the usual course of professional practice. *See* 21 U.S.C. 802(21) (''The term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by * * * the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance.''); *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975) (''In the case of a physician, the [CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice.''); *see also United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007) (''[A] physician who engages in the unauthorized practice of medicine under state laws is not a 'practitioner acting in the usual course of * * * professional practice' under the CSA.'').

I therefore conclude that Mr. Dailey's/Powermedica's experience in dispensing controlled substances (factor two) and his/its record of non-compliance with applicable Federal and State laws (factor four) amply demonstrate that granting Respondent's application for a new registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f).[5] Accordingly, Respondent's application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) & 0.104, I order that the application of Wonderyears, Inc., for a DEA Certificate of Registration as a retail pharmacy be, and it hereby is, denied. This Order is effective February 5, 2009.

Dated: December 19, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–31414 Filed 1–5–09; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03–8]

Jayam Krishna-Iyer, M.D.; Suspension of Registration; Granting of Renewal Application Subject to Condition

On September 1, 2006, I, the Deputy Administrator of the Drug Enforcement Administration, ordered that the DEA Certificate of Registration issued to Jayam Krishna-Iyer, M.D. (Respondent), of Clearwater, Florida, be revoked. *Jayam Krishna-Iyer, M.D.*, 71 FR 52148, 52159 (2006). The Order also denied Respondent's pending application for renewal of her registration.

As grounds for the Order, I noted that Respondent had issued prescriptions for controlled substances to three separate undercover operatives notwithstanding that each of the operatives had indicated that he was not in pain, and had told Respondent that he was obtaining controlled substances from non-legitimate sources such as friends. *Id.* at 52158. I further noted that Respondent had failed to conduct a physical exam on each of the undercover operatives and had falsified each operative's medical record to indicate that she had done an exam. *Id.* I also noted that Respondent had made statements during each operative's visit indicating that she knew that the operative was seeking the drugs to abuse them and not to treat pain. *Id.* Finally, I noted that Respondent had pre-signed prescriptions and given them to a registered nurse in her employ, and that she allowed the nurse to issue prescriptions to one of the operatives even though she did not attend to the operative during the visit and the nurse lacked authority under both Federal law and Florida law to prescribe controlled substances. *Id.*

In the decision, I noted that Respondent had undertaken substantial measures to reform her practice including hiring a private investigation firm to review patient records to determine which patients were likely substance abusers and should be discharged from her practice; the firm also developed procedures for recognizing drug abusers, doctor shoppers, prescription fraud, patients with a drug-related criminal history, and dealing with claims of lost and stolen medications. *Id.* at 52156. I also noted that the firm had conducted extensive criminal history checks on Respondent's patients and that she had discharged a large of number of patients. *Id.*

While I recognized the substantial measures that Respondent had undertaken to reform her practice, I adopted the ALJ's finding that Respondent failed to accept responsibility for her misconduct based on her testimony that she did not intentionally or knowingly distribute a controlled substance to the undercover operatives because she knew the drugs would not be sold on the street. *Id.* at 52159. As I explained in the Order, ''[i]t is no less a violation that the 'patient' will personally use the drug rather than sell it on the street.'' *Id.* I further concluded that because Respondent had ''refuse[d] to acknowledge her responsibilities under the law,'' the reforms she had undertaken would ''still not adequately protect public health and safety,'' and that this finding was dispositive as to whether her continued registration would be consistent with the public interest. *Id.*

Thereafter, Respondent filed a petition for review in the U.S. Court of Appeals for the Eleventh Circuit. On September 25, 2007, following briefing and oral argument, the Court vacated the Agency's Order in an unpublished opinion. *Krishna-Iyer* v. *DEA*, No. 06–15034 (11th Cir. 2007), Slip Op. at 3. The Court declared:

> In considering Petitioner's experience in dispensing controlled substances under factor 2, the DEA identified only four visits by three undercover 'patient,' who were all attempting to make a case against her. The DEA failed to consider Petitioner's experience with twelve patients whose medical charts were seized by the DEA, or with thousands of other patients. In short, the DEA did not consider any of Petitioner's positive experience in dispensing controlled substances. This is an arbitrary and unfair analysis of Petitioner's experience.

