revoke or deny a registration if an applicant has been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a).

Under Section 1320a–7(a), the Secretary of the HHS is required to exclude from participation in any federal health care program any individual convicted of a criminal offense ''related to the delivery of an item or service under [42 U.S.C. 1395 et. seq.] or under any State health care program,'' 1320a–7(a)(1), as well as any individual convicted ''in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program . . . of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct,'' 1320a–7(a)(3).

I find that Respondent's 2009 health care fraud conviction and subsequent exclusion from all federal health care programs are supported by substantial evidence. The evidence at hearing includes a plea agreement and judgment pertaining to Respondent's conviction for health care fraud, pursuant to 18 U.S.C. 1347. (Gov't Exs. 2, 3.) Additionally, the evidence includes a letter from the HHS dated April 30, 2010, excluding Respondent from all federal health care programs for the minimum statutory period of five years. (Gov't Ex. 4.) Consequently, exclusion from participation in any federal health care programs pursuant to 42 U.S.C. 1320a-7(a) is an independent ground for denying or revoking Respondent's DEA registration. *See Johnnie Melvin Turner, M.D.,* 67 FR 71,203, 71,204 (DEA 2002).

Respondent does not dispute the evidence of conviction or exclusion, but argues, correctly, that revocation of a COR and denial of a pending application for renewal of registration on this ground is a matter of discretion. *See Dinorah Drug Store, Inc.,* 61 FR 15,972, 15,973 (DEA 1996) (denial of registration under Section 824(a)(5) discretionary so long as granting registration not inconsistent with public interest).

Accordingly, on these facts, the Government has met its burden of proving its Section 824(a)(5) claim, *see* 21 CFR 1301.44(d) and (e), placing the burden on Respondent to show that despite his conviction, granting him a COR would not be contrary to the public interest. *See Medicine Shoppe—Jonesborough,* 73 FR at 380 (burden of proof shifts to the respondent once the Government puts on *prima facie* case); *see also Thomas Johnston,* 45 FR at 72,311 (same).

II. The Public Interest Standard

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

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

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

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

(4) Compliance with applicable state, federal or local laws relating to controlled substances.

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

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: the Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 FR 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 FR 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (DEA 1989).

III. The Factors to Be Considered

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record under Federal or State Laws Relating to the Manufacture, Distribution or Dispensing of Controlled Substances

As described in the Evidence and Incorporated Findings of Fact Section of this Recommended Decision, Respondent holds a valid state medical license in the State of Illinois, but Respondent's state medical license has been the subject of discipline in the past. In or about 1996, Respondent's medical license was reprimanded for conduct related to prescribing Ritalin, a Schedule II controlled substance.[14] Additionally, as a result of Respondent's September 28, 2009 federal conviction for health care fraud, and pursuant to state law,[15] the State of Illinois suspended Respondent's medical license for a period of four months,[16] imposed a fine of $1,000, and placed Respondent on conditional probation

[8] That subsection provides that a DEA registration may be revoked upon a finding that the registrant: (1) has materially falsified an application for DEA registration; (2) has been convicted of a felony under the CSA or any other federal or state law relating to any controlled substance; (3) has had a state license or registration suspended, revoked or denied and is no longer authorized by state law to handle controlled substances; (4) has committed such acts as would render registration inconsistent with the public interest; or (5) has been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a). It should also be noted that Section 824(a) contains a reciprocal reference incorporating the public interest factors from Section 823(f). *See* 21 U.S.C. 824(a)(4).

[9] *Kuen H. Chen, M.D.,* 58 FR 65,401, 65,402 (DEA 1993) (citing *Serling Drug Co. & Detroit Prescription Wholesaler, Inc.,* 40 FR 11918, 11,919 (DEA 1975)); *accord Scott J. Loman, D.D.S.,* 50 FR 18,941 (DEA 1985); *Roger Lee Palmer, D.M.D.,* 49 FR 950 (DEA 1984).

[10] *See Chen,* 58 FR at 65,402.

[11] 21 CFR 1301.44(e) (2011).

[12] 21 CFR 1301.44(d) (2011).

[13] *Medicine Shoppe—Jonesborough,* 73 FR 364, 380 (DEA 2008); *see also Thomas Johnston,* 45 FR 72,311, 72,311 (DEA 1980).

[14] *See* discussion infra.