Id. The Court therefore vacated the Order and remanded the case for reconsideration, directing that ''DEA should pay particular attention to the entire corpus of Petitioner's record in dispensing controlled substances, not only the experience of [the] undercover officer.'' *Id.* The Court further ordered that ''[t]he five factors should * * * be re-balanced.'' *Id.*

On September 15, 2008, the Parties submitted a joint motion which proposed a resolution of the matter. More specifically, the Parties propose that I ''issue a new final Order consistent with the direction of the * * * Court of Appeals.'' Joint Motion at 2. The Parties also request that were I to find that ''revocation or suspension is still an appropriate outcome,'' that the sanction be limited ''to suspension of [her] registration for the time'' that the Final Order remained in effect. The Parties also requested that I direct that Respondent's pending renewal application be acted upon expeditiously. Finally, the Parties represented that if I concurred with their proposed resolution, they would enter into a Memorandum of Agreement (MOA) under which Respondent's registration will be renewed subject to the condition that for a one year period, she file monthly reports with the Agency's Miami Field Division providing information regarding her prescribing of controlled substances.

Attached to the Joint Motion was Respondent's statement. In her

[5] In light of my findings with respect to factors two and four, I conclude that it is unnecessary to make findings with respect to the remaining factors.

statement, Respondent: (1) ''Acknowledge[d] wrongdoing for failing to conduct physical examinations of the three undercover patients in this case''; (2) ''acknowledge[d] wrongdoing for improperly indicating on the charts of the undercover patients that she had conducted a physical examination of'' them; and (3) ''acknowledge[d] that she had presigned various prescriptions and * * * understands that this was improper.'' Respondent's Statement at 1. Respondent also apologized for her conduct with respect to each of the above actions and promises that she will not engage in similar conduct in the future.[1] *Id.*

Respondent also stated that she has reviewed the Agency's earlier decision, that she ''has reexamined her conduct with respect to the three undercover patients in light of the [Agency's] decision and has re-evaluated the transcripts of the visits of the undercover patients in light of the * * * decision.'' *Id.* Respondent further stated that ''she regret[ed] that she prescribed the medications which she prescribed to the undercover patients'' and ''apologized * * * for her conduct.'' *Id.* Respondent also promised that ''such conduct has not occurred since [the undercover visits] and will not occur again.'' [2]

Findings

I incorporate by reference my findings of fact contained in the original order and found at pages 71 FR at 52149–56. As previously found, and as Respondent acknowledges, she issued controlled substance prescriptions to three undercover operatives without performing physical examinations on them and falsified medical records to indicate that she had performed a physical exam. Moreover, Respondent prescribed controlled substances to the undercover operatives even though each of them represented that they were not in pain and were obtaining the drugs from non-legitimate sources such as friends or family members. Moreover, during each of the visits, Respondent made statements that indicated that she knew the patients were seeking the drugs to abuse them and not to treat a legitimate medical condition. *See id.* at 52150 (Respondent stating during first undercover visit: ''Lorcet 10/650. See, this is a shame then that you have to take the medicine for the habit.''); *id.* at 52152 (after acknowledging that second undercover operative had told her that he was taking four to five Vicodin a day even though he did not have pain, and was taking them because he ''functioned better,'' Respondent asked him if he ''want[ed] to go to substance abuse program or * * * be maintained on the vicodin?''); *id.* (stating to second undercover operative ''maybe I'm sympathetic to the people that allow themselves to slip into drugs''); *id.* at 52154 (during visit of third operative, when asked by her nurse, ''what's the source of the pain?,'' replying: ''I guess he feels no pain, he just feels better.''); *id.* (stating to third visitor: ''we will not be supporting just a drug habit'').

Having reviewed—for a second time—the twelve patient files that were seized during the January 26, 2000 search, I further find that Respondent discharged five of these patients prior to the search. More specifically, I find that: (1) Respondent discharged K.L. on February 2, 1998, upon her office's being notified that she had altered a prescription; (2) Respondent discharged R.H. on February 11, 1999, for various reasons including his having claimed that his drugs had been lost or stolen, and his coming in early to obtain new prescriptions claiming that he was going out of town; (3) Respondent discharged J.B. on December 1, 1998, after her office was notified that she had been arrested for photocopying prescriptions and presenting them for filling to multiple pharmacies; (4) Respondent discharged R.S. on December 2, 1999, after being called by his mother who reported that he was abusing his medications; and (5) Respondent discharged J.L. on January 24, 2000, after an anonymous caller reported to Respondent's office that he was simultaneously receiving treatment at a methadone clinic. *See* RX 21, at 4, 17, 23, 24 & 34

As stated above, the Court of Appeals vacated the original Order on the ground that it failed to consider ''any of'' what it termed [Respondent's] ''positive experience in dispensing controlled substances.'' Slip. Op. at 3. The Court specifically noted that I had not considered Respondent's experience with the twelve patients whose charts were seized in a search of her office, ''or with thousands of other patients.'' *Id.* at 3.