[15] Disciplinary action against an Illinois licensee may be imposed upon: ''(3) The conviction of a felony in this or any other jurisdiction . . . . (5) Engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public.'' 225 Ill. Comp. Stat. 60//222(A)(3), (5).

[16] Respondent's medical license was suspended for four continuous months beginning on December 3, 2009.

for an indefinite period of not less than two years. (Resp't Ex. B.)

The most recent action by the State of Illinois reflects a determination that Respondent, notwithstanding findings of unprofessional conduct, can be entrusted with a medical license subject to probationary terms and conditions. While not dispositive,[17] this action by the State of Illinois does weigh against a finding that Respondent's continued registration would be inconsistent with the public interest under Factor One. *Cf. Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (DEA 2003) (under Factor One, prior suspension of respondent's state medical license held not dispositive where state license currently under no restrictions).

Regarding Factor Three, there is no evidence that Respondent has ever been convicted under any federal or state law relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, *see Leslie,* 68 FR at 15,230, weighs against a finding that Respondent's registration would be inconsistent with the public interest.

Factors 2, 4 and 5: Respondent's Experience in Dispensing Controlled Substances; Compliance with Applicable State, Federal or Local Laws Relating to Controlled Substances; and Such Other Conduct Which May Threaten the Public Health and Safety

In this case, there is evidence that Respondent has committed acts inconsistent with the public interest by prescribing a Schedule II controlled substance, Ritalin, to one patient over a two to three month time period in or about 1996.[18] As an initial matter, the issue of Respondent's prescribing was not specifically noticed by the Government in the OSC or prehearing statement, nor was it referenced in any Government exhibits prior to hearing. The issue was first introduced during Respondent's cross-examination of DI Pacella, without objection, and further explained by Respondent during his direct and cross examination. (Tr. 50–53, 68–72.)

To comport with due process requirements, the DEA must ''provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of [his] registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action.'' *CBS Wholesale Distribs.,* 74 FR 36,746, 36,749 (DEA 2009) (citing *NLRB v. I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc., v. NLRB,* 920 F.2d 130, 134 (2d Cir. 1990)). An issue cannot be the basis for a sanction when the Government has failed to ''disclose 'in its prehearing statements or indicate at any time prior to the hearing' that an issue will be litigated.'' *Id.* at 36,750 (citing *Darrell Risner, D.M.D.,* 61 FR 728, 730 (DEA 1996)). The DEA has also previously found, however, that a respondent may waive objection to the admission of evidence not noticed by the Government prior to the hearing when the respondent does not timely object and when the respondent also raises the issue. *Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,755 (DEA 2009).

In accordance with agency precedent, I find in this case that the issue of Respondent's 1996 prescribing of Ritalin to one patient may properly be considered under factors one, two, four, and five, as well as on the issue of sanction, notwithstanding the lack of prehearing notice. Respondent's lack of timely objection to the evidence of the 1996 incident and introduction of additional testimony on the subject effectively waived any notice issue.

The Government did not substantively address the lack of notice in its post-hearing brief, but argues that ''Respondent's version of his prescribing of a schedule II controlled substance to a nurse is *similar* to the facts that the Supreme Court recounted in . . . '' *United States v. Moore,* 423 U.S. 122 (1975). (Gov't Br., at 5 (*emphasis added*)). The issue before the Court in *Moore* involved whether a registered physician can be prosecuted under the CSA when the physician's activities fall outside the usual course of professional practice, which was answered in the affirmative. *Moore,* 423 U.S. at 124. Notably, the facts in *Moore* involved a practitioner's issuance of 11,169 prescriptions for ''some 800,000 methadone tablets,'' which were acknowledged by the practitioner to have been issued without observing ''generally accepted medical practices.'' *Id.* at 126. I find the Government's argument that Respondent's prescribing conduct was similar to *Moore* to be glaringly at odds with the facts.