The Court of Appeals did not cite to any decision of either this Agency or another court defining the term ''positive experience.'' Nor did the Court offer any guidance as to the meaning of this term, which is not to be found in the Act.

For the purpose of resolving this matter, I therefore assume—without deciding—that the twelve patient charts establish that Respondent's prescribing of controlled substance to these individuals constitutes ''positive experience''—whatever that means.[3]

[1] With respect to the pre-signing of prescriptions, Respondent stated that ''she had not engaged in such conduct since being advised by the DEA that such conduct was improper and promises that she will not in the future.'' Respondent's Statement at 1.

[2] Respondent also expressed regret and apologized for doctor-shopping and inappropriate diversion of drugs at her clinic. Respondent's Statement at 2. I acknowledge (as I did in the original decision) the extensive efforts Respondent has undertaken to prevent the diversion and abuse of drugs by her patients. I also acknowledge Respondent's successful completion of the one-year period of monitoring of her practice.

[3] Having carefully re-reviewed the charts, it should be noted that some of the files suggest that this is an assumption which is highly favorable to Respondent. Under agency precedent, DEA's authority to suspend or revoke a registration is not limited to those instances in which a practitioner intentionally diverts. *See Paul J. Caragine, Jr.*, 63 FR 51592 (1998). A practitioner who ignores the warning signs that her patients are either personally abusing or diverting controlled substances commits ''acts inconsistent with the public interest,'' 21 U.S.C. 824(a)(4), even if she is merely gullible or naïve. 63 FR at 51600. The twelve patient charts cited by Respondent as evidence of her ''positive experience'' included numerous instances in which Respondent appears to have ignored warning signs that the patient was either abusing or diverting controlled substances.

For example, according to Respondent's evidence, ''[o]n 10/05/99 a notation written in [C.A.'s] progress notes states, 'That the patient called to say that a [D.M.] will call and tell you I'm selling my drugs.' It was later discovered that the patient was in jail for violation of probation and marijuana.'' RX 21, at 2. In her testimony, Respondent did not address what action she took in response to this unusual phone call. *See* Tr. 433–34. Moreover, the actual progress note for C.A.'s October 5 visit is missing. Also missing are the progress notes for numerous other office visits which occurred (according to Respondent's billing records) on October 7 and 25, November 8 and December 17.

On July 28, 1998, Respondent issued a prescription for a drug (Soma) to C.C. RX 21, at 8. That same day, Respondent's office received a phone call from a Walgreens pharmacy reporting that two days earlier, C.C. had filled a prescription for the same drug which was issued by a different physician. *Id.* C.C. was thus clearly engaged in doctor shopping.

Respondent saw C.C. three days later and yet there is no indication in the progress note that she even questioned him about the incident and whether he was seeing other doctors. RX 90, at 29. At this visit, Respondent issued him a prescription for Dilaudid, a schedule II controlled substance. *Id.* C.C. also demonstrated a consistent pattern of coming in early. Respondent nonetheless continued to prescribe controlled substances to him and did not discharge him until approximately a year and a half after the Walgreen's incident. RX 90, at 1.

Respondent had previously discharged R.H. based on a drug test which showed that he was ''positive for drug dependency.'' RX 92, at 22. Respondent, however, accepted him back into her practice. *Id.* It is acknowledged that upon his return to her practice, Respondent counseled R.H. that if he returned ''to the same state of medications taking'' as ''in the past, we will not be not be able to continue.'' *Id.* During the visit, Respondent issued him a prescription for Dilaudid. *Id.*

Two days later, however, R.H. returned to Respondent and complained that he could only get part of his prescription filled and that he had come back to get the balance of forty tablets. Respondent ''continued his prescription for Dilaudid,'' *id.* at 21, even though the original prescription was still valid under Federal law.