Additionally, the Government's argument that there ''was no evidence that a physical examination was performed . . . '' by Respondent, to include lack of diagnostic tests or records kept, (Gov't Br., at 6), is wholly unpersuasive. As an initial matter, in an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied.[19] The Government's sole witness first introduced the 1996 issue of Respondent's record-keeping and prescribing misconduct, arguably in response to a question posed by Respondent's counsel, clearly demonstrating the Government was aware of the issue in advance of hearing. Once raised at hearing, the Government did not offer any other relevant evidence, to include such things as the findings of a state regulatory authority or patient records, nor did the Government pursue the matter with DI Pacella or Respondent in any meaningful way. (Tr. 42–47, 70–71.) In fact, Respondent's limited testimony on the topic was consistent with him seeing the patient and making chart entries. ''[O]nce I write the prescription in my chart, you know, on such day that I, I prescribe this, those and this amount and then she comes in after three, four days that oh, I had a problem at home[,]'' further explaining how the patient had misled him to issue another prescription. (Tr. 71.) The only evidence in the record of misconduct due to record-keeping is DI Pacella's testimony that ''[w]e did receive information that back in 1997, 96–97, he was actually reprimanded from the State of Illinois for not keeping records for Schedule II Ritalin for a particular patient, ...'' (Tr. 33–34.) The record is otherwise devoid of any information about Respondent's physical examination of the patient, diagnostic tests, or lack thereof.

In *Calhoun v. Bailar,* 626 F.2d 145 (9th Cir. 1980), the court found that to constitute substantial evidence, the probative value and reliability of hearsay evidence may be analyzed using many factors, such as: a consideration regarding the independence or possible bias of the declarant; the type of hearsay material presented; whether the statements are signed and sworn or anonymous, oral or unsworn; whether the statements are contradicted by direct testimony; whether the declarant is available to testify and, if so, whether the objecting party subpoenas the declarant or whether the declarant is unavailable and no other evidence is available; the credibility of the witness testifying to the hearsay; and whether or not the hearsay is corroborated. *Id.* at 149; *see also Richardson v. Perales,* 402 U.S. 389, 402–06 (1971). The evidence offered by DI Pacella regarding ''not keeping records for Schedule II Ritalin for a particular patient'' is so lacking in

[17] *Mortimer B. Levin, D.O.,* 55 FR 8,209, 8,210 (DEA 1990) (finding DEA maintains separate oversight responsibility and statutory obligation to make independent determination whether to grant registration).

[18] Respondent recalls 1996 or 1997, which was consistent with DI Pacella's limited testimony on the issue. (*Compare* Tr. 33–34, *with* Tr. 68.)

[19] 21 CFR 1301.44(e) (2011).

factual basis, that it simply cannot constitute substantial evidence. Accordingly, I do not find the Government's cited authority to be similar in any material respect to the instant case, nor has the Government sustained its burden with regard to the issue of Respondent's lack of physical examination, diagnostic tests, or record-keeping.

In addition to the foregoing, the Government also elicited opinion testimony, without objection, from DI Pacella to the effect that a small percentage of practitioners divert drugs for monetary gain or self use, to include fraudulent documentation. (Tr. 31.) DI Pacella acknowledged that the foregoing testimony was only speculation insofar as Respondent's past or future prescribing conduct was concerned, since he had no independent evidence of such conduct by Respondent. (Tr. 36–37.) ''Speculation is, of course, no substitute for evidence, and a decision based on speculation is not supported by substantial evidence.'' *White ex rel. Smith v. Apfel,* 167 F.3d 369, 375 (7th Cir. 1999) (citing *Erhardt v. Sec'y, DHS,* 969 F.2d 534, 538 (7th Cir. 1992)). Accordingly, I give absolutely no weight to DI Pacella's opinion testimony pertaining to diversion of controlled substances for monetary gain or related document fraud, since at best it is mere speculation as to what Respondent may or may not do in the future.

While I have carefully considered Respondent's admitted prior conduct with regard to prescribing Ritalin to one patient in or about 1996, I do not find that this single incident, which occurred approximately fifteen years ago, and Respondent's otherwise unblemished prescribing record both before and after, to weigh appreciably against Respondent under any public interest factor. Respondent was fully credible and candid in his explanation of this event and there is no evidence of record to indicate any similar conduct before or after. Moreover, Respondent admitted his misconduct at the time of the incident, explaining that ''I admitted that, you know, I prescribed more than I intended for her.'' (Tr. 51.) In reaching a negotiated reprimand, Respondent further testified that he acknowledged he had done something wrong. ''I should be more attentive . . . I admit, at that time, that I prescribed more than I intended for that particular patient.'' (Tr. 52–53.). The lack of any recurrence for the past fifteen years amply demonstrates that Respondent will not engage in similar misconduct in the future. *Patrick W. Stodola, M.D.,* 74 FR 20,727 (DEA 2009).