After a number of additional visits, in early October, R.H. came in and represented that his

Moreover, although there is absolutely no evidence in the record regarding the propriety of Respondent's prescribing of controlled substances to the ''thousands of other patients'' she has treated, for the purpose of resolving this matter, I again assume that her prescribings to these individuals constitutes ''positive experience.''

Discussion

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

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

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

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

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

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

Id. § 823(f).

[T]hese factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.'' *Id.*; *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, I am ''not required to make findings as to all of the factors.'' *See Hoxie*, 419 F.3d at 482; *see also Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).59

As explained below, I adhere to my initial findings regarding factors one through four. As found in the original Order, the State of Florida took no action against Respondent's state medical license and Respondent has not been convicted of an offense under either Federal or State laws relating to controlled substances. 71 FR at 52158–59. DEA has long held, however, that a State's failure to take action against a registrant's medical license is not dispositive in determining whether the continuation of a registration is in the public interest. *See, e.g., Mortimer B. Levin*, 55 FR 8209, 8210 (1990) (holding that practitioner's reinstatement by state board ''is not dispositive''; ''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''). Nor is the fact that a registrant/applicant has not been convicted of a controlled substance offense dispositive of whether the continuation of her registration is in the public interest. *See also Edmund Chein*, 72 FR 6580, 6593 n.22 (2007).

Pursuant to the Court of Appeals' judgment, I have re-considered the additional evidence pertaining to Respondent's ''positive experience.'' Having done so, I again conclude that Respondent violated Federal law and regulations in issuing the prescriptions to the undercover operatives. I also conclude that Respondent violated Federal law and regulations when she pre-signed prescriptions (which she gave to her nurse) and delegated to him her authority to prescribe controlled substances, even though he was not registered to prescribe under Federal law and could not lawfully prescribe controlled substances under state law. I therefore conclude that Respondent committed acts inconsistent with the public interest and which support the suspension or revocation of her registration. 21 U.S.C. 824(a)(4).

However, Respondent has now credibly acknowledged that her prescribing to the undercover operatives and her pre-signing of the prescriptions was improper. She has also credibly stated that she has not engaged in such conduct since the events at issue here and has promised that she will not do so in the future.[4] I therefore further conclude that Respondent has accepted responsibility for her misconduct and can be entrusted with a new registration subject to the condition agreed to by the parties.

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

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act ''in the usual course of * * * professional practice'' and to issue a prescription for a ''legitimate medical

drugs had been ruined because he lived in a duplex and the landlord's hot water heater had failed and flooded the whole house. *Id.* at 16. As Respondent noted, R.H. had brought in ''the whole bottle of Dilaudid with water in it. I cannot tell if it is just a powder or medicine.'' *Id.* Respondent issued R.H. a new prescription notwithstanding the likely implausibility of his story and his past record as a drug abuser. *Id.* Nor is there any evidence that she attempted to verify whether the substance in the bottle was in fact Dilaudid. In addition, R.H. made numerous early visits, and on another occasion, obtained prescriptions for Oxycontin and Percocet after having claimed that he lost a prescription for Dilaudid. *Id.* at 9.

While Respondent discharged J.B. on December 1, 1998, and represents that J.B. was discharged after being arrested for photocopying prescriptions, *see* RX 21, at 4; the online records of the Pinellas County, Florida courts indicate that she had been convicted on July 10, 1996, of attempting to obtain a controlled substance by fraud, and that on June 9, 1998, a new complaint charging her with obtaining or attempting to obtain a controlled substance by fraud had been filed against her. Moreover, J.B. made numerous early visits, a classic behavior of drug seekers. *See* RX 93.

R.C. came in on October 21, 1998, nine days after his initial visit with Respondent, and told her that he had to come in early because he was going to New York for four weeks and would run out of medicine while he was out of town. RX 94, at 12. Yet eight days later, R.C. was back to see Respondent and seeking additional narcotics because he was ''going to Puerto Rico for some relief work.'' *Id.* at 11. However, during R.C.'s initial visit, R.C. had stated that he was ''on disability'' and was ''not working.'' *Id.* at 13. Respondent nonetheless issued him new prescriptions. *Id.* at 11. While it is unclear whether R.C. told Respondent that he would be gone for six weeks or six months, R.C. went back to see Respondent on November 18 and 24, as well as on December 1, 1998. *Id.* at 15.

On August 21, 1998, Respondent gave B.B. a prescription for Dilaudid (and Soma) for pain in various body parts and indicated that she would be seen ''next month for the followup.'' RX 99, at 7. On September 2 (eleven days later), B.B. returned to Respondent and reported that ''she is going to Miami for about three to four weeks for her deposition.'' *Id.* at 6. Respondent ''continued[d] her prescriptions for Dilaudid and Soma.'' *Id.* Twelve days later, B.B. returned to Respondent. *Id.* at 5. According to the progress note: B.B. ''is going to Miami for her case. She will be gone four to six weeks. She came in early today because she does not have enough medicine for four to six weeks. '' *Id.* Respondent issued B.B. additional prescriptions for Dilaudid (and Soma) and indicated that she would be seen again in a month. *Id.* Ten days later, B.B. returned again to Respondent. *Id.* at 4. According to the progress note, B.B. ''came early today because she will be evacuated from the Fort Lauderdale area. No more court cases.'' *Id.* B.B. also told Respondent that the pharmacy had called and told her that ''they could not fill the prescription, because it was unreadable,'' (as if the pharmacy would not have called Respondent to verify the script) and that B.B. ''could not get the prescription back from the pharmacy, so she does not have any medicine [because] she had to leave it in Fort Lauderdale.'' *Id.*

[4] In the original Order, I acknowledged that Respondent had undertaken substantial measures to reform her practice. 71 FR at 52156 & 52159.

purpose.'' *See United States* v. *Moore*, 423 U.S. 122 (1975); *see also* 21 CFR 1306.04(a) (''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances'').

As the Supreme Court recently explained, ''the prescription requirement* * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon*, 546 U.S. 243, 274 (2006) (citing *Moore*, 423 U.S. 122, 135 & 143 (1975)).

In this matter, the Government's presentation largely focused on two allegations: (1) That Respondent lacked a legitimate purpose in issuing the prescriptions to the undercover operatives, and (2) that Respondent pre-signed blank prescriptions which she gave to her nurse and allowed him to prescribe drugs even though the nurse was not authorized under either Federal or State law to prescribe controlled substances.

Whether this conduct is evaluated under factor two—the experience factor, or factor four—the compliance factor, or both, is of no legal consequence. In establishing its *prima facie* case, the fundamental question is whether Respondent ''has committed such acts as would render [her] registration * * * inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). As explained above, this Agency has long held—and other courts of appeals have at least implicitly recognized—that findings under a single factor are sufficient to support the revocation of a registration. *See Hoxie*, 419 F.3d at 482; *Morall*, 412 F.3d at 173–74.

In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.[5]

As previously found, on three separate occasions, undercover operatives went to Respondent seeking prescriptions for controlled substances. Each of the operatives stated that they were not in pain and that they had been obtaining controlled substances from such non-legitimate sources as a ''girlfriend'' (first visitor), ''a friend'' (second visitor) and ''a family member who has a prescription'' (third visitor). 71 FR at 52150, 52152, and 52154. Respondent did not perform a physical examination on any of the three operatives, even though she acknowledged that performing a physical exam ''is the standard of practice'' and ''our Rule No.1.'' *Id.* at 52154. Moreover, she falsified each operative's medical record to indicate that she had performed a physical exam. *Id.* at 52150 (first visitor), 52153 (second visitor), & 52154 (third visitor).

Most significantly, Respondent's statements as recorded on the wire amply demonstrate that she knew that the operatives were seeking the drugs not for the purpose of treating a legitimate medical condition, but to abuse them. *See* 71 FR at 52150 (stating to first visitor: ''this is a shame * * * that you have to take the medicine for the habit,'' ''you can tell me that you want to come out of drugs''); *id.* at 52152 (asking second visitor: ''you don't have pain but you are taking vicodin?'' and do you ''want to go to substance abuse program or do you want to be maintained on the vicodin?''); *id.* (stating to second visitor: ''maybe I'm sympathetic to the people that allow themselves to slip into drugs''); *id.* at 52154 (during visit of third operative, when asked by her nurse, ''what's the source of the pain?'', replying: ''I guess he feels no pain, he just feels better.''); *id.* (stating to third visitor: ''we will not be supporting just a drug habit'').