Accordingly, I find that Respondent's past experience in dispensing controlled substances, compliance with applicable laws relating to controlled substances and absence of any other conduct relating to controlled substances[20] that may threaten the public interest weighs heavily in favor of finding that Respondent's registration would be fully consistent with the public interest.

IV. Community Impact Evidence

Respondent testified consistent with his prehearing statement, and without objection or rebuttal, that to his knowledge he is the only Korean speaking psychiatrist in the Chicago, Illinois area at this time. (Tr. 55.) Respondent further testified that prior to his conviction in September 2009, his practice focused on twelve nursing homes, six of which were ''small nursing homes'' with geriatric Korean populations. (Tr. 54.) Respondent argues that his plan ''to return to work as a psychiatrist for the underserved geriatric Korean community in the Chicago area'' weighs in favor of registration. (Resp't Br., at 13.)

As a threshold matter, there is some question as to whether this issue is relevant at all in a DEA administrative proceeding regarding the registration of a practitioner. Agency precedent has found community impact testimony and evidence relevant with regard to pharmacies but has also rejected community impact evidence altogether in more recent cases. For example, the Agency has considered and credited a respondent's argument that loss of registration would severely and adversely impact the local community by eliminating one of two pharmacies serving the poor. *Pettigrew Rexall Drugs,* 64 FR 8855, 8859–60 (DEA 1999). In recent cases, the Agency held that ''DEA has never applied [the *Pettigrew*] rule in a subsequent case . . . it would be ill-advised to extend it to the case of a prescribing practitioner.'' *Gregory Owens, D.D.S.,* 74 FR 36,751, 36,757 (DEA 2009); *see also Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,078 (DEA 2009) (rejecting community impact evidence).

Although not discussed in *Owens,* there are cases since *Pettigrew* that have considered and given weight to community impact evidence, without specifically citing *Pettigrew.* For example, in a 2004 decision the Deputy Administrator explained that ''regardless of any demographic showing as to what proportion of Louisiana's population is medically underserved[,] such information does not detract from the fact that Respondent provides needed medical services to such an area . . . [W]hile this provides some support for maintaining registration under the facts of this case, it also has a negative implication for continued registration.'' *Imran I. Chaudry, M.D.,* 69 FR 62,081, 62,083–84 (DEA 2004).

There are also cases prior to *Pettigrew* that have considered community impact evidence on facts similar to the instant case. For example, the Agency specifically considered community impact in a 1996 decision finding that ''given the needs of the community in which he practices and the action already taken by the [state and HHS] . . . revocation of [respondent's] DEA registration is not appropriate.'' *Anibal P. Herrera, M.D.,* 61 FR 65,075, 65,078 (DEA 1996); *see also Marta I. Blesa, M.D.,* 60 FR 53,434, 53,436 (DEA 1995) (finding relevant to continuing registration practitioner's ''continued contributions to that community'' and community impact). In light of this precedent, I find that community impact evidence as a threshold matter is not an entirely irrelevant evidentiary consideration, to include on the issue of sanction.

Respondent testified that he has not actively practiced medicine since his conviction, explaining that his decision to return to practice will depend on the outcome of the DEA registration decision. (Tr. 63–64.) Respondent further testified that although he is not prohibited from practicing medicine in Illinois, and generally does not prescribe controlled substances, a DEA registration, as a practical matter, is necessary in order to ''work with a hospital or a pharmacy.'' (Tr. 64.) Respondent explained: ''My Illinois license is active and Illinois substance license is also active. So, I can practice if I want, but because of the DEA situation that I cannot maintain the relationship with the hospital that I've been working with before and the pharmacies.'' (Tr. 78.)

Respondent's testimony regarding his future intentions was equivocal, initially testifying that he intends to return to work with six nursing homes he has experience with that currently have a lot of geriatric Korean patients who are not being served now ''because there's no psychiatrist dealing with their mental difficulties.'' (Tr. 65.) On cross-examination, Respondent equivocated on whether he actually intends to return to practice, regardless of the outcome of his DEA registration hearing. (Tr. 74–

[20] *See Terese, Inc., D/B/A Peach Orchard Drugs, Admonition of Registrant,* 76 FR 46,843, 46,848 n.11 (DEA 2011) (with respect to factor five, DEA's case law has generally recognized that misconduct must relate to controlled substances).

75.) On re-direct, Respondent clarified, stating that if the DEA situation can be cleared up, ''I'd like to go back to work. . . . I consider myself as a resource for my community in Chicago, Korean community. And I'd like to do the work no matter whether it's being compensated or not.'' (Tr. 78.)

In light of Respondent's equivocation on future intentions, I give the evidence related to potential community impact little if any weight for purposes of this recommended decision, other than to find that it is not inconsistent with the public interest.

V. Sanction

I find the Government has established by substantial evidence a prima facie case in support of revoking Respondent's DEA COR and denying any pending applications for renewal or modification for registration pursuant to 21 U.S.C. 824(a)(5), which forms the sole basis for the Government's request for revocation of Respondent's registration and denial of any pending applications for renewal. While mandatory exclusion can provide an independent basis for revocation,[21] DEA has often reserved that sanction to cases where ''there were serious questions as to the integrity of the registrant.'' *Anibal P. Herrera, M.D.,* 61 FR 65,075, 65,078 (DEA 1996) (continuation of registration with restriction where respondent fully accepts responsibility and has paid restitution).

The Government cites several cases in its post-hearing brief in support of revocation,[22] although each case is significantly distinguishable from the facts presented in the instant case. *Orlando Ortega-Ortiz, M.D.,* 70 FR 15,122 (DEA 2005) (respondent waived hearing); *Daniel Ortiz-Vargas, M.D.,* 69 FR 62,095 (DEA 2004) (respondent waived hearing);[23] *Johnnie-Melvin Turner, M.D.,* 67 FR 71,203 (DEA 2002) (respondent waived hearing and offense conduct involved fraudulent claims in excess of $100,000 and order to pay restitution of $106,132); *KK Pharmacy,* 64 FR 49,507, 49,510 (DEA 1999) (respondent waived hearing and ''[n]o evidence of explanation or mitigating circumstances was offered'' by interested party on revocation grounds under 21 U.S.C 824(a)(1), (4), and (5)); *Stanley Dubin, D.D.S.,* 61 FR 60,727, 60,728 (DEA 1996) (respondent's testimony at hearing not credited in part and respondent found to have directly violated termination letter, casting substantial doubt on respondent's integrity).

There is other Agency precedent, in addition to *Herrara,* 61 FR at 65,078, refraining from imposing a revocation sanction on facts similar to the instant case where the respondent has fully accepted responsibility, demonstrated remorse, among other positive factors, and in the absence of other evidence that continued registration would be contrary to the public interest. For example, in *Melvin N. Seglin, M.D.,* 63 FR 70,431 (DEA 1998), the respondent's COR was renewed and continued based on a finding that respondent had accepted responsibility for his misconduct which was not likely to recur. *Id.* at 70,433.

Turning to the evidence in this case, the Government's evidence essentially consists of the court records relating to Respondent's federal health care fraud conviction, to include an exclusion letter from HHS. DI Pacella testified that his investigation was limited essentially to a review of those records.[24] (Tr. 33.)

Respondent's evidence included two Consent Orders from the Illinois Department of Financial and Professional Regulation, the most recent bearing an effective date of July 2, 2010, placing Respondent on indefinite probation for a minimum period of two years, effective April 3, 2010, with various conditions of probation. (Resp't Ex. C.) Additionally, Respondent's evidence included a completion certificate documenting his participation in an ''educational activity titled Intensive Course in Medical Ethics, Boundaries & Professionalism . . . on 9/2/2010–9/3/2010 . . . .'' (Resp't Ex. D.)

Respondent also credibly testified at length during hearing, explaining his educational and professional background, along with the circumstances surrounding the allegations in the OSC. Respondent's manner throughout his testimony was serious and deliberate. Respondent testified without reference to notes or other written material, unless specifically directed by counsel, and he was accurately able to recall events with a reasonable level of certainty. Respondent did not display hostility during testimony or other visible mannerisms that adversely impacted his credibility, and unhesitatingly acknowledged and admitted past instances of misconduct. I find Respondent's testimony to be fully credible in that it was internally consistent and consistent with other objective evidence of record.