In various briefs, Respondent maintains that at the time of the search, she had already discharged 6 of the 12 patients ''for various reasons including non-compliance with the Prescription Pain Medication Agreement, criminal acts or arrest.'' Resp. Exceptions to ALJ Dec. at 42. She contends that this is exculpatory evidence of her intent to not improperly prescribe drugs. *Id.*

As found above, it is true that five of the patients whose files were seized had been discharged before the search was conducted. Yet even assuming that this evidence is relevant as to Respondent's intent with respect to her prescribings to the undercover operatives, it is not more probative of her intent during the visits than the evidence as to what actually occurred during those visits. Indeed, even if the operatives' initial statements to Respondent were ambiguous as to why they were seeking the drugs, Respondent did not perform a physical exam on any of the operatives (yet falsified the records to indicate that she had done so) and her subsequent statements during the visits made clear that she had resolved any doubt as to why the operatives were seeking the drugs. In short, the evidence is clear that Respondent issued prescriptions to each of the undercover operatives knowing that they were seeking controlled substances for the purpose of abusing them and not to treat a legitimate medical condition.[6] I thus conclude that Respondent lacked a legitimate medical purpose and thus violated Federal law and DEA regulations when she issued the prescriptions to the undercover operatives.

In her exceptions, Respondent argued that ''her treatment of each of the [twelve] patients [whose files were seized] was proper,'' and that the ''Government presented no evidence suggesting that the treatment of those twelve patients was anything but proper.'' *Id.* Respondent also contends that she ''properly treated thousands of patients for chronic pain,'' and that ''the Government was unable to present any evidence that there was any problem with any non-undercover patient.'' *Id.* at 64. Relatedly, the Court of Appeals has instructed that the experience factor be reconsidered ''pay[ing] particular attention to the entire corpus of Petitioner's record in dispensing controlled substances.'' Slip Op. at 3.

As stated above, for the purpose of resolving this matter, I have assumed that Respondent's prescribings of

[5] The Court of Appeals interpreted my prior decision as ''[b]alancing the factors and according 'dispositive' weight to factor five.'' Slip. Op. at 5. This suggests that the factors that favored Respondent's continued registration (factors one and three) were in equipoise with the factors that did not support her continued registration. They were not. As explained above, even if Respondent's conduct had been discussed under a single factor, the conduct still would have established a *prima facie* case that her continued registration was inconsistent with the public interest. Factor five was dispositive because once the Government established a *prima facie* case, the burden shifted to the Respondent to demonstrate that her continued registration was consistent with the public interest.

[6] I acknowledge that some courts allow a defendant in criminal matters to admit evidence of her ''prior good acts'' to prove she lacked criminal intent. *See United States* v. *Thomas*, 134 F.3d 975, 979 (9th Cir. 1998); *United States* v. *Garvin*, 565 F.2d 519, 521–22 (8th Cir. 1977). Putting aside that this is not a criminal proceeding and the Federal Rules of Evidence do not apply, Respondent made no showing that the factual circumstances surrounding her discharging of these patients were similar to the circumstances involved in the undercover visits. Indeed, in four of the five instances, the patients had been caught by others engaging in problematic behavior such as criminal acts present altering or photocopying prescriptions, (K.L. and J.B.), that the patient was receiving drugs from another clinic (J.L.), or a report from the patient's mother that he was abusing drugs (R.S.). RX 21, at 4, 23, 24 and 34.

controlled substances to every other person she has treated constitute ''positive experience.'' Her prescribings to thousands of other patients do not, however, render her prescribings to the undercover officers any less unlawful, or any less acts which ''are inconsistent with the public interest.'' 21 U.S.C. § 823(f).

In enacting the CSA, Congress recognized that ''[m]any of the drugs included within [the CSA] have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.'' 21 U.S.C. 801(1). Moreover, under the CSA, a practitioner is not entitled to a registration unless she ''is authorized to dispense * * * controlled substances under the laws of the State in which [she] practices.'' 21 U.S.C. 823(f). Because under law, registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career.

Thus, in past cases, this Agency has given no more than nominal weight to a practitioner's evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion. *See, e.g., Caragine,* 63 FR at 51599 (''[T]he Government does not dispute that during Respondent's 20 years in practice he has seen over 15,000 patients. At issue in this proceeding is Respondent's controlled substance prescribing to 18 patients.''); *id.* at 51600 (''[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.'').

While in *Caragine*, my predecessor did consider ''that the patients at issue ma[de] up a very small percentage of Respondent's total patient population,'' he also noted—in contrast to the prescribings at issue here—''that [those] patients had legitimate medical problems that warranted some form of treatment.'' *Id.* at 51601. Moreover, in contrast to this case, in *Caragine*, there was no evidence that the practitioner had intentionally diverted. *Id. See also Medicine Shoppe—Jonesborough*, 73 FR 364, 386 & n.56 (2008) (noting that pharmacy ''had 17,000 patients,'' but that ''[n]o amount of legitimate dispensings can render * * * flagrant violations [acts which are] 'consistent with the public interest.' ''), *aff'd, Medicine Shoppe-Jonesborough* v. *DEA*, slip. op. at 11 (6th Cir. Nov. 13, 2008). Indeed, DEA has revoked other practitioners' registrations for committing as few as two acts of diversion. *See Alan H. Olefsky*, 57 FR 928, 928–29 (1992) (revoking registration based on physician's presentation of two fraudulent prescriptions to pharmacy and noting that the respondent ''refuses to accept responsibility for his actions and does not even acknowledge the criminality of his behavior''). *See also Sokoloff* v. *Saxbe*, 501 F.2d 571, 576 (2d Cir. 1974) (upholding revocation of practitioner's registration based on *nolo contendere* plea to three counts of unlawful distribution).

Accordingly, evidence that a practitioner has treated thousands of patients does not negate a *prima facie* showing that the practitioner has committed acts inconsistent with the public interest. While such evidence may be of some weight in assessing whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, such evidence is entitled to no weight. As I held in the original decision, I again conclude that Respondent's dispensings to the undercover officers and her pre-signing of prescriptions and unlawful delegation of her prescribing authority to her nurse, establish a *prima facie* case that her continued registration is ''inconsistent with the public interest.''

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

In this matter, I previously revoked Respondent's registration because notwithstanding all of the measures she had undertaken to reform her practice, she was the person with the prescribing authority and had refused to acknowledge her responsibility under the law. 71 FR at 52159. Had this case come back to me with the same evidentiary record as before, I would again revoke her registration. Respondent, however, has now acknowledged wrongdoing with respect to both her prescribings to the undercover operatives, as well as her pre-signing of prescriptions and delegation of her prescribing authority to her nurse, who could not legally prescribe a controlled substance under either the CSA or Florida Law. Moreover, Respondent's registration was effectively suspended for a period of approximately one year. I therefore conclude that the parties' proposed resolution of this matter is in the public interest.

* * * * *

The diversion of controlled substances has become an increasingly grave threat to this nation's public health and safety. According to The National Center on Addiction and Substance Abuse (CASA), ''[t]he number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003.'' National Center on Addiction and Substance Abuse, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* 3 (2005). Moreover, ''[a]pproximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000).'' *Id.* Relatedly, ''[b]etween 1992 and 2003, there has been a * * * 140.5 percent increase in the self-reported abuse of prescription opioids,'' and in the same period, the ''abuse of controlled prescription drugs has been growing at a rate twice that of marijuana abuse, five times greater than cocaine abuse and 60 times greater than heroin abuse.'' *Id.* at 4.[7]

[7] According to a recent newspaper article, ''[p]rescription painkiller and anti-anxiety drugs

Continued

While some isolated decisions of this Agency may suggest that a practitioner who committed only a few acts of diversion was entitled to regain his registration even without having to accept responsibility for his misconduct, *see Anant N. Mauskar*, 63 FR 13687, 13689 (1998), the great weight of the Agency's decisions are to the contrary. In any event, the increase in the abuse of prescription controlled substances calls for a clarification of this Agency's policy. Because of the grave and increasing harm to public health and safety caused by the diversion of prescription controlled substances, even where the Agency's proof establishes that a practitioner has committed only a few acts of diversion, this Agency will not grant or continue the practitioner's registration unless he accepts responsibility for his misconduct.[8] Put another way, even where the Government proves only a few instances of illegal prescribing in the ''entire corpus'' of a practitioner's experience, the Government has nonetheless made out a *prima facie* case and thus shifted the burden to the registrant to show why he should be entrusted with a new registration.[9]

I have abided by the judgment of the Court of Appeals in this matter. However, some may interpret the Court's decision as suggesting that ''the entire corpus'' of a practitioner's record in dispensing controlled substances can outweigh a practitioner's intentional acts of diversion where DEA only proves that a few acts of diversion have occurred.