Standing alone, Respondent's criminal conviction for a federal health care fraud offense, and mandatory exclusion from participation in the Medicare program pursuant to 42 U.S.C. 1320a-7(a) could certainly support a revocation sanction. But that is not the case here. Respondent' s testimony at hearing, which I find to be sincere and credible, demonstrates that revocation is not an appropriate sanction given Respondent's full acceptance of responsibility for past misconduct, demonstration of remorse, and tangible efforts at rehabilitation following conviction. The un-rebutted evidence of record reflects that Respondent timely admitted full responsibility for his criminal conduct,[25] pursuant to a plea agreement, for which he was sentenced to two years' probation, with the first four months ''to be served in [a] work release program with the Salvation Army.'' (Gov't Ex. 2, at 2.) Respondent testified that he pled guilty because he knew he was wrong and expressed remorse for his misconduct. (Tr. 56–57.) Respondent has also met all of the terms and conditions of his sentence, to include payment of a $10,000 fine, a $100 assessment, and restitution of $28,349. (Tr. 57–58; Gov't Ex. 3.) Additionally, Respondent has completed his four-month period of work release with the Salvation Army, along with 250 hours of community service. (Tr. 58–59.) Of significance, Respondent's fully successful completion of the terms of his federal probation resulted in early termination

[21] ''[M]andatory exclusion from participation in the Medicare program constitutes an independent ground for revocation pursuant to 21 U.S.C. [ ]824(a)(5).'' *Gilbert L. Franklin, D.D.S.,* 57 FR 3,441, 3,441 (DEA 1992).

[22] Gov't Br., at 6.

[23] The Government's citation to this case is incorrect.

[24] Contrary to the Government's prehearing statement, DI Pacella offered no testimony factually related to Respondent's criminal conduct, to include an allegation that he ''delivered apparently fictitious medical records in response to a grand jury subpoena.'' (ALJ Ex. 4, at 2.) In fact, DI Pacella's testimony made clear that his investigation was limited solely to a review of court records offered at hearing. (Tr. 32–33.) DI Pacella testified that he did not review or request any of Respondent's state or federal prescribing practice records . (Tr. 35–36.) Nor did he interview Respondent about the details of his criminal conviction. (Tr. 38.) DI Pacella also testified that he did not participate in or consult with the prosecutor at any time during the criminal case, apparently having no role or independent knowledge of Respondent's criminal case. (Tr. 42–44.) Not surprisingly, DI Pacella credibly acknowledged during cross-examination that all of his testimony pertaining to whether a practitioner might improperly profit from prescribing controlled substances was pure speculation, as he had no knowledge of any such conduct by Respondent. (Tr. 37, 41–42.)

[25] ''Defendant has clearly demonstrated a recognition and affirmative acceptance of personal responsibility for his criminal conduct.'' (Gov't Ex. 3 at 7.)

on January 29, 2011, eight months earlier than scheduled. (Tr. 41, 59.)

In addition to the foregoing, there is no other credible evidence of record that Respondent's registration would be inconsistent with the public interest, to include issues with his prescribing practices, making unnecessary any recommendation that the registration be subject to conditions. The Government's argument that ''Respondent cannot be trusted to tell the truth'' because of his fraud conviction, (Gov't Br., at 6), is inconsistent with the evidence of record. Such an argument might be persuasive in a case where a respondent does not testify at all or testifies untruthfully, but Respondent did credibly testify at length. There is also no evidence that Respondent impeded the criminal investigation or was untruthful at any stage of the sentencing process, which was required by Respondent's plea agreement with the United States. (Gov't Ex. 3 at 10–11.) This is not to minimize the seriousness of Respondent's criminal misconduct, but the Government's argument that Respondent cannot be trusted to tell the truth based solely on his fraud conviction ignores the significant recent positive evidence to the contrary. I find by substantial evidence of record that Respondent's post-offense conduct and testimony at hearing demonstrate that he has been truthful, and can continue to be entrusted to tell the truth.

Respondent has also fulfilled the requirements of discipline related to his Illinois medical license, to include serving a four-month suspension, payment of a $1,000 fine, and completion of a continuing medical education requirement. (Tr. 60–61; Resp't Ex. D.) Respondent is also in compliance with the terms of his medical license probation. (Tr. 61.) In light of the foregoing, and consistent with DEA precedent, I find that revocation of Respondent's registration is not an appropriate sanction in this case.

Conclusion And Recommendation

I recommend continuation of Respondent's DEA COR and approval of any pending applications for renewal or modification on the grounds that Respondent's continued registration would be fully consistent with the public interest as that term is used in 21 U.S.C. 823(f).

Dated: October 13, 2011.

Timothy D. Wing

Administrative Law Judge

[FR Doc. 2012–14319 Filed 6–11–12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Serenity Café; Decision and Order

On December 2, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Serenity Café (Applicant), of Chicago, Illinois. The Show Cause Order proposed the denial of Serenity Café's application for a DEA Certificate of Registration as a Maintenance Narcotic Treatment Program, on the grounds that the Applicant does ''not have authority to handle controlled substances in the state of Illinois,'' and because its registration would be inconsistent with the public interest. Show Cause Order, at 1 (citing 21 U.S.C. 824(a)(3) and 21 U.S.C. 823(f)).

Specifically, the Show Cause Order alleged that on January 26, 2011, Applicant, while doing business as Recovery Café, had voluntarily surrendered its DEA Certificate of Registration for cause. *Id.* at 1. The Order alleged that an investigation of Recovery Café found that it ''failed to maintain the mandatory records required to be kept for controlled substances, had an unexplained shortage of approximately 199,476 mg of methadone, and left controlled substances in an open safe unattended.'' *Id.*

The Show Cause Order further alleged that Applicant had failed to disclose on its application that Recovery Café had voluntarily surrendered for cause its DEA registration. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)). Next, the Order alleged that Applicant does not have a valid Illinois Department of Human Services Alcoholism and Substance Abuse Treatment and Intervention License as required by state law. *Id.* (citing 20 Ill. Comp. Stat. 301/15–5; Ill. Admin. Code tit. 77, 2060.201). Finally, the Order also notified Applicant of its right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for doing either, and the consequence for failing to do either. *Id.* (citing 21 CFR 1301.43).

On December 8, 2011, Diversion Investigators (DIs) personally served the Show Cause Order on Mr. Derrick Arna, who, according to the affidavit of a DI, is the Chief Executive Officer and owner of Serenity Café. GX 1, at 3; GX 6. Since the date of service of the Order, thirty days have now passed and neither Applicant, nor anyone purporting to represent it, has requested a hearing or submitted a written statement in lieu of a hearing. I therefore find that Applicant has waived its right to a hearing or to submit a written statement in lieu of a hearing, and issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

Findings

Serenity Café is owned by Mr. Derrick Arna. GX 1, at 3. Mr. Arna is also the authorized agent of Recovery Café, a former Opioid Treatment Program in Chicago, Illinois, which, on January 26, 2011, voluntarily surrendered its DEA Registration for cause following a January 6, 2001 on-site inspection which found numerous violations. *Id.* at 1; GX 3. More specifically, during the on-site inspection, DEA DIs found that Recovery Café had multiple record-keeping violations. *Id.* at 2. These included, *inter alia,* that it: (1) Failed to record on DEA Form 222s, the date of receipt and quantity of schedule II controlled substances it received; (2) failed to maintain accurate and complete controlled substance records; and (3) failed to maintain dispensing records for the methadone it dispensed, including the date of the dispensing and the name of the patient receiving the drug. *Id.*

In addition, the DIs performed an audit of its handling of methadone hcl (5mg & 40mg) for the period from October 19, 2009 to January 6, 2011. *Id.* The audit found that the clinic was short approximately 199,476 mg of methadone. *Id.* Finally, on January 25, 2011, the DIs found that controlled substances were left unattended in an open safe. *Id.* The next day, Mr. Arna executed a voluntary surrender of Recovery Café's DEA registration.

On February 14, 2011, Mr. Arna filed an application under the name of Serenity Café for registration as a Narcotic Treatment Program—Maintenance, at the proposed address of 110 E. 78th Street, Chicago, Illinois. GX 2, at 1. Mr. Arna sought authorization to handle methadone, a schedule II narcotic controlled substance, and buprenorphine, a schedule III narcotic controlled substance. *Id.*

In Section 4 of the application, Mr. Arna was required to list Applicant's state of licensure, license number and its expiration date. GX 2, at 2. Mr. Arna completed only the state of licensure block, writing ''Illinois'' and the word ''pending.'' *Id.* at 2.

In Section 5 of the application, Mr. Arna was required to answer four liability questions. Among them was question 2, which asked: ''Has the