The Court's decision was not published and the Court did not instruct the Agency as to how much weight the entire corpus should be given. Nor did the Court explain whether ''the entire corpus'' should be considered as part of the Government's *prima facie* case, or as part of the registrant's rebuttal of the Government's case.

DEA therefore does not interpret the decision as altering the manner in which similar arguments have been dealt with in prior cases. While such evidence may have some probative value, it does not negate a *prima facie* showing that a registrant/applicant has committed acts that are inconsistent with the public interest. It may, however, be entitled to some weight in assessing whether a registrant/applicant has demonstrated that she can be entrusted with a new registration where the Government's proof is limited to relatively few acts and a registrant puts forward credible evidence that she has accepted responsibility for her misconduct.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that the DEA Certificate of Registration issued to Jayam Krishna-Iyer, M.D., be, and it hereby is, suspended. I further order that the suspension shall be retroactive and limited to the period beginning on October 2, 2006, and ending on October 2, 2007, when her registration was restored pursuant to the judgment of the Court of Appeals. I further order that the application of Jayam Krishna-Iyer, M.D., for renewal of her registration be, and it hereby is, granted subject to the condition that she file monthly reports with the Special Agent in Charge (or his designee) of the Miami Field Division for a period of one year. The reports shall list all controlled substances prescribed by the patient's name, the date, the name of the drug, its strength, the quantity prescribed, and the number of refills authorized. The reports shall be due no later than the tenth day of the subsequent month and shall list all patients in alphabetical order.[10] Failure to comply with the terms of this Order shall be grounds for the suspension or revocation of Respondent's registration. This Order is effective immediately.

Dated: December 19, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–31412 Filed 1–5–09; 8:45 am]

BILLING CODE 4410–09–P

now kill about 500 people a year in the Tampa Bay area, triple the number killed by illegal drugs such as cocaine and heroin.'' Chris Tisch & Abbie Vansickle, *Deadly Combinations*, St. Petersburg Times (Feb. 17, 2008), at 1. This article further noted that while at the time of publication, the figures for the year 2007 were not complete, ''the area is on pace for about 550 deaths,'' and that ''prescription drug overdoses are likely to overtake car crashes as the leading cause of accidental death.'' *Id.* In contrast, in 2006, 433 people died of prescription drug overdoses, and in 2005, 339 died. *Id.* According to the Circuit Judge who runs the Pinellas County drug court, ''This has become an epidemic.'' *Id.*

[8] Depending upon the facts and circumstances, a registrant/applicant may also be required to show what corrective measures he/she has instituted to prevent such acts from re-occurring.

[9] To the extent *Mauskar*, or any other decision of this Agency suggests otherwise, it is overruled.

[10] If a patient received multiple prescriptions, all prescriptions issued to the patient within the calendar month shall be listed before the prescriptions for the next patient are reported.

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Proposed Collection, Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information, in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Bureau of Labor Statistics (BLS) is soliciting comments on the proposed extension of the Labor Market Information (LMI) Cooperative Agreement application package. A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the Addresses section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section of this notice on or before March 9, 2009.

ADDRESSES: Send comments to Carol Rowan, BLS Clearance Officer, Division of Management Systems, Bureau of Labor Statistics, Room 4080, 2 Massachusetts Avenue, NE., Washington, DC 20212, telephone number 202–691–7099. (This is not a toll free number.)

FOR FURTHER INFORMATION CONTACT: Carol Rowan, BLS Clearance Officer, telephone number 202–691–7099. (See **ADDRESSES** section.)

SUPPLEMENTARY INFORMATION:

I. Background

The BLS enters into Cooperative Agreements with State Workforce Agencies (SWAs) annually to provide financial assistance to the SWAs for the production and operation of the following LMI statistical programs: Current Employment Statistics, Local Area Unemployment Statistics, Occupational Employment Statistics, Quarterly Census of Employment and Wages, and Mass Layoff Statistics. The Cooperative Agreement provides the basis for managing the administrative and financial aspects of these programs